# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**PURSUANT TO SECTION 13 OR 15(d)**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): November 6, 2013**

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

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

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

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

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

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

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

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

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

**Item 2.02 – Results of Operations and Financial Condition.**

On November 6, 2013, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended September 30, 2013, and providing financial guidance for the fourth quarter of 2013. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information in this Item and attached Exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

**Item 7.01 – Regulation FD Disclosure.**

On November 6, 2013, the Company held a webcast conference call with analysts and investors, during which Douglas A. Michels, the Company's President and Chief Executive Officer, and Ronald H. Spair, the Company's Chief Financial Officer and Chief Operating Officer, discussed the Company's consolidated financial results for the quarter ended September 30, 2013, provided financial guidance for the fourth quarter of 2013 and described certain business developments. A copy of the prepared remarks of Messrs. Michels and Spair is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

The information in this Item and attached Exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

**Item 9.01 – Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated November 6, 2013, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2013, and providing financial guidance for the fourth quarter of 2013. |
| 99.2 | Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2013 Analyst/ Investor Conference Call Held November 6, 2013. |

**Signatures**

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

ORASURE TECHNOLOGIES, INC.

Date: November 6, 2013

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

## Index to Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated November 6, 2013, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2013, and providing financial guidance for the fourth quarter of 2013. |
| 99.2 | Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2013 Analyst/ Investor Conference Call Held November 6, 2013. |

**Exhibit 99.1**

OraSure Technologies, Inc.

Company Contact:

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

**OraSure Announces 2013 Third Quarter Financial Results**

*— Quarterly Revenues Reach Record High —*

**BETHLEHEM, PA** – November 6, 2013 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the third quarter and nine months ended September 30, 2013.

**Financial Highlights**

- Consolidated net revenues for the third quarter of 2013 were $24.7 million, a 12% increase from the comparable quarter of 2012. Consolidated net revenues for the nine months ended September 30, 2013 were $70.2 million, a 7% increase from the comparable period of 2012. During the current quarter and nine month period, net product revenues increased 13% and 9%, respectively, compared to the year ago periods. These increases were primarily due to sales of the Company's OraQuick® In-Home HIV test and record revenues from the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG").
- Net revenues for the third quarter and first nine months of 2013 included $1.9 million and $5.6 million in gross sales of the OraQuick® In-Home HIV test, respectively. These gross sales were reduced by customer allowances for cooperative advertising, cash discounts and other allowances, resulting in net revenues of $1.8 million and $5.2 million recorded in each respective period. There were no sales recorded for this product in the comparable 2012 periods.
- Net revenues generated by DNAG during the third quarter of 2013 were $5.0 million, a 48% increase from the comparable period in 2012. DNAG net revenues during the nine months ended September 30, 2013 were $13.6

million, a 36% increase from the comparable period in 2012. The increase in both periods was primarily the result of higher sales to commercial customers.

- Consolidated net loss for the third quarter of 2013 was $1.9 million, or $0.03 per share, which compares to a net loss of $2.4 million, or $0.04 per share, for the third quarter of 2012. Consolidated net loss for the nine months ended September 30, 2013 was $17.4 million, or $0.31 per share, which compares to a net loss of $9.2 million, or $0.18 per share, for the comparable period of 2012. The net loss for the third quarter and first nine months of 2013 included $1.9 million and $14.2 million in advertising and promotional expenses, respectively, associated with the Company's OraQuick® In-Home HIV test.

"We are pleased with the Company's record revenue performance for the third quarter," said Douglas A. Michels, President and CEO of OraSure Technologies. "Our molecular collection systems business continues to deliver strong growth and we are encouraged by the higher sales of our OraQuick® HCV test. We have also launched a new targeted promotional campaign for the OraQuick® In-Home HIV test in an effort to accelerate growth of that important product line."

**Financial Results**

Consolidated net product revenues for the third quarter and nine month periods of 2013 increased 13% and 9%, respectively, primarily as a result of higher sales of the Company's infectious disease testing and molecular collection systems products. These increases were partially offset by lower sales of the Company's substance abuse testing, cryosurgical systems and insurance risk assessment products.

