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 2, 2011

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 2, 2011, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended September 30, 2011, and providing financial guidance for the fourth quarter of 2011. 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 2, 2011, 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, 2011, provided financial guidance for the fourth quarter 2011 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 2, 2011, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2011, and providing financial guidance for the fourth quarter of 2011.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2011 Analyst/Investor Conference Call Held November 2, 2011.

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 2, 2011

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 2011 Third Quarter Consolidated Financial Results

BETHLEHEM, PA – November 2, 2011 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the third quarter of 2011.

Quarterly Highlights

- The Company completed the acquisition of DNA Genotek Inc. ("DNAG") on August 17, 2011.
- Consolidated revenues totaled $21.7 million for the quarter, a 14% increase from the comparable period of 2010. Revenues included $19.7 million from OraSure operations and $2.0 million from DNAG operations. The Company had previously forecasted $19.0 to $19.5 million in third quarter revenues for OraSure operations, exclusive of DNAG performance.
- Non-GAAP adjusted net loss per share for the quarter totaled $0.03, which excludes both DNAG financial results and certain costs incurred by OraSure as a result of the acquisition. This compares to a $.07 per share net loss previously forecasted for the Company, exclusive of DNAG results and certain acquisition costs. The GAAP consolidated net loss for the quarter was $0.08 per share.
- During the quarter, the Company completed the final clinical study required in connection with FDA approval of an at-home HIV test and submitted additional data requested by the FDA in support of its pending CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver submission for the Company's OraQuick® rapid HCV test.

“We enjoyed a highly productive third quarter and we are very pleased with the Company’s performance,” said Douglas A. Michels, President and CEO of OraSure Technologies. “Our financial results were strong with the OraSure base business exceeding our guidance on both the top and bottom lines and we closed the DNA Genotek acquisition. In addition, we made excellent progress against our strategic initiatives by completing the final clinical study for our OraQuick® HIV over-the-counter test and submitting additional data in support of our CLIA submission for our OraQuick® HCV test. We look forward to ending 2011 with a successful fourth quarter.”

Financial Results

The Company recorded consolidated revenues of $21.7 million for the three months ended September 30, 2011, compared to $19.0 million for the three months ended September 30, 2010. Revenues for the third quarter included $2.0 million contributed by DNAG for the period following the closing of the acquisition.

Excluding the DNAG sales, product revenues for the current quarter increased 6% primarily as a result of higher sales of the Company’s infectious disease testing and cryosurgical systems products, partially offset by lower sales of its substance abuse and insurance risk assessment products. The higher product revenues were partially offset by a reduction in licensing and product development revenues caused by a decrease in royalties received pursuant to the Company’s license and settlement agreement with Merck.

The Company reported a consolidated net loss of $3.9 million, or $0.08 per share, for the third quarter of 2011, compared to net income of $274,000, or $0.01 per share, for the third quarter of 2010. The consolidated results included $0.02 of loss attributable to a purchase accounting adjustment discussed below. DNAG’s operating results were impacted by the incurrence of $380,000 of amortization of intangibles in connection with the acquisition. The consolidated net loss also included $0.03 of loss resulting from certain transaction costs incurred by OraSure as a result of the acquisition.

The purchase accounting adjustment was required to write up DNAG’s inventory from production cost to fair market value as of the acquisition date. For the third quarter, this adjustment increased DNAG’s cost of products sold by $763,000 based on the amount of the adjusted inventory sold during that period. The remainder of the inventory write up is expected to increase fourth quarter cost of products sold by $115,000 calculated at September 30, 2011 exchange rates.

For the nine months ended September 30, 2011, the Company recorded total revenues of $58.2 million, compared to $56.2 million for the nine months ended September 30, 2010. Revenues for the 2011 period included the $2.0 million contributed by DNAG.

Excluding the DNAG sales, product revenues for the current nine month period increased 5% as a result of higher sales of the Company's infectious disease and substance abuse testing products, partially offset by lower cryosurgical systems and insurance risk assessment revenues. This increase was partially offset by lower licensing and product development revenues caused by the absence of $2.0 million in milestone payments received from Merck during the year ago period under the terms of the Company's collaboration with Merck related to the development and promotion of the OraQuick® rapid HCV test.

