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 7, 2012

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

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

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

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

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

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

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

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

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

Item 2.02 – Results of Operations and Financial Condition.

On November 7, 2012, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended September 30, 2012, and providing financial guidance for the fourth quarter of 2012. 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 7, 2012, 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, 2012, provided financial guidance for the fourth quarter of 2012 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 7, 2012, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2012, and providing financial guidance for the fourth quarter of 2012.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2012 Analyst/Investor Conference Call Held November 7, 2012.

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 7, 2012

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

Index to Exhibits

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Exhibit 99.1

OraSure Technologies, Inc.

Company Contact:

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

OraSure Announces 2012 Third Quarter Financial Results

BETHLEHEM, PA – November 7, 2012 – (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, 2012.

Quarterly Highlights

- Consolidated revenues were $22.1 million for the third quarter of 2012, a 2% increase from the comparable quarter of 2011. Revenues for the current quarter included $3.3 million from the Company's molecular collection systems subsidiary, DNA Genotek Inc. ("DNAG"), acquired in August 2011. DNAG revenues from the August 17, 2011 acquisition date through September 30, 2011 were $2.0 million.
- Consolidated revenues were $65.7 million for the nine months ended September 30, 2012, a 13% increase from the comparable period of 2011. Revenues for the current period included $10.0 million from DNAG operations compared to $2.0 million in the nine months ended September 30, 2011.
- On July 3, 2012, the FDA issued a pre-market approval for the Company's OraQuick® In-Home HIV Test for sale into the over-the-counter ("OTC") market. The OraQuick® In-Home HIV Test can detect antibodies to both HIV-1 and HIV-2 with an oral swab, providing a confidential in-home testing option with results in as little as 20 minutes. This is the first rapid diagnostic test for any infectious disease that has been approved by the FDA for sale over the counter.

- During the last week of September 2012, the Company completed its first shipments of its OraQuick® In-Home HIV test to various retailers. No revenue was recorded related to these shipments as revenue will be deferred until consummation of sales to retail customers either in a store or over the internet. Approximately $3.6 million was recorded for this product in accounts receivable and accrued in deferred revenue as of September 30, 2012.
- Consolidated net loss for the third quarter of 2012 was $2.4 million, or $0.04 per share, which compares to a net loss of $3.9 million, or $0.08 per share, for the third quarter of 2011. The third quarter 2011 net loss included $2.1 million of transaction related costs and a $763,000 purchase accounting adjustment associated with the acquisition of DNAG.
- Consolidated net loss for the nine months ended September 30, 2012 was $9.2 million, or $0.18 per share, which compares to a net loss of $9.0 million, or $0.19 per share, for the nine months ended September 30, 2011.

“The third quarter included historic achievements for our Company,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. “We began the quarter with the receipt of FDA approval for our OraQuick® In-Home HIV Test, making it the first and only rapid infectious disease test ever approved for OTC sale, and we ended with the completion of our first shipments of this product to retailers around the country. We also commenced the commercial launch of this product in October with the initiation of a robust promotional campaign to build product and brand awareness on a national basis. We intend to continue to devote the time and resources needed to maximize both the public health benefits and market potential of this important new product.”

Financial Results

Product revenues for the quarter and the nine month period ended September 30, 2012 increased 1% and 12%, respectively, primarily as a result of higher molecular collection system sales and higher sales of the Company’s cryosurgical systems products. These increases were partially offset by lower sales of the Company’s infectious disease testing, substance abuse testing and insurance risk assessment products.

Licensing and product development revenues for the third quarter of 2012 increased $108,000, or 39%, reflecting royalties received under a license related to the Company’s cryosurgical patents. Licensing and product development revenues for the nine months ended September 30, 2012 increased by $863,000, or 86%, primarily as a result of a $1.0 million milestone payment received under the terms of the Company’s HCV collaboration agreement with Merck, partially offset by lower royalties related to the Company’s cryosurgical patents.

Consolidated gross margin for the three and nine months ended September 30, 2012 and 2011 was 63% and 64%, respectively.

Consolidated operating expenses decreased to $16.8 million in the third quarter of 2012 from $17.8 million in the comparable period of 2011. For the nine months ended September 30, 2012, consolidated operating expenses were $52.4 million, an increase over the $46.2 million reported for the nine months ended September 30, 2011.