Consolidated licensing and product development revenues for the third quarter of 2013 decreased to $147,000 from $386,000 for the third quarter of 2012 as a result of the expiration of certain patents licensed to a third party. Consolidated licensing and product development revenues for the nine months ended September 30, 2013 decreased to $623,000 from $1.9 million in the comparable period of the prior year, primarily due to the absence of a $1.0 million milestone payment received in the first quarter of 2012 under the Company's HCV collaboration agreement with Merck. No similar payment was received during 2013 because the collaboration agreement with Merck was terminated in November 2012.

Consolidated gross margin for the three and nine months ended September 30, 2013 was 61% and 59%, respectively. Consolidated gross margin for the three and nine months ended September 30, 2012 was 63% and 64%, respectively. The current quarter gross margin was negatively impacted by higher royalties paid on sales of the Company's OraQuick® HIV products and an unfavorable change in product mix partially offset by an improvement in overhead absorption and a

decline in scrap and spoilage costs. Gross margin for the current nine month period was negatively impacted by the higher royalties, the change in product mix and the absence of the $1.0 million HCV milestone payment, partially offset by the improvement in overhead absorption.

Consolidated operating expenses remained relatively flat at $17.0 million during the third quarter of 2013 compared to $16.8 million in the comparable period of 2012. For the nine months ended September 30, 2013, consolidated operating expenses were $59.7 million, an increase over the $52.4 million reported for the nine months ended September 30, 2012. The increase for the first nine months of 2013 was primarily the result of higher promotional and advertising expenses associated with the Company's OraQuick® In-Home HIV test. The current quarter and nine month period expenses included $1.9 million and $14.2 million of promotional and advertising costs related to this product, compared to $1.8 million and $4.7 million spent in the third quarter and first nine months of 2012, respectively.

For the three and nine months ended September 30, 2013, the Company recorded a Canadian income tax benefit of $127,000 and $786,000, respectively, associated with the loss before income taxes and certain Canadian research and development and investment tax credits at DNAG.

The Company's cash balance totaled $82.6 million at September 30, 2013 compared to $87.9 million at December 31, 2012. Working capital was $92.1 million at September 30, 2013 compared to $103.5 million at December 31, 2012. For the nine months ended September 30, 2013, the Company used $3.1 million to fund operations, including the advertising and promotional activities related to the OraQuick® In-Home HIV test. Cash generated by operations in the third quarter of 2013 was $6.1 million.

**Fourth Quarter 2013 Outlook**

The Company expects consolidated net revenues to range from $27.5 to $28.0 million and is projecting a consolidated net loss of approximately $0.07 - $0.08 per share for the fourth quarter of 2013.

**Financial Data**

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

**Unaudited**

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| **Results of Operations** | | | | |
| Net revenues | $24,671 | $22,115 | $ 70,172 | $ 65,675 |
| Cost of products sold | 9,738 | 8,227 | 28,711 | 23,356 |
| Gross profit | 14,933 | 13,888 | 41,461 | 42,319 |
| Operating expenses: | | | | |
| Research and development | 2,670 | 2,994 | 8,720 | 9,551 |
| Sales and marketing | 8,981 | 8,602 | 35,224 | 25,490 |
| General and administrative | 5,342 | 5,220 | 15,742 | 17,398 |
| Total operating expenses | 16,993 | 16,816 | 59,686 | 52,439 |
| Operating loss | (2,060) | (2,928) | (18,225) | (10,120) |
| Other income (expense) | 41 | (34) | 36 | (267) |
| Loss before income taxes | (2,019) | (2,962) | (18,189) | (10,387) |
| Income tax benefit | (127) | (527) | (786) | (1,138) |
| Net loss | $ (1,892) | $ (2,435) | $(17,403) | $ (9,249) |
| Loss per share: | | | | |
| Basic and Diluted | $ (0.03) | $ (0.04) | $ (0.31) | $ (0.18) |
| Weighted average shares: | | | | |
| Basic and Diluted | 55,592 | 54,441 | 55,534 | 50,177 |