The Company recorded a consolidated net loss of $8.9 million, or $0.19 per share, for the nine months ended September 30, 2011, compared to a net loss of $2.5 million, or $0.05 per share, for the nine months ended September 30, 2010. The consolidated net loss for 2011 included the loss attributable to the purchase accounting adjustment and the transaction costs incurred by OraSure described above.

Consolidated gross margin for the three months ended September 30, 2011 was 63% compared to 62% for the three months ended September 30, 2010. Consolidated gross margin for the nine months ended September 30, 2011 was 64%, compared to 63% for the comparable nine months of 2010. Gross margin in both periods of 2011 was negatively impacted by the purchase accounting adjustment related to the write up of DNAG inventory. This adjustment accounted for 350 and 130 basis points of margin for the three and nine months ended September 30, 2011, respectively. Gross margins in the 2011 periods benefitted from the inclusion of DNAG results, lower direct labor costs and improved absorption of overhead costs as a result of staffing optimization and a change to automated manufacturing during 2011.

Consolidated operating expenses for the third quarter of 2011 increased to $17.8 million, from $11.5 million in the comparable period of 2010, and to $46.2 million for the nine months ended September 30, 2011, from $37.8 million for the first nine months of 2010. These increases resulted primarily from the inclusion of DNAG operating expenses, higher research and development expenses due to clinical trial spending related to the Company's OraQuick® HIV over-the-counter product and higher legal, accounting, consultant and other transaction costs incurred by OraSure in connection with the DNAG acquisition.

Fourth Quarter 2011 Outlook

The Company expects total consolidated revenues of approximately $22.0 to $23.0 million for the fourth quarter of 2011 and a fourth quarter net loss of approximately $0.07 - $0.08 per share.

Financial Data

Condensed Consolidated Financial Data (In thousands, except per-share data) Unaudited				
	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Results of Operations				
Revenues	$21,714	$19,034	$58,191	$56,197
Cost of products sold	8,120	7,220	21,070	20,802
Gross profit	13,594	11,814	37,121	35,395
Operating expenses:				
Research and development	5,546	3,008	15,110	9,143
Sales and marketing	5,742	4,593	16,026	15,898
General and administrative	6,510	3,924	15,103	12,776
Total operating expenses	17,798	11,525	46,239	37,817
Operating income (loss)	(4,204)	289	(9,118)	(2,422)
Other expense	(30)	(15)	(153)	(52)
Income (loss) before income taxes	(4,234)	274	(9,271)	(2,474)
Income tax benefit	(315)	—	(315)	—
Net income (loss)	$ (3,919)	$ 274	$ (8,956)	$ (2,474)
Earnings (loss) per share:				
Basic and Diluted	$ (0.08)	$ 0.01	$ (0.19)	$ (0.05)
Weighted average shares:				
Basic	47,028	46,213	46,788	46,176
Diluted	47,028	46,566	46,788	46,176

Non-GAAP Financial Measure

In this press release, the Company has provided adjusted net loss as a non-GAAP financial measure. The Company believes this non-GAAP measure provides investors with an additional analytical tool for understanding the Company's financial performance by excluding the impact of certain items that may obscure trends in the core operating performance of the business. In particular, this measure excludes certain non-operating and non-cash expenses that management believes are not indicative of the Company's core operating results. Non-GAAP adjusted net loss represents the consolidated GAAP net loss exclusive of DNAG operating results, certain transaction costs incurred by

OraSure in connection with the acquisition and the purchase accounting adjustment described above.

This financial measure is not recognized under U.S. GAAP and may not be comparable to similar measures used by other companies. Accordingly, while the Company believes that disclosing non-GAAP financial measures allows for greater transparency in the review of its underlying financial performance, investors are cautioned not to consider such measures to be substitutes for, or superior than, consolidated net loss determined in accordance with GAAP.

The following reconciles the non-GAAP adjusted net loss to the consolidated GAAP net loss for the three months ended September 30, 2011.

