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): February 8, 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 February 8, 2012, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter and full year ended December 31, 2011, and providing financial guidance for the first 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 February 8, 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 and full year ended December 31, 2011, provided financial guidance for the first 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 February 8, 2012, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2011, and providing financial guidance for the first quarter of 2012.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year

2011 Analyst/Investor Conference Call Held February 8, 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: February 8, 2012

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

Index to Exhibits

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99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2011 Analyst/Investor Conference Call Held February 8, 2012.

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 Fourth Quarter and Full-Year 2011 Financial Results
– Company Reports Record Quarterly Revenues –

BETHLEHEM, PA – February 8, 2012 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the fourth quarter and full year of 2011.

Financial Highlights

- Consolidated revenues were $23.7 million for the fourth quarter of 2011, a 26% increase from the comparable quarter of 2010. Revenues for the current quarter included $19.5 million from OraSure operations and $4.2 million from DNA Genotek (“DNAG”) operations. The Company completed its acquisition of DNAG on August 17, 2011.
- Consolidated revenues were $81.9 million for the full-year 2011, a 9% increase from 2010. Full-year revenues included $75.7 million from OraSure operations and $6.2 million from DNAG operations.
- Consolidated net income for the fourth quarter of 2011 was $115,000, or $0.00 per share, which compares to a net loss of $1.0 million, or $0.02 per share, for the fourth quarter of 2010. The current quarter net income includes a net loss of $195,000, and an income tax benefit of $553,000, both attributable to DNAG.
- Consolidated net loss for the full-year 2011 totaled $8.8 million, or $0.19 per share, which compares to a net loss of $3.5 million, or $0.08 per share, for 2010. The current year loss includes a $693,000 net loss attributable to DNAG, which reflects $2.1

million in non-cash charges associated with amortization of intangible assets and certain purchase accounting inventory adjustments related to the acquisition, partially offset by $869,000 in related tax benefits. The 2011 consolidated net loss also includes approximately $2.6 million of acquisition-related transaction costs incurred by OraSure and $7.9 million of clinical trial spending related to the Company's OraQuick® HIV over-the-counter ("OTC") product.

"During the fourth quarter of 2011, we achieved two major milestones in our principal clinical development programs," said Douglas A. Michels, President and CEO of OraSure Technologies. "We successfully obtained a CLIA waiver for our OraQuick® HCV rapid test, thereby substantially expanding the potential market for this product, and we filed with the FDA the final of three modules to our pre-market approval application for an OraQuick® HIV OTC test. These significant developments along with the acquisition of DNA Genotek earlier in the year, resulted in a successful 2011 and will provide us with the opportunity to drive growth through new product offerings and access to new markets in 2012 and years to come."

Financial Results

Excluding DNAG sales, product revenues for the quarter and year ended December 31, 2011 increased 4% and 5%, respectively, primarily as a result of higher sales of the Company's infectious disease testing, substance abuse and cryosurgical systems products, partially offset by lower sales of its insurance risk assessment products. Licensing and product development revenues for the full year decreased by $2.6 million primarily as a result of the absence of $2.0 million in milestone payments received in 2010 under the terms of the Company's collaboration agreement with Merck for the development and promotion of the OraQuick® rapid HCV test.

The Company reported consolidated net income of $115,000, or $0.00 per share, for the fourth quarter of 2011, compared to a net loss of $1.0 million, or $0.02 per share, for the fourth quarter of 2010. The current quarter results include $813,000 of intangible asset amortization and a $102,000 purchase accounting inventory adjustment resulting from the DNAG acquisition.

The purchase accounting inventory adjustment is related to the write up of DNAG's finished goods inventory to fair market value as of the acquisition date. For the quarter and year ended December 31, 2011, this adjustment increased cost of products sold by $102,000 and $852,000, respectively, based on the amount of the acquired inventory sold during each period.

The Company reported a consolidated net loss of $8.8 million, or $0.19 per share, for the year ended December 31, 2011, compared to a net loss of $3.5 million, or $0.08 per share, for the year ended December 31, 2010. The current year's consolidated loss included $6.2 million of incremental costs associated with the OraQuick® HIV OTC clinical trials, $2.6 million of transaction costs associated with

the acquisition of DNAG, $1.2 million in amortization of acquired intangible assets and the $852,000 purchase accounting inventory adjustment described above.