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

| | Three Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| Market | 2013 | 2012 | % Change | 2013 | 2012 |
| Infectious disease testing | $12,873 | $10,718 | 20% | 52% | 48% |
| Substance abuse testing | 2,092 | 2,331 | (10) | 8 | 11 |
| Cryosurgical systems | 3,649 | 4,199 | (13) | 15 | 19 |
| Molecular collection systems | 4,964 | 3,353 | 48 | 20 | 15 |
| Insurance risk assessment | 946 | 1,128 | (16) | 4 | 5 |
| Net product revenues | 24,524 | 21,729 | 13 | 99 | 98 |
| Licensing and product development | 147 | 386 | (62) | 1 | 2 |
| Net revenues | $24,671 | $22,115 | 12% | 100% | 100% |

| | Nine Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| Market | 2013 | 2012 | % Change | 2013 | 2012 |
| Infectious disease testing | $35,526 | $30,880 | 15% | 51% | 47% |
| Substance abuse testing | 6,455 | 7,305 | (12) | 9 | 11 |
| Cryosurgical systems | 10,910 | 12,181 | (10) | 16 | 19 |
| Molecular collection systems | 13,550 | 9,992 | 36 | 19 | 15 |
| Insurance risk assessment | 3,108 | 3,448 | (10) | 4 | 5 |
| Net product revenues | 69,549 | 63,806 | 9 | 99 | 97 |
| Licensing and product development | 623 | 1,869 | (67) | 1 | 3 |
| Net revenues | $70,172 | $65,675 | 7% | 100% | 100% |

| OraQuick® Revenues | Three Months Ended September 30 , 2013 | 2012 | % Change | Nine Months Ended September 30, 2013 | 2012 | % Change |
|---|---|---|---|---|---|---|
| Domestic HIV | $ 8,093 | $ 8,527 | (5)% | $23,854 | $25,106 | (5)% |
| International HIV | 1,157 | 884 | 31 | 2,457 | 2,287 | 7 |
| Domestic HIV OTC | 1,762 | — | N/A | 5,196 | — | N/A |
| Domestic HCV | 653 | 678 | (4) | 1,772 | 1,958 | (9) |
| International HCV | 924 | 241 | 283 | 1,409 | 734 | 92 |
| Net OraQuick® revenues | $12,589 | $10,330 | 22% | $34,688 | $30,085 | 15% |

| Intercept® Revenues | Three Months Ended September 30, 2013 | 2012 | % Change | Nine Months Ended September 30, 2013 | 2012 | % Change |
|---|---|---|---|---|---|---|
| Domestic | $ 1,495 | $ 1,499 | 0% | $ 4,240 | $ 4,981 | (15)% |
| International | 29 | 279 | (90) | 385 | 616 | (38) |
| Net Intercept® revenues | $ 1,524 | $ 1,778 | (14)% | $ 4,625 | $ 5,597 | (17)% |

| Cryosurgical Systems Revenues | Three Months Ended September 30, 2013 | 2012 | % Change | Nine Months Ended September 30, 2013 | 2012 | % Change |
|---|---|---|---|---|---|---|
| Professional domestic | $ 1,803 | $ 2,025 | (11)% | $ 4,192 | $ 5,342 | (22)% |
| Professional international | 435 | 453 | (4) | 1,039 | 1,110 | (6) |
| Over-the-Counter | 1,411 | 1,721 | (18) | 5,679 | 5,729 | (1) |
| Net cryosurgical systems revenues | $ 3,649 | $ 4,199 | (13)% | $10,910 | $12,181 | (10)% |

| Condensed Consolidated Balance Sheets (Unaudited) | September 30, 2013 | December 31, 2012 |
|---|---|---|
| Assets | | |
| Cash | $ 82,590 | $ 87,888 |
| Accounts receivable, net | 14,292 | 17,545 |
| Inventories | 12,000 | 12,758 |
| Other current assets | 2,516 | 2,212 |
| Property and equipment, net | 17,989 | 18,546 |
| Intangible assets, net | 23,701 | 27,207 |
| Goodwill | 24,510 | 25,445 |
| Other non-current assets | 614 | 124 |
| Total assets | $ 178,212 | $ 191,725 |
| Liabilities and Stockholders' Equity | | |
| Accounts payable | $ 3,859 | $ 3,380 |
| Deferred revenue | 4,472 | 5,580 |
| Accrued expenses | 10,995 | 7,960 |
| Other non-current liabilities | 539 | 89 |
| Deferred income taxes | 3,456 | 4,401 |
| Stockholders' equity | 154,891 | 170,315 |
| Total liabilities and stockholders' equity | $ 178,212 | $ 191,725 |

| Additional Financial Data (Unaudited) | Nine months ended September 30, 2013 | 2012 |
|---|---|---|
| Capital expenditures | $1,696 | $1,402 |
| Depreciation and amortization | $4,846 | $5,455 |
| Stock based compensation | $4,187 | $3,845 |
| Cash used in operating activities | $3,142 | $4,006 |