	(In thousands, except per share data) Unaudited				
	OraSure Technologies, Inc. Results (Non-GAAP Adjusted Net Loss)	**Adjust for Acquisition Related Costs Note 1**	**Adjust for DNA Genotek, Inc. Results Note 2**	**Purchase Accounting Adjustment Note 3**	**Consolidated Results (GAAP Net Loss)**
Results of Operations					
Revenues	$ 19,692	$ —	$ 2,022	$ —	$ 21,714
Gross profit	12,936	—	1,421	(763)	13,594
Gross margin	*66%*		*70%*		*63%*
Total operating expenses	14,754	1,507	1,537	—	17,798
Operating loss	(1,818)	(1,507)	(116)	(763)	(4,204)
Net loss	$ (1,611)	$ (1,507)	$ (38)	$ (763)	$ (3,919)
Loss per share:	$ (0.03)	$ (0.03)	$ —	$ (0.02)	$ (0.08)

The following reconciles non-GAAP adjusted net loss to the consolidated GAAP net loss for the nine months ended September 30, 2011.

	(In thousands, except per share data) Unaudited				
	OraSure Technologies, Inc. Results (Non-GAAP Adjusted Net Loss)	Adjust for Acquisition Related Costs Note 1	Adjust for DNA Genotek, Inc. Results Note 2	Purchase Accounting Adjustment Note 3	Consolidated Results (GAAP Net Loss)
Results of Operations					
Revenues	$ 56,169	$ —	$ 2,022	$ —	$ 58,191
Gross profit	36,463	—	1,421	(763)	37,121
Gross margin	*65%*		*70%*		*64%*
Total operating expenses	43,195	1,507	1,537	—	46,239
Operating loss	(6,732)	(1,507)	(116)	(763)	(9,118)
Net loss	$ (6,648)	$ (1,507)	$ (38)	$ (763)	$ (8,956)
Loss per share:	$ (0.14)	$ (0.03)	$ —	$ (0.02)	$ (0.19)

Note 1 – Represents success-based investment banking fees incurred by OraSure at the time of the closing of the DNAG acquisition. Additional legal, accounting, tax and consulting costs of $629,000 and $1,028,000 were incurred by OraSure in connection with the acquisition, and are included in the results reported in the first column for the three and nine month periods ended September 30, 2011, respectively.

Note 2 – The DNAG results include non-cash charges of $380,000 for the three and nine months ended September 30, 2011, related to the amortization of intangibles recorded in connection with the acquisition.

Note 3 – In connection with the DNAG acquisition, a purchase accounting adjustment totaling approximately $892,000 was recorded to write up DNAG's inventory from actual production cost to fair market value at the date of acquisition. Of this amount, $763,000 was included in cost of products sold during the three and nine months ended September 30, 2011 to reflect the amount of adjusted inventory sold during those periods.

Market	Three Months Ended September 30, Dollars 2011	2010	% Change	Percentage of Total Revenues 2011	2010
Infectious disease testing	$11,854	$10,843	9%	55%	57%
Substance abuse testing	2,765	3,019	(8)	13	16
Cryosurgical systems	3,395	3,008	13	16	16
Molecular collection systems	2,022	—	100	9	—
Insurance risk assessment	1,399	1,529	(9)	6	8
Product revenues	21,435	18,399	17	99	97
Licensing and product development	279	635	(56)	1	3
Total revenues	$21,714	$19,034	14%	100%	100%

Market	Nine Months Ended September 30, Dollars 2011	2010	% Change	Percentage of Total Revenues 2011	2010
Infectious disease testing	$33,100	$30,297	9%	57%	54%
Substance abuse testing	9,011	8,785	3	16	16
Cryosurgical systems	8,907	9,122	(2)	15	16
Molecular collection systems	2,022	—	100	3	—
Insurance risk assessment	4,145	4,471	(7)	7	8
Product revenues	57,185	52,675	9	98	94
Licensing and product development	1,006	3,522	(71)	2	6
Total revenues	$58,191	$56,197	4%	100%	100%

OraQuick® Revenues	Three Months Ended September 30, 2011	2010	% Change	Nine Months Ended September 30, 2011	2010	% Change
Domestic	$10,342	$10,102	2%	$29,411	$28,083	5%
International	971	436	123	2,574	1,089	136
Total OraQuick® revenues	$11,313	$10,538	7%	$31,985	$29,172	10%

Intercept® Revenues	Three Months Ended September 30, 2011	2010	% Change	Nine Months Ended September 30, 2011	2010	% Change
Domestic	$1,947	$1,913	2%	$5,909	$5,391	10%
International	438	562	(22)	1,472	1,522	(3)
Total Intercept® revenues	$2,385	$2,475	(4)%	$7,381	$6,913	7%