Consolidated gross margin for the three months ended December 31, 2011 was 62% compared to 64% for the three months ended December 31, 2010. Consolidated gross margin was 63% for the years ended December 31, 2011 and 2010. The decrease in gross margin in the current quarter was largely due to an unfavorable change in product revenue mix. Gross margin remained relatively flat for the full year 2011 as the negative impact of the purchase accounting inventory adjustment discussed above was offset by the benefits derived from lower direct labor costs, improved absorption of overhead costs as a result of staffing optimization, and the full implementation of automated manufacturing during 2011.

Consolidated operating expenses increased to $14.9 million in the fourth quarter of 2011 from $12.9 million in the comparable period of 2010 and also increased to $61.1 million for the year ended December 31, 2011, from $50.7 million for the year ended December 31, 2010. These increases reflect the inclusion of DNAG operating expenses, higher clinical trial spending related to the Company's OraQuick® HIV OTC product and increased legal, accounting, consulting and other transaction costs incurred by OraSure in connection with the DNAG acquisition.

For the quarter and year ended December 31, 2011, the Company also recorded an income tax benefit associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits.

Cash, cash equivalents and short-term investments totaled $23.9 million and working capital was $30.9 million at December 31, 2011, compared to $75.7 million and $77.8 million, respectively, at December 31, 2010. The decrease in cash and working capital was largely due to the use of $52.3 million in cash to fund the DNAG acquisition and related transaction expenses.

First Quarter 2012 Outlook

The Company expects total consolidated revenues for the first quarter of 2012 to range from $20.5 to $21.0 million and is projecting a net loss of approximately $0.08 - $0.09 per share for the first quarter of 2012.

Financial Data

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

Unaudited

	Three months ended December 31,		Year ended December 31,	
	2011	2010	2011	2010
Results of Operations				
Revenues	$ 23,690	$ 18,817	$ 81,881	$ 75,015
Cost of products sold	9,094	6,853	30,164	27,656
Gross profit	14,596	11,964	51,717	47,359
Operating expenses:				
Research and development	3,297	4,048	18,407	13,192
Sales and marketing	6,357	4,830	22,383	20,727
General and administrative	5,222	4,018	20,325	16,794
Total operating expenses	14,876	12,896	61,115	50,713
Operating loss	(280)	(932)	(9,398)	(3,354)
Other expense	(158)	(91)	(312)	(143)
Loss before income taxes	(438)	(1,023)	(9,710)	(3,497)
Income tax benefit	(553)	—	(869)	—
Net income (loss)	$ 115	$ (1,023)	$ (8,841)	$ (3,497)
Earnings (loss) per share:				
Basic and Diluted	$ —	$ (0.02)	$ (0.19)	$ (0.08)
Weighted average shares:				
Basic	47,264	46,221	46,908	46,187
Diluted	48,893	46,221	46,908	46,187

Market	Three Months Ended December 31, Dollars 2011	Dollars 2010	% Change	Percentage of Total Revenues 2011	Percentage of Total Revenues 2010
Infectious disease testing	$11,592	$11,437	1%	49%	61%
Substance abuse testing	3,487	2,886	21	15	15
Cryosurgical systems	3,139	2,844	10	13	15
Molecular collection systems	4,194	—	100	17	—
Insurance risk assessment	1,087	1,355	(20)	5	7
Product revenues	23,499	18,522	27	99	98
Licensing and product development	191	295	(35)	1	2
Total revenues	$23,690	$18,817	26%	100%	100%

Market	Year Ended December 31, Dollars 2011	Dollars 2010	% Change	Percentage of Total Revenues 2011	Percentage of Total Revenues 2010
Infectious disease testing	$44,691	$41,738	7%	55%	55%
Substance abuse testing	12,498	11,671	7	15	16
Cryosurgical systems	12,046	11,965	1	15	16
Molecular collection systems	6,216	—	100	8	—
Insurance risk assessment	5,232	5,825	(10)	6	8
Product revenues	80,683	71,199	13	99	95
Licensing and product development	1,198	3,816	(69)	1	5
Total revenues	$81,881	$75,015	9%	100%	100%

OraQuick® Revenues	Three Months Ended December 31, 2011	2010	% Change	Year Ended December 31, 2011	2010	% Change
Domestic HIV	$ 9,775	$10,093	(3)%	$38,722	$38,172	1%
International HIV	721	766	(6)	3,011	1,800	67
Domestic HCV	426	44	868	890	46	1,835
International HCV	387	63	514	672	119	465
Total OraQuick® revenues	$11,309	$10,966	3%	$43,295	$40,137	8%