**Conference Call**

The Company will host a conference call and audio webcast to discuss the Company's 2013 third quarter financial results, business developments and financial guidance for the fourth quarter of 2013, 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, Ronald H. Spair, Chief Financial Officer and Chief Operating Officer, and Kathleen Weber, Senior Vice President and General Manager, Consumer Products. 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 877-348-9357 (Domestic) or 970-315-0488 (International) and reference Conference ID #87563319 or go to

OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until November 13, 2013, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #87563319.

**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. In July 2012, the Company received approval from the U.S. Food and Drug Administration to sell its OraQuick® In-Home HIV Test directly to consumers in the over-the-counter (OTC) market – making it the first and only rapid OTC HIV test approved 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 OraSure Technologies, 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 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; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company's acquisition of DNA Genotek; 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 and high unemployment; 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; 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 our 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 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, 2012, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

# # #

**Exhibit 99.2**

**OraSure Technologies, Inc.**

**2013 Third Quarter**

**Analyst/Investor Conference Call**

**November 6, 2013**

**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 Judy. Good afternoon everyone and welcome to our call.

The Company delivered strong overall results for the third quarter.

- Consolidated net revenues reached a record high, growing 12% over the third quarter of 2012.
- The principal drivers of this growth were a 48% increase in DNA Genotek revenues and a 20% increase in our infectious disease business.
- Our molecular collection systems business continues to deliver record results driven by higher sales to commercial customers.
- Our infectious disease revenues also increased nicely, primarily driven by sales of our OraQuick® In-Home HIV test and higher international sales of our OraQuick® HCV test.

During the third quarter, we also launched a new promotional campaign for our OraQuick® In-Home HIV test, and I will provide additional insight into how this campaign is progressing and certain other business items later in the call.

So, with that let me now turn the call over to Ron for a more detailed financial review.

***Third Quarter 2013 Financial Results – Ron Spair***

Thanks Doug, and good afternoon everyone.

***Revenues – Ron Spair***

Our third quarter 2013 consolidated revenues were $24.7 million, compared to $22.1 million reported in 2012. Our consolidated product revenues increased 13% as a result of the record sales from our molecular collection systems segment and higher sales of our infectious disease testing products. These increases were partially offset by lower sales of our substance abuse testing, cryosurgical systems and insurance risk assessment products.

Our molecular collection systems revenues, primarily representing sales of the Oragene® product line, increased to $5.0 million in the third quarter of 2013 compared to $3.4 million in 2012. This 48% increase was the result of higher sales in the commercial market.

Our infectious disease testing revenues were $12.9 million in the third quarter of 2013, compared to $10.7 million in the third quarter of 2012. The overall 20% increase was primarily a result of $1.8 million in net sales of our OraQuick® In-Home HIV test, which we began selling in the fourth quarter of 2012. Q3 sales of our professional HIV and HCV tests in the international markets also increased.

During the current quarter, gross sales of our OraQuick® In-Home HIV test were $1.9 million which were offset by $172,000 in customer allowances, including cooperative advertising, cash discounts and other allowances. Net sales of this product included approximately $217,000 of direct sales of our OraQuick® In-Home HIV test to public health customers.

In addition to the increase in net revenues from our OraQuick® In-Home HIV test, sales of our OraQuick® HIV and HCV professional products in the international market increased 31% and 283%, respectively. International sales of our professional HIV test in the third quarter of 2013 increased to $1.2 million from $884,000 in the same period last year primarily due to sales in support of a significant testing program in Africa. International sales of our HCV test in Q3 increased to $924,000 from $241,000 in the prior year due to the first installment of product shipped under an order from a multi-national humanitarian organization. These sales increases in the international market were partially offset by a decline in domestic HIV revenues, which were down $434,000, or 5%, due to competition from other rapid and automated laboratory-based HIV tests, reductions in government funding, and the timing of customer purchases.