Cryosurgical Systems Revenues	Three Months Ended September 30, 2011	2010	% Change	Nine Months Ended September 30, 2011	2010	% Change
Professional domestic	$2,042	$1,690	21%	$5,097	$4,476	14%
Professional international	402	326	23	989	865	14
Over-the-Counter	951	992	(4)	2,821	3,781	(25)
Total cryosurgical systems revenues	$3,395	$3,008	13%	$8,907	$9,122	(2)%

Consolidated Balance Sheets (Unaudited)	September 30, 2011	December 31, 2010
Assets		
Cash, cash equivalents and short-term investments	$ 21,374	$ 75,738
Accounts receivable, net	14,361	12,471
Inventories	9,448	7,346
Other current assets	2,239	1,930
Property and equipment, net	20,000	19,611
Intangible assets, net	29,246	—
Goodwill	25,939	—
Other non-current assets	200	5,424
Total assets	$ 122,807	$ 122,520
Liabilities and Stockholders' Equity		
Current portion of long-term debt	$ 7,417	$ 7,791
Accounts payable	3,485	2,899
Accrued expenses	9,397	8,987
Deferred income taxes	6,534	—
Stockholders' equity	95,974	102,843
Total liabilities and stockholders' equity	$ 122,807	$ 122,520

Additional Financial Data (Unaudited)	Nine months ended September 30, 2011	2010
Capital expenditures	$ 1,806	$ 1,643
Acquisition of DNA Genotek, Inc.	$ 50,710	$ —
Depreciation and amortization	$ 3,011	$ 2,101
Stock based compensation	$ 3,016	$ 2,479
Cash provided by (used in) operating activities	$ (4,079)	$ 241
Accounts receivable – days sales outstanding	67 days	64 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2011 third quarter financial results, business developments and certain 2011 financial guidance, 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 #18091365, 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 9, 2011, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #18091365.

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 addition, through its wholly-owned subsidiary, DNA Genotek Inc., the Company also 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 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; 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 meet financial covenants in agreements with financial institutions; ability to refinance outstanding debt under expiring credit facilities on acceptable terms or at all; 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, 2010, 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.

2011 Third Quarter

Analyst/Investor Conference Call

November 2, 2011

Prepared Remarks of Douglas A. Michels and Ronald H. Spair

Please see "Important Information" at the conclusion of the following prepared remarks. The following remarks include a discussion of certain non-GAAP financial measures. Non-GAAP reporting is provided to help you better understand the Company's business and certain items which impacted the Company's results. However, non-GAAP financial results are not meant to be considered as a stand-alone measurement of performance, or as a substitute for, or as superior to, GAAP results. You should be aware that non-GAAP measures have inherent limitations and should be used only in conjunction with OraSure's consolidated financial statements prepared in accordance with GAAP. The Company issued a press release on November 2, 2011 which includes a table detailing the non-GAAP measures together with the corresponding GAAP results and a reconciliation to GAAP. You are encouraged to review these items.

Introduction – Doug Michels

Thanks Judy, and good afternoon everyone.

We are very pleased with the Company's third quarter financial performance and the considerable progress we have made toward our strategic initiatives as we lay the groundwork for future growth. Today we will cover several positive clinical developments that occurred during the quarter, the exceptional performance of our HCV device, our progress on readying the over-the-counter ("OTC") HIV product for commercialization and the impending initial launch of our drugs of abuse high throughput oral fluid assays.

Another significant development in the quarter was the completion of the DNA Genotek acquisition in mid-August for just over $50 million in cash. This acquisition complements our existing oral fluid business and will help OraSure

diversify into the fast-growing molecular diagnostics market. The DNA Genotek management team remains in place, and the two newly combined organizations are working extremely well together. We expect this new subsidiary to make strong contributions to our business for many years to come.

Our third quarter consolidated financial results were very strong, with revenues up over 14% compared to the third quarter of 2010. These numbers include approximately six weeks of DNA Genotek results following the closing of the acquisition. Excluding the DNA Genotek results, we exceeded our financial guidance previously provided for OraSure's base business on both the top and bottom lines.

Ron will start with a financial review for the third quarter, and I will follow with some additional comments on our progress and business. We will then take your questions.

And with that, I will turn the call over to Ron.