The decrease in operating expenses for the third quarter of 2012 was the result of lower clinical trial costs related to the Company's OraQuick® In-Home HIV test and lower general and administrative expenses caused by the absence in the current period of $2.1 million of DNAG transaction costs incurred during the third quarter of 2011. These decreases in expenses were partially offset by $1.8 million of additional sales and marketing costs related to the commercialization of the Company's OraQuick® In-Home HIV test and the inclusion of a full quarter of DNAG operating expenses in the third quarter of 2012.

The increase in operating expense for the nine months ended September 30, 2012 resulted from the inclusion of DNAG operating expenses for the full nine months in 2012, an additional $4.7 million of sales and marketing costs related to the OraQuick® In-Home HIV Test commercialization and higher staffing costs included in general and administrative expenses. These increases were partially offset by lower clinical trial costs related to the Company's OraQuick® In-Home HIV Test and lower consulting and legal fees reflecting the absence of $2.5 million of DNAG transaction costs incurred in 2011.

For the three and nine months ended September 30, 2012, the Company recorded an income tax benefit of $527,000 and $1.1 million, respectively, associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits. The income tax benefit recorded for the nine month period was negatively impacted by a second quarter adjustment to the Company's Canadian deferred tax liability to reflect a change in enacted Canadian provincial income tax rates.

Cash totaled $89.4 million at September 30, 2012 compared to $23.9 million at December 31, 2011. Working capital was $106.6 million at September 30, 2012 compared to $30.9 million at December 31, 2011. On July 11, 2012, the Company completed a secondary offering of 6.1 million shares of its common stock, resulting in net proceeds of $70.3 million after expenses of the offering.

Fourth Quarter 2012 Outlook

The Company expects total consolidated revenues to range from $20.5 to $21.0 million and is projecting a consolidated net loss of approximately $0.13 – $0.15 per share for the fourth quarter of 2012.

Financial Data

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

	Unaudited			
	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Results of Operations				
Revenues	$22,115	$21,714	$ 65,675	$58,191
Cost of products sold	8,227	8,120	23,356	21,070
Gross profit	13,888	13,594	42,319	37,121
Operating expenses:				
Research and development	2,994	5,546	9,551	15,110
Sales and marketing	8,602	5,742	25,490	16,026
General and administrative	5,220	6,510	17,398	15,103
Total operating expenses	16,816	17,798	52,439	46,239
Operating loss	(2,928)	(4,204)	(10,120)	(9,118)
Other expense	(34)	(30)	(267)	(153)
Loss before income taxes	(2,962)	(4,234)	(10,387)	(9,271)
Income tax benefit	(527)	(315)	(1,138)	(315)
Net loss	$ (2,435)	$ (3,919)	$ (9,249)	$ (8,956)
Loss per share:				
Basic and Diluted	$ (0.04)	$ (0.08)	$ (0.18)	$ (0.19)
Weighted average shares:				
Basic and Diluted	54,441	47,028	50,177	46,788

Summary of Revenues by Market and Product (Unaudited)

	Three Months Ended September 30,				
	Dollars			Percentage of Total Revenues	
Market	2012	2011	% Change	2012	2011
Infectious disease testing	$10,717	$11,854	(10)%	48%	55%
Substance abuse testing	2,331	2,765	(16)	11	13
Cryosurgical systems	4,199	3,395	24	19	16
Molecular collection systems	3,353	2,022	66	15	9
Insurance risk assessment	1,128	1,399	(19)	5	6
Product revenues	21,728	21,435	1	98	99
Licensing and product development	387	279	39	2	1
Total revenues	$22,115	$21,714	2%	100%	100%

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Revenues	
Market	2012	2011	% Change	2012	2011
Infectious disease testing	$30,880	$33,100	(7)%	47%	57%
Substance abuse testing	7,305	9,011	(19)	11	16
Cryosurgical systems	12,181	8,907	37	19	15
Molecular collection systems	9,992	2,022	394	15	3
Insurance risk assessment	3,448	4,145	(17)	5	7
Product revenues	63,806	57,185	12	97	98
Licensing and product development	1,869	1,006	86	3	2
Total revenues	$65,675	$58,191	13%	100%	100%

	Three Months Ended September 30,			Nine Months Ended September 30,		
OraQuick® Revenues	2012	2011	% Change	2012	2011	% Change
Domestic HIV	$ 8,527	$10,010	(15)%	$25,106	$28,948	(13)%
International HIV	884	878	1	2,287	2,290	—
Domestic HCV	678	332	104	1,958	464	322
International HCV	241	93	159	734	284	158
Total OraQuick® revenues	$10,330	$11,313	(9)%	$30,085	$31,986	(6)%