Third quarter 2013 cryosurgical revenues decreased 13% to $3.6 million from $4.2 million in the third quarter of 2012, primarily as a result of lower professional sales in the domestic marketplace and lower OTC sales. Professional domestic cryosurgical sales decreased 11% compared to the third quarter of 2012 due to variability in distributor order patterns. OTC sales decreased 18% to $1.4 million in the third quarter of 2013 from $1.7 million in the third quarter of 2012. This decrease was primarily the result of the timing of orders placed by our Latin American distributor as well as a net decrease in sales to our European distributor.

Substance abuse testing revenues decreased to $2.1 million in the third quarter of 2013 from $2.3 million in the third quarter of 2012, primarily as a result of lower Intercept® sales. This decrease resulted primarily from reductions in purchases by our U.K. distributor, who began selling its own competing oral specimen collection device.

***Gross Margin – Ron Spair***

Turning to Gross Margin, our overall margin for Q3 of 2013 was 61% compared to 63% reported for the third quarter of 2012. The lower 2013 margin was primarily a result of higher royalties paid on sales of our OraQuick® products and an unfavorable change in product mix, partially offset by an improvement in overhead absorption and a decline in scrap and spoilage costs.

***Operating Expenses – Ron Spair***

Our consolidated operating expenses for the third quarter of 2013 remained relatively flat at $17.0 million, compared to $16.8 million in the third quarter of 2012. Increases in sales and marketing expenses and general and administrative expenses were partially offset by lower research and development expenses. Sales and marketing expense increased $379,000 largely due to higher staffing costs, partially offset by lower tradeshow expense. Spending associated with advertising and promotional activities for our OraQuick® In-Home HIV test increased slightly to $1.9 million in the third quarter of 2013, compared to $1.8 million spent in the third quarter of 2012. General and administrative expenses increased $122,000 due an increase in staffing-related expenses partially offset by lower spending on legal and professional services. Research and development expense for the third quarter declined $324,000 million due to lower staffing and supply costs.

***Net Loss – Ron Spair***

From a bottom line perspective, we reported a net loss of $1.9 million, or $0.03 per share, for the third quarter of 2013, compared to a net loss of $2.4 million, or $0.04 per share, for the same period of 2012.

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

Turning briefly to our balance sheet and cash flow, our cash balance at September 30, 2013 was $82.6 million compared to $87.9 million at December 31, 2012. Cash provided by operating activities in the third quarter of 2013 was $6.1 million compared to $1.7 million used in operating activities in the third quarter of 2012.

***Fourth Quarter 2013 Consolidated Financial Guidance – Ron Spair***

Looking forward, we expect to spend $5.6 million on advertising and promotion activities in Q4 related to our OraQuick® In-Home HIV product. A significant portion of this represents a shift in spending from the third quarter of 2013 to the fourth quarter and is one of the primary reasons why we exceeded our Q3 guidance for the bottom line.

As we have discussed in prior calls, our current revenue recognition practices for the OraQuick® In-Home HIV product have us deferring revenue recognition from the time of shipment to the retailer or distributor until the consummation of a sale by the retailer or distributor either in a store or over the internet. Under U.S. generally accepted accounting principles, product revenue cannot be recognized unless the amount of future returns can be reasonably estimated. Since the launch of the product in September of 2012, we have continued gathering information regarding retailer and distributor inventory levels and return practices. We expect to change to a more traditional revenue recognition policy, under which revenue is recognized upon shipment to the retailers or distributors, once we believe we have a sufficient amount of this data to develop a reasonable estimate of the level of expected returns. We anticipate that this change in accounting policy may occur in the fourth quarter of 2013 and, assuming it does, could positively impact our revenues by approximately $2.0 million. We have included these additional revenues and corresponding gross margin contribution in our guidance for Q4.

In light of the foregoing, we are now projecting consolidated net revenues of approximately $27.5 to $28.0 million and a consolidated net loss per share of approximately $0.07 to $0.08 for the fourth quarter.

As we look out to the first quarter of 2014, we will likely be recognizing revenues for our HIV-OTC product based on shipments to the distribution channel and, of course, would not have a similar revenue recognition adjustment. Additionally, I would like to take this opportunity to remind everyone that the first quarter has historically been our weakest quarter for both our infectious disease and cryosurgery businesses. Therefore, we anticipate a sequential decline in revenues from Q4 2013 to Q1 2014.

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

***Business Update – Doug Michels***

Thanks, Ron.