Third Quarter 2011 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Third quarter 2011 revenues were $21.7 million compared to $19.0 million reported in 2010. Revenues for the current quarter included $2.0 from our DNA Genotek subsidiary. Excluding DNA Genotek's results, our revenues increased 3% as higher sales of our infectious disease and cryosurgical systems products were partially offset by lower sales of our substance abuse testing and insurance risk assessment products and lower licensing and product development revenue.

Infectious disease testing revenues were $11.9 million in the third quarter of 2011 compared to $10.8 million in the third quarter of 2010. The overall 9% increase was driven by a 108% increase in international OraQuick® HIV sales and the inclusion of $425,000 of OraQuick HCV revenues. HCV revenues in the third quarter of 2010 were minimal. International HIV sales increased largely because certain private and government customers were able to make purchases for HIV testing during the quarter**.** Domestic OraQuick® HIV sales were flat when compared to the prior year period.

Third quarter 2011 cryosurgical revenues increased 13% compared to the third quarter of 2010. Professional sales in the U.S. increased 21% and international professional sales increased 23%. OTC sales were down 4%.

The higher domestic professional sales reflect the continued efforts of our manufacturers' sales representatives, improved focus by our distributors, and an increase in sales to governmental entities. International sales increased across all regions in the quarter. Our new Australian distributor made its first purchase in order to stock its inventory and sales into Europe increased primarily as a result of higher sales in France.

OTC cryosurgical sales during the quarter decreased $41,000 when compared to 2010, largely as a result of lower sales to our European and Latin American distributors.

In substance abuse testing, revenues decreased from $3.0 million in the third quarter of 2010 to $2.8 million in the comparable period of 2011, primarily as a result of lower QED sales caused by a temporary disruption of production. However, we resumed production again in October, and are now shipping product and working our way through the backlog.

Our insurance risk assessment sales decreased from $1.5 million in 2010 to $1.4 million in 2011. This is largely the result of the loss of one of our customers who changed its underwriting methodologies to move away from oral fluid testing and now instead simply uses a signed questionnaire to screen applicants.

Gross Margin – Ron Spair

Turning to Gross Margin, our overall margin for Q3 of 2011 was 63% compared to 62% reported for the third quarter of 2010. OraSure's original core business generated a margin of 66% while DNA Genotek generated margin of 33%. OraSure's core business gross margin for 2011 benefited from improved product mix coupled with more efficient manufacturing operations. DNA Genotek's gross margin included $763,000 of increased costs of products sold due to a non-cash inventory adjustment. We recorded a purchase accounting adjustment of approximately $892,000 related to the write-up of the acquired DNA Genotek inventory to fair value. The adjustment is commonly referred to as a "stepped-up value" adjustment and is charged to cost of products sold as the related finished goods inventory is sold. We expect the remaining inventory subject to this adjustment to be sold in the fourth quarter. Had we not recorded this purchase accounting adjustment, DNA Genotek would have generated a gross margin of 70%.

Operating Expenses – Ron Spair

Our total operating expenses for the third quarter increased $6.3 million compared to the third quarter of 2010. Third quarter 2011 expenses included $1.5 million of DNA Genotek expenses. Research and development expenses increased by approximately $2.5 million, reflecting higher clinical trial costs associated with our OraQuick® HIV OTC program. Sales and marketing expenses increased largely due to higher consulting and staffing costs. General and administrative expenses increased primarily as a result of transaction costs associated with the

acquisition of DNA Genotek.

Net Loss – Ron Spair

From a bottom line perspective, we reported a GAAP net loss of $3.9 million, or $0.08 per share for the third quarter of 2011. This compares to net income of $274,000, or $0.01 per share, for the same period of 2010. If we strip out the DNAG results, the purchase accounting adjustment discussed earlier and the investment banking fees that became payable upon closing of the acquisition, the OraSure base business would have generated a net loss of $1.6 million, or $0.03 per share. I would note that this number does reflect the impact of other transaction-related expenses such as legal, accounting and consulting costs, as we had included an estimate of these costs in our guidance for Q3.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, our cash balance at September 30, 2011 was $21.4 million. This was down from the $75.7 million on hand at December 31, 2010 as a result of the DNA Genotek acquisition and related expenses.

During the third quarter, we used $3.7 million in cash to fund operations compared to $3.3 million generated from operations in the third quarter of 2010.