Intercept® Revenues	Three Months Ended September 30, 2012	2011	% Change	Nine Months Ended September 30, 2012	2011	% Change
Domestic	$1,499	$1,947	(23)%	$4,981	$5,909	(16)%
International	279	438	(36)	616	1,472	(58)
Total Intercept® revenues	$1,778	$2,385	(25)%	$5,597	$7,381	(24)%

Cryosurgical Systems Revenues	Three Months Ended September 30, 2012	2011	% Change	Nine Months Ended September 30, 2012	2011	% Change
Professional domestic	$2,025	$2,042	(1)%	$ 5,342	$5,097	5%
Professional international	453	402	13	1,110	989	12
Over-the-Counter	1,721	951	81	5,729	2,821	103
Total cryosurgical systems revenues	$4,199	$3,395	24%	$12,181	$8,907	37%

Condensed Consolidated Balance Sheets

(Unaudited)	September 30, 2012	December 31, 2011
Assets		
Cash	$ 89,415	$ 23,878
Accounts receivable, net	19,310	17,159
Inventories	12,845	9,621
Other current assets	2,037	2,178
Property and equipment, net	18,811	19,855
Intangible assets, net	28,351	30,383
Goodwill	25,682	24,740
Other non-current assets	105	47
Total assets	$ 196,556	$ 127,861
Liabilities and Stockholders' Equity		
Current portion of long-term debt	$ —	$ 7,292
Accounts payable	5,132	4,142
Accrued expenses	11,867	10,542
Other liabilities	67	—
Deferred income taxes	4,705	5,636
Stockholders' equity	174,785	100,249
Total liabilities and stockholders' equity	$ 196,556	$ 127,861

Additional Financial Data (Unaudited)	Nine months ended September 30, 2012	2011
Capital expenditures	$ 1,402	$ 1,806
Net proceeds from public offering	$70,293	$ —
Acquisition of DNA Genotek, Inc., net of cash acquired	$ —	$49,973
Depreciation and amortization	$ 5,455	$ 3,011
Stock based compensation	$ 3,845	$ 3,016
Cash used in operating activities	$ 4,006	$ 4,079

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2012 third quarter financial results, business developments and financial guidance for the fourth quarter of 2012, 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 877-348-9357 (Domestic) or 970-315-0488 (International) and reference Conference ID #51186733, or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Info link. 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 14, 2012, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #51186733.

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 for the Company's OraQuick® In-Home HIV Test for sale 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 an 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 and success of direct sales efforts; 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; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, 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, extended shelf life 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 product 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, 2011, 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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Exhibit 99.2

OraSure Technologies, Inc.

2012 Third Quarter

Analyst/Investor Conference Call

November 7, 2012

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 and good afternoon everyone. Thank you all for joining our call.

Third quarter consolidated revenues fell within the low end of our guidance range while our net loss beat our guidance for the bottom line. Revenues were up slightly over the third quarter of 2011, primarily as a result of our molecular collection systems subsidiary, DNA Genotek.

The third quarter included historic achievements for OraSure. In July, we received FDA approval of our OraQuick® In-Home HIV Test, the first and only rapid infectious disease test approved for sale in the over-the-counter ("OTC") market. We also completed initial shipments of this product to retailers around the country at the end of the third quarter. In October, we commenced the commercial launch of our OraQuick® In-Home HIV Test with support from celebrity spokespersons and the initiation of a nationwide promotional campaign. I will provide an update on the progress we have made with this exciting new product as well as certain other developments in our business.

However, before I do that, let me ask Ron to review our third quarter financial results.

Third Quarter 2012 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our third quarter 2012 consolidated revenues were $22.1 million compared to $21.7 million reported in 2011. Revenues for the current quarter included $3.3 million from our molecular collection systems subsidiary, DNA Genotek, acquired in August 2011. DNA Genotek's revenues for the period post acquisition date through September 30, 2011 were $2.0 million. Our consolidated product revenues increased 1% as a result of the higher molecular collection systems sales and higher sales of our cryosurgical systems products. These increases were partially offset by lower sales of our infectious disease, substance abuse and insurance risk assessment products.

Our infectious disease testing revenues were $10.7 million in the third quarter of 2012 compared to $11.9 million in the third quarter of 2011. The overall 10% decrease was primarily a result of lower domestic OraQuick® HIV sales, partially offset by higher OraQuick® HCV sales. Third quarter domestic HIV revenues were down $1.5 million, or 15%, due to various factors, including changes in public health testing programs and their timing of purchases, reductions in government funding, price competition, and a shift to automated laboratory-based blood tests by some customers. HCV revenues were $919,000 for the quarter, a $494,000 increase over the third quarter of 2011.