***HIV-OTC – Doug Michels***

As mentioned on our last call, we intentionally reduced our marketing activities related to the OraQuick® In-Home HIV test during the third quarter as we prepared for and ultimately launched our new promotional campaign. Consequently, third quarter sales of this product declined about 12% compared to the second quarter. During the third quarter, our OTC marketing team assessed what practices and strategies proved to be most effective during the first nine months of the launch and developed new marketing activities based on that analysis. This retooled campaign has already launched and elements will continue to be added through the first quarter of next year.

Importantly, our OraQuick® In-Home HIV test maintains a strong ranking at major retailers. For example, the product holds top 10 positions in the categories in which it is merchandized at both Walgreen's and CVS. In addition, internet or .com sales now represent 8% of total brand retail sales and grew 1% from the second quarter. Interest from public health customers and advocacy groups also remains strong, with sales of the product to these entities approximating $200,000 in Q3.

Our new marketing campaign, entitled “Life. As We Know It,” was officially launched in late September, in conjunction with Gay Men’s HIV Awareness Day. As previously communicated, this new campaign is designed to address several key elements of our analysis from the first nine months of product availability. Of most significance was the need to significantly increase brand awareness among key consumer target groups such as MSM (men who have sex with men) and African American women. Our new campaign focuses on the importance of urban, high prevalence markets and incorporates influential and trusted spokespeople from within the target communities we serve. The campaign also addresses some of the sensitivities involved with starting a conversation with consumers about HIV.

Initially, the campaign will be reaching out to two groups among those at highest risk for HIV – gay men and African American women. Our activities include programs with national reach such as television, and a number of more focused efforts in critical local markets. Today, 15 markets account for nearly half of our sales, and we are planning local efforts in all of these markets. Importantly, nine of these markets are additions to our earlier local marketing efforts which were piloted in Q2.

As part of the campaign, we have teamed up with powerful and influential voices in these communities to reach consumers through testimonials, interactive panel discussions, sharable discussion guides and informative videos. In addition to Magic Johnson, we have engaged television host and best-selling author Ross Mathews, actor Darryl Stephens, television host Dr. Rachael Ross, author, blogger and life coach Demetria Lucas, journalist Jacque Reid, and Drag queen star Jinkx Monsoon.

The campaign also uses leading media properties to communicate with these target communities, including LOGO TV and its online properties for the gay community – a network that reaches into over 52 million homes – and BET, Essence and Interactive One, all top-rated media brands for African Americans. The campaign also includes high profile consumer events, as well as targeted broadcast, outdoor, digital and print advertising.

Although the campaign officially began on September 27th, many of the campaign elements are planned to launch at various times during the fourth quarter. For example, our press tour with Ross Mathews and our TV partnership with LOGO launched in late September, but additional elements followed in Q4. Similarly, radio targeting African American women launched in mid October and the majority of our out-of-home and print advertising intended to reach the MSM community launched during the last week of October. For the month of October, we placed about 13% of the total campaign impressions expected in the 4th quarter, with the balance hitting in November and December. We will continue to add new elements through the first quarter of next year, with the most notable first quarter addition being our TV partnership with BET, a television network with strong delivery to the African American community. We estimate that by the end of this year, when multiple elements are up and running, our program will have reached over 60% of the MSM community and over 40% of African American women.

As we've introduced various elements of the campaign, we've started to see some positive signs. We are driving highly interested consumers to our website, with 64% of MSM consumers visiting the site since the September 2013 campaign launch stating that they intend to purchase (vs. 45% of Q3 visitors) and 50% of female visitors indicating an intent to purchase (vs. 30% of Q3 visitors). Social media mentions of OraQuick® are also up and have more than doubled since the launch of the new campaign. Although our success will ultimately be measured by sales, these early signs indicate that our programs are reaching and connecting with our targeted consumers.

As discussed on prior calls, the retail environment remains challenging, but here again I am pleased to report that we are making progress. We continue to improve store inventory levels, with out of stocks now running below 5% even in our highest volume stores. This is a substantial improvement from earlier in the year. However, significant barriers to consumer access at retail, particularly in high

prevalence markets, continue to impact sales. An audit conducted in Q1 of this year revealed that 23% of stores nationally and 56% of stores in high prevalence areas have some type of barrier to access at retail. These include placement of the product in locked cases or behind the counter and other theft prevention devices.