Fourth Quarter 2011 Financial Guidance – Ron Spair

Turning to guidance for the fourth quarter of 2011, we are projecting consolidated revenues of approximately $22.0 to $23.0 million and a consolidated net loss per share of approximately $0.07 to $0.08 for the quarter.

And now back to Doug.

Program and Business Update – Doug Michels

Thanks, Ron. I'd now like to spend the next few minutes outlining the progress we have made on our strategic initiatives. After a considerable financial commitment and years of planning and hard work, we are in the final stages for two of our key growth objectives.

HIV-OTC – Doug Michels

Beginning with HIV-OTC — The final phase of clinical testing, which involved the use of our test in an unobserved setting, is now complete. This marks a significant step forward in the approval process for this product. In total, we enrolled and tested over 5,600 subjects, and identified more than 100 previously undiagnosed HIV infected individuals.

Enrollment and testing at all clinical sites in the study are complete, the database is locked and we are now analyzing the final data, which will be used to prepare a final report. We are on track to complete our FDA submission before the end of the year.

As indicated on prior calls, our FDA filing is being submitted in three separate modules. The first module, which contains data from all studies performed prior to the final phase, was filed in August and is under active FDA review. The second module, which will contain information about our manufacturing operations and Customer Care Call Center, is expected to be filed late this month. And the final module, containing the results of the unobserved clinical trial, is scheduled to be filed by year end. We hope to get on the agenda for the FDA's Blood Products Advisory Committee ("BPAC") during the first half of 2012.

During the third quarter, we continued planning for the commercial launch of our HIV OTC test. We are completing an intensive interview process to select both an advertising agency and public relations firm to help market our test and we are

nearing a decision on the selection of a third party to manage our Customer Care Call Center. In addition, we have initiated a new round of market research to refresh our messaging and product positioning and to sharpen our demand forecast. These activities are expected to drive meaningful spend levels in the fourth quarter and ramp up as we approach commercial launch.

A major initiative that we have pursued for the last two years has been to extend the shelf life of our OraQuick *ADVANCE*® HIV professional product. We announced an FDA-approved extension to 30 months during our last earnings call. Since our at-home test will consist of the same device as our professional product, we expect to have at least the same 30-month dating for our OTC test. So we should be in good shape from a product dating perspective. Additionally, since we have FDA approval to manufacture OraQuick® on fully-automated equipment, we should have no difficulty meeting the demand likely to result from an OTC approval and launch.

We are extremely excited about our OTC product and expect the updated market research to confirm the attractiveness of this opportunity. We received a bit of confirmation in a recent study reported in the July 2011 issue of the Annals of Internal Medicine. In that study, which was conducted by Johns Hopkins in urban Emergency Departments, patients being tested for HIV were given the option of taking a self test using either our OraQuick® oral test or a rapid finger stick blood test. According to the article, ninety one percent of the self testers chose oral fluid over blood and an even higher percentage indicated they would “probably” or “definitely” use a home test if one were to become available. This independent study is consistent with the market research we conducted several years ago. We believe this study is further evidence of both the value of oral fluid testing and the urgent need to make HIV home testing a reality here in the U.S.

OraQuick® HCV – Doug Michels

Turning now to our OraQuick® HCV test, the primary focus has been on securing a CLIA waiver for this product. As you know, in response to an FDA request, we conducted an additional reproducibility study which has now been completed. We are very pleased with the results and have submitted final data to the FDA. At this stage, we believe we have given the FDA all information required for it to act on our CLIA submission. Hopefully, receipt of the CLIA waiver will occur shortly.

Even though we have not yet received a CLIA waiver, we continue to promote this product to customers licensed to use moderately complex tests.

- As Ron indicated, we reported over $400,000 in HCV sales during the third quarter. We believe this level of activity confirms that interest in this product is high.
- In September, we supported Merck's "Step Up To The Plate" testing initiative with Major League Baseball that I mentioned during our last earnings call. Under this initiative, we sold over 7,000 OraQuick® HCV tests to Merck to be used for HCV testing by local public health agencies at various major league ballparks and within the communities they serve. We believe initiatives of this type will help increase awareness and demand for HCV testing.
- In anticipation of receiving a CLIA waiver, we have been working closely with Merck to prepare training and deployment plans for the Merck sales team who will start detailing our product to physicians as soon as possible after the CLIA waiver is received. We will be utilizing Merck's National Business Group which is a customer facing headquarters sales team that capitalizes on technology to meet the needs of customers and business. Additionally, Merck's HCV Specialist Organization will also be detailing the product. We expect to have training

completed by early December.