In substance abuse testing, revenues decreased to $2.3 million in the third quarter of 2012 from $2.8 million in the third quarter of 2011, primarily as a result of lower Intercept® sales partially offset by higher sales of our Q.E.D.® point-of-care saliva alcohol test. The higher Q.E.D.® revenues resulted from the absence of production issues experienced last year, which were resolved in October 2011. The decrease in Intercept® sales was the result of lower purchases by our largest

domestic laboratory distributor who began selling its own competitive oral fluid drug testing system at the end of 2011, and lower international sales due to a reduction in purchases by our UK laboratory distributor who has also started selling its own competing oral specimen collection device.

Third quarter 2012 cryosurgical revenues increased 24% compared to the third quarter of 2011, primarily as a result of higher OTC sales and higher professional sales in the international marketplace. Professional sales in the domestic market remained flat.

OTC cryosurgical sales during the quarter increased $770,000, or 81%, when compared to 2011, largely as a result of higher sales to both our Latin American OTC distributor, Genomma, and our European distributor, Reckitt Benckiser. As discussed in previous calls, early in 2011 the Mexican government imposed restraints on the advertising Genomma could use for our product. At the same time, the Brazilian government required us to make changes to our package insert. Both of these issues negatively impacted our sales to Genomma during 2011 but were resolved by the end of that year. The higher sales to Reckitt Benckiser were the result of increased advertising and promotional activities and expansion into additional European countries.

International professional cryosurgical sales in the current period increased 13% compared to the third quarter of 2011. The increase was primarily due to higher sales in Europe, Australia and Asia.

As mentioned earlier, our molecular collection systems revenues were $3.3 million for Q3 2012 compared to $2.0 million for the period August 17, 2011 through September 30, 2011 and primarily represent sales of the Oragene® product line.

Gross Margin – Ron Spair

Turning to Gross Margin, our overall margin remained strong at 63% for both the third quarters of 2012 and 2011.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the third quarter decreased $982,000, or 6%, compared to the third quarter of 2011. Research and development expenses decreased from $5.5 million to $3.0 million for the quarter due to lower clinical trial costs associated with our OraQuick® In-Home HIV test. General and administrative expense decreased by approximately $1.3 million as a result of the absence in the current quarter of $2.1 million of DNA Genotek transaction costs incurred during the third quarter of 2011. This decrease was partially offset by the higher DNA Genotek expenses incurred for a full quarter in Q3 2012 compared to the partial period in 2011. Sales and marketing expenses were $8.6 million for the third quarter, an increase of $2.9 million over 2011 due to $1.8 million of additional sales and marketing costs related to the commercialization of our OraQuick® In-Home HIV test and a full quarter of DNA Genotek expenses. The third quarter 2012 expenses included $3.1 million from our molecular collection systems subsidiary compared to $1.5 million for the last six weeks of Q3 2011.

Net Loss – Ron Spair

From a bottom line perspective, we reported a net loss of $2.4 million, or $0.04 per share, compared to a net loss of $3.9 million, or $0.08 per share, for the same period of 2011.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, our cash balance at September 30, 2012 was $89.4 million compared to $23.9 million at December 31, 2011. We completed a secondary stock offering in Q3 2012 which increased our cash balance by approximately $70 million.

Cash used in operating activities in the third quarter of 2012 was $1.7 million compared to $3.7 million used during the third quarter of 2011.

Fourth Quarter 2012 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the fourth quarter of 2012, we are projecting consolidated revenues of approximately $20.5 to $21.0 million and a consolidated net loss per share of approximately $0.13 to $0.15 for the quarter.

During the fourth quarter, we expect to spend $4.2 million on sales and marketing efforts related to our OraQuick® In-Home HIV product launch. This is above the level we had previously envisioned largely due to the costs of celebrity spokespersons and a delay in expenditures originally projected for Q3. Additionally, we have reduced our revenue estimates in a number of our business units as a result of disruptions caused by Hurricane Sandy.

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

Business Update – Doug Michels

Thanks, Ron.