We place high priority on addressing these issues at retail and recently completed a substantial retail project with representatives personally, calling on over 5,000 stores to assess and improve retail conditions. The results from this project are still being tabulated, but we believe we have been able to improve retail placement in over 30% of the stores visited in one large retail pharmacy chain alone. We will continue to work with the retail community, at the headquarters level as well as at the store level, to ensure that all consumers have easy access to our product.

Finally, we continue to advance our international activities and are encouraged by positive signals from health authorities, advocacy organizations and retailers in key markets. I hope to have more to report on this in the near future.

***OraQuick® HCV – Doug Michels***

Turning next to our OraQuick® HCV test:

Total HCV sales increased 72% for the current quarter compared to last year and were up sequentially over the second quarter. As Ron mentioned, a major contributor to this growth was a significant international NGO, which placed large orders for both the third and fourth quarters.

There have also been positive developments on the hepatitis front since our last call. As previously discussed, the New York state legislature passed a law early this year that would require NY healthcare providers to offer Hepatitis C testing as a routine part of healthcare provided to baby boomers. I am happy to report that this

law has now been signed by the Governor of New York and will take effect on January 1, 2014. We believe this law will be a model for other states and should help expand HCV testing in the future.

As indicated previously, we believe the expected approval of new and more effective therapeutic treatments for HCV will not only provide significant benefits for patients suffering with the disease, but will also positively impact the amount of testing for Hepatitis C. As you may know, there have been some recent developments in this area as well.

- Earlier this month the Antiviral Drugs Advisory Committee of the FDA voted unanimously that available data supports approval of the use of Gilead Science's sofosbuvir in combination with ribavirin for the treatment of HCV in adults with genotype 2 and 3 infection. The Committee also unanimously supported approval of sofosbuvir in combination with pegylated interferon and ribavirin for treatment of HCV and treatment in adult patients with genotype 1 and 4 infection.
- The Committee also recommended approval of simeprevair, which is made by a Johnson & Johnson affiliate, for use in combination with pegylated interferon and ribavirin for the treatment of HCV genotype 1 in adults with compensated liver disease.
- A final development was the FDA's recent decision to grant what is known as a "Breakthrough Therapy Designation" for an oral combination drug regimen being developed by Merck for the treatment of HCV genotype 1 infected patients. This designation is significant in that it is used by the FDA to help expedite drug development for the treatment of a serious disease when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies.

Finally, the National Medical Association (“NMA”) has just officially released a consensus panel paper about Hepatitis C in the African American community. As you may know, the NMA is the largest and oldest association representing the interests of over 50,000 African American physicians. Among other things, this paper recommends the broader use of rapid HCV testing to better serve the African American community, primarily because rapid testing greatly increases the probability that positive test results are actually received by the affected patient.

So in view of the strong growth in our HCV sales, coupled with the many continuing positive developments in this area, we believe there is much to be optimistic about for our OraQuick® HCV test.

***DNA Genotek – Doug Michels***

The last area I want to address is our molecular collections systems business.

The third quarter was another record quarter by DNA Genotek. The company continued its strong growth trend by generating a 48% revenue increase over the same quarter in 2012. Large, repeat customers in the commercial market were key to driving this growth, although sales to academic customers worldwide were also up over Q3 2012. In addition to servicing the growing needs of its commercial customers in the US market, the company also signed on new commercial customers outside the US. We expect to see continued revenue growth by DNA Genotek in Q4 2013 and well into 2014.

To meet this expected growth, DNA Genotek began a manufacturing capacity expansion in the middle of 2013. This expansion, which is expected to triple the company’s current production capacity, is well underway and projected to be fully operational in Q1 of next year.

***Conclusion***

So, as we finish the year, I believe there is much to build upon and much to be excited about. Our new marketing campaign for the OraQuick® In-Home HIV test is moving into full swing and should begin contributing to higher revenues. There continue to be many positive developments that we believe will help expand our rapid HCV testing business. We are also very pleased that DNA Genotek continues to deliver against the high expectations we set when we first acquired that business. We look forward to a strong finish in 2013, and we also look forward to updating you on our progress in future calls.

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; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company's acquisition of DNA Genotek; 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 and high unemployment; 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; 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 our 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 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, 2012, 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.