- On the international front, we also continue to collaborate with Merck through their various country organizations. Detailing efforts continue to progress. Currently, our HCV sales are growing above plan expectations due in part to the work of our two organizations.
- Finally, we continue to see strong performance by our HCV test when it is used in studies conducted by third parties. For example –
    - A study published in the Journal of Infectious Disease in September compared our test with two other rapid HCV assays that have not been approved by the FDA. Although all three tests had comparable specificity (i.e. the ability to correctly detect true negatives), the study reported that the OraQuick® HCV test had better sensitivity (i.e. the ability to correctly detect true positives) and was more accurate when used to test individuals infected with HIV.
    - Another study by the Centers for Disease Control and Prevention that was published in October in Clinical Infectious Diseases reported similar performance for our OraQuick® test compared to the other non-approved rapid HCV tests, when used to identify HCV infection in prospective testing of human subjects.
    - Finally, the New York City Department of Health reported results of a study of the use of our product in oral fluid in the November issue of the American Journal of Public Health. This study showed that our oral fluid test had accuracy comparable to blood-based HCV immunoassays performed in a laboratory and was preferred over laboratory tests by the clinical staff conducting the study. The study concluded that an oral rapid test could help reach individuals who are unaware of their HCV status and extend testing into non-clinical settings such as mobile testing units.

HIV Testing – Doug Michels

On the HIV testing front, we were very pleased to see this past Monday the policy statement issued by the American Academy of Pediatrics regarding HIV testing for adolescents. The policy advocates regular, routine HIV screening for all adolescents 16 to 18 years of age in health care settings when the prevalence of HIV in the patient population is more than 0.1%. We believe this policy statement, which also acknowledges the use of rapid oral fluid testing and its high acceptance by youth, will lead to more testing of individuals in this age group.

Drugs-of-Abuse High Throughput Oral Fluid Assays – Doug Michels

In substance abuse, we expect to begin launching several of the high throughput oral fluid drug assays developed with Roche Diagnostics this quarter. As you know, the FDA issued 510(k) clearances for assays for PCP, cocaine, opiates, methamphetamine and amphetamine for use with our Intercept® oral fluid collection device.

As for the THC assay (marijuana), the final clinical studies have begun and are expected to be completed around year end. As soon as they are completed and the data is compiled and analyzed, Roche will submit this assay for 510(k) clearance, likely during January of 2012.

OraSure QuickFlu™– Doug Michels

Another area I'd like to address is our OraSure QuickFlu™ test. As you know, flu testing is a seasonal business that is affected by the timing and severity of the flu season each year. In contrast to last year, the current flu season has been relatively mild. Nevertheless, we have been assisting numerous customers in their evaluations of our product and, overall, customer interest in the QuickFlu™ test is high. We will continue to aggressively promote this product as the flu season evolves during the rest of this year and into 2012.

DNA Genotek Acquisition – Doug Michels

And last, but certainly not least, I'd like to reiterate how happy we are to have DNA Genotek as part of the OraSure family. The Company has built an excellent business in the collection and stabilization of genetic material in oral fluid samples. Their products are industry-leading and enjoy a strong and loyal customer following, especially in the academic and commercial research areas. Activities are well underway to integrate a few critical business processes and our respective management teams are now focused on developing strategies to maximize the respective strengths of the companies and grow our combined businesses.

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So before we move to take your questions, I would like to thank the employees of OraSure and the newest members of our team from Canada for their efforts in helping deliver a strong quarter. We are very excited to have added DNA Genotek and its exceptional products, and we look forward to pursuing the opportunities this acquisition provides in the large molecular diagnostic market. Moreover, the completion of our final HIV-OTC study was a fantastic achievement and was years in the making. We were also able to provide the FDA with the additional information they requested on our CLIA submission for HCV, all while delivering strong quarterly financial results that exceeded the guidance for our base business exclusive of DNA Genotek. We firmly believe that these successes will serve as the foundation for future growth at OraSure.

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, earnings/loss per share, and expected clinical development, regulatory filings and approvals. 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 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; 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 meet financial covenants in agreements with financial institutions; ability to refinance outstanding debt under expiring credit facilities on acceptable terms or at all; 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, 2010, 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.