HIV-OTC – Doug Michels

As mentioned earlier, during the third quarter we received FDA approval of our OraQuick® In-Home HIV Test and completed the first shipments of this product to retailers. We also sold approximately $3.6 million of this product in Q3, although most of this revenue cannot yet be recognized for financial reporting purposes. Because we do not yet have a track record for this product, we can only recognize revenue upon the consummation of sales to retail customers, either in a store or over the internet.

- These initial shipments primarily represent pipeline fill for retailers and their distribution centers. From the time a new product, such as our OraQuick® In-Home HIV test, is purchased, it typically takes 2 to 3 weeks to start appearing on retailers' shelves. As you might expect, there is variability in the timing of retailers' shipments from distribution centers to their stores and in how quickly individual store managers place new product on their store shelves.
- Our initial shipments covered the leading Drug and Mass Merchandise chains, including Wal-Mart, Walgreens, CVS, Rite-Aid, Kroger, and Duane Reade. We are also selling to large drug wholesalers such as Amerisource Bergen, Cardinal Health and certain regional food retailers. We have seen strong initial support by our key retailers as several have run multiple circular and internet ads for our OraQuick® In-Home HIV test.
- Since its launch in early October, our OraQuick® In-Home HIV test has been placed on the shelf in thousands of retail outlets across the country. We have started to conduct retail audits in order to help retailers optimize their execution. Based on initial data from these audits, we estimate that over 90% of the largest retail outlets have product on the shelf. Most of these retailers are selling the test for $39.99, although pricing can vary a bit by location.
- We have been receiving initial data on the volume of consumer purchases at the various retailers and we will be tracking this very closely. So far, initial consumer purchase levels have been modest, reflecting the time required for product to move through retail distribution networks. We expect consumer purchases to ramp up as the retail network distribution process continues and our promotional activities intensify through the fourth quarter and into next year.

- We have also begun selling the test over the internet. Our comprehensive website, **www.oraquick.com**, has been active since September 24th. As previously discussed, this site provides information about HIV/AIDS and our product, including a high-quality instructional video on how to take the test and interpret the results. Importantly, the site provides electronic access to a comprehensive referral network for counseling and care services in any consumer's geographic area. Since the full website was launched, we have seen over 165,000 visitors. The website also provides consumers with the opportunity to purchase our test online or find a retail store near them that sells the product.
- Our promotional and advertising campaign has been structured in two key phases. The first phase was kicked off on October 9th with the objective of driving awareness and product trial and letting people know that the OraQuick® In-Home HIV test is now available at retail. This phase included a strong public relations campaign and a targeted digital advertising plan.
- Perhaps the most exciting element of our first phase was the engagement of former NBA star, Earvin "Magic" Johnson, as a spokesperson for the test. Mr. Johnson appeared on a number of national broadcast shows as well as in print and online media, generating more that 105 million media impressions. His participation at the launch kick-off in New York City also led to an increase of nearly 350% in branded social media posts on Twitter and Facebook. Under our agreement with Mr. Johnson, he will participate in further promotional activities during 2013.
- We also retained former Miss Universe, Dayana Mendoza, as another highly credible and influential spokesperson. Ms. Mendoza promoted our product and advocated for expanded HIV testing in connection with National Latino AIDS Awareness day on October 15th in New York. Her appearances are also being used in our digital activities.

- The second phase of our campaign includes more traditional advertising. During the fourth quarter, we have started to implement internet banner advertisements, paid search and targeted print. Our banner advertising began appearing on hundreds of popular websites on October 15th and will run through the remainder of 2012 and into 2013. We are seeing strong early results with CTRs, or click-thru-rates, 3 times industry averages. Print advertisements are also appearing in publications serving our core target consumers.
- The second phase will continue into next year, beginning in January with significantly increased advertising support and PR activities with Magic Johnson and other events. Our ad campaign, which quantitatively scored well in consumer testing, will be designed to drive awareness and product trial and encourage people to get tested for HIV. The ad campaign will feature a 45 second spot and include a heavy emphasis on TV, along with digital and print placements designed to reach a broad consumer audience with increased focus on those most at risk and most likely to test. This includes men who have sex with men (MSM), African Americans, Latino Americans and sexually active adults 18-49 years old. This is the same campaign that began running in banner ads during Q4.
- As discussed on prior calls, pharmacists and medical professionals play a key role in educating consumers and driving the usage of medical products, such as our In-Home HIV test. Thus, an important part of our communication program has focused on these individuals. During the third quarter, we finalized our educational materials and they have now been deployed to thousands of pharmacies through the major retail chains. In addition, this information is being made available through our website. For physicians, we will target medical journal advertising in Q4 to make physicians aware of the OraQuick® In-Home HIV test and provide them access to our educational materials.

- Briefly turning to production, our manufacturing process is operating smoothly. We are well positioned to meet future product demand.
- Finally, I would like to briefly discuss our consumer support center. This center has been operating since July 6 and provides consumers with toll-free support on a 24/7, 365-day per year basis. To date, we have received thousands of calls with usage continuing to build as product awareness and purchases increase. As previously discussed, our support center representatives are bi-lingual and highly trained, and are prepared to answer questions and provide consumers with resource referrals for follow-up confirmatory testing, counseling and medical treatment.

So, in summary, the initial commercialization of our OraQuick® In-Home HIV Test is well underway. Although there is still a lot of work to do, particularly to drive increased awareness and consumer sales velocity, we are making progress. As Ron indicated in his guidance discussion, creating awareness is not without cost. We expect that our promotional expenses will be significant in the fourth quarter of this year. Looking further ahead, we believe promotional spending in 2013 is likely to exceed the annualized spend rate incurred in the fourth quarter of 2012. The precise level will be determined after the creative development and testing is completed in Q4.

Our expectation for 2013 is that spending will be front-end loaded early in the year to maximize product exposure and support and will decline sequentially as the year progresses. Given the potential market size and the fact that this is a first-of-its kind product, we believe it is critical to support the market launch with ample resources.

I look forward to providing additional updates in the future about this exciting new product.

OraQuick® HCV – Doug Michels

Turning now to our OraQuick® HCV test, we continue to focus on market development in order to grow product sales. Current quarter HCV revenues were up substantially over the same quarter of last year. The primary drivers for this performance were higher sales to public health and hospital customers in the US market and sales to certain international customers.

A major development in Q3 was the adoption by the Centers for Disease Control ("CDC") of new guidelines for HCV testing. These guidelines recommend that all persons born between 1945 and 1965 – or approximately 81 million people, according to the 2010 census – receive a one-time test for HCV. We believe these new "birth cohort" guidelines will help to substantially increase HCV testing over the long term.

While the issuance of the new CDC guidelines is a positive development, there is still much work needed in order to make physicians and their patients aware of the need for greater HCV testing. As a result, we continue to assist our distributors in their efforts to educate medical professionals about the guidelines and the availability of our OraQuick® HCV test to meet their testing needs. We have also been working closely with other parties, such as the Chronic Liver Disease Foundation and the National Medical Association, to implement HCV education, awareness and testing campaigns.

A major factor affecting sales of our OraQuick® HCV test has been the availability of government funding which is relied upon by many of our customers, especially in the public health market. The economic downturn has placed significant pressure on government budgets, in both the US and other countries, and this pressure is likely to continue for the forseeable future.

There was some good news on funding during the third quarter. The CDC received a $10 million appropriation for Hepatitis testing, indicating that there is still congressional support for expanded testing despite budgetary concerns. As a result, 26 public health jurisdictions and community-based organizations received $5.2 million in CDC funding specifically for HCV testing and linkage to care. These type of grants support increased awareness of the CDC guidelines and will enable the recipients to start HCV testing initiatives. Based on our discussions with the CDC, we believe over half of the grantees will use rapid HCV testing in their programs.

DNA Genotek Acquisition – Doug Michels

With respect to DNA Genotek, this business showed progress in Q3. The Company sold a significant amount of product to a large-scale commercial customer whose test is demonstrating rapid uptake among its customer base. This is a great example of commercial customers offering alternative, non-health-related tests using DNA. As these types of alternative tests become more prevalent, we expect DNA Genotek's business to benefit.

In addition, we saw continuing growth and sustainability from other commercial customers providing health-related DNA tests. DNA Genotek's full range of DNA sample collection products are now being used by commercial customers either for diagnostics or commercial research. Five of the top 8 sales in the third quarter were to commercial customers. The Company's academic business also continues to perform well given the global funding challenges facing academic researchers.

* * * *

Conclusion

So in conclusion, we are advancing the commercialization of our new OraQuick® In-Home HIV Test, the first and only FDA approved rapid HIV test for consumers. We are also focused on maximizing the opportunity for our OraQuick® HCV test. This is an exciting time for our Company, and we look forward to advancing our strategic and financial initiatives as we move into 2013.

And with that, I will now open the floor to your questions. Operator please proceed.

[Q&A session]

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 an 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 and success of direct sales efforts; 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; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, 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, extended shelf life 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 product 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, 2011, 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.