Intercept® Revenues	Three Months Ended December 31, 2011	Three Months Ended December 31, 2010	% Change	Year Ended December 31, 2011	Year Ended December 31, 2010	% Change
Domestic	$2,096	$1,883	11%	$ 8,004	$ 7,274	10%
International	439	454	(3)	1,912	1,976	(3)
Total Intercept® revenues	$2,535	$2,337	8%	$ 9,916	$ 9,250	7%

Cryosurgical Systems Revenues	Three Months Ended December 31, 2011	Three Months Ended December 31, 2010	% Change	Year Ended December 31, 2011	Year Ended December 31, 2010	% Change
Professional domestic	$1,678	$1,492	12%	$ 6,775	$ 5,967	14%
Professional international	412	520	(21)	1,400	1,385	1
Over-the-Counter	1,049	832	26	3,871	4,613	(16)
Total cryosurgical systems revenues	$3,139	$2,844	10%	$12,046	$11,965	1%

Consolidated Balance Sheets (Unaudited)	December 31, 2011	December 31, 2010
Assets		
Cash, cash equivalents and short-term investments	$ 23,878	$ 75,738
Accounts receivable, net	17,159	12,471
Inventories	9,621	7,346
Other current assets	2,178	1,930
Property and equipment, net	19,855	19,611
Intangible assets, net	30,383	4,807
Goodwill	24,740	—
Other non-current assets	47	617
Total assets	$ 127,861	$ 122,520
Liabilities and Stockholders' Equity		
Current portion of long-term debt	$ 7,292	$ 7,791
Accounts payable	4,142	2,899
Accrued expenses	10,542	8,987
Deferred income taxes, net	5,636	—
Stockholders' equity	100,249	102,843
Total liabilities and stockholders' equity	$ 127,861	$ 122,520

Additional Financial Data (Unaudited)	Year ended December 31, 2011	2010
Capital expenditures	$ 2,505	$ 2,106
Acquisition of DNA Genotek, Inc. (net of cash acquired)	$ 49,730	$ —
Depreciation and amortization	$ 4,915	$ 3,012
Stock based compensation	$ 4,101	$ 3,229
Cash provided by (used in) operating activities	$ (2,991)	$ 3,887
Accounts receivable – days sales outstanding	68 days	61 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2011 fourth quarter and full-year financial results, business developments and first quarter 2012 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 #44923763, 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 February 15, 2012, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #44923763.

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.

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Exhibit 99.2

OraSure Technologies, Inc.

2011 Fourth Quarter and Full Year

Analyst/Investor Conference Call

February 8, 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 for joining us on our call.

2011 was a year filled with several milestone achievements, which should help pave the way for a very successful 2012. We made substantial progress on our two main clinical development programs involving our OraQuick® HCV test and our OraQuick® HIV over-the-counter ("OTC") test. In addition, we completed the acquisition of DNA Genotek earlier in the year, with Q4 being the first full quarter of consolidated operations.

Our clinical programs are key to our growth strategy and have been the focus of the Company for the last several years. We are also happy that DNA Genotek is now part of OraSure and we are excited about the potential of the molecular diagnostics market. We believe OraSure is extremely well positioned for growth that is diversified across multiple business lines.

Consolidated revenues for the fourth quarter were up 26% compared to the fourth quarter of 2010. The increase includes newly-acquired revenue from the DNA Genotek acquisition.

Ron will provide a detailed review of our fourth quarter financial results. I will

follow with some additional comments on our clinical programs and business, and then we will take your questions.

And now, I will turn the call over to Ron.

Fourth Quarter 2011 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Fourth quarter 2011 revenues were a record $23.7 million compared to $18.8 million reported in 2010. Revenues for the current quarter included $4.2 million from our DNA Genotek subsidiary. Included in that $4.2 million was $1.5 million of product shipped to DNA Genotek's largest customer. This customer makes bulk purchases generally once a year. Excluding DNA Genotek's results, our revenues increased 4% as higher sales of our infectious disease, substance abuse testing, and cryosurgical systems products were partially offset by lower sales of our insurance risk assessment products and lower licensing and product development revenue.

Infectious disease testing revenues were $11.6 million in the fourth quarter of 2011 compared to $11.4 million in the fourth quarter of 2010. Fourth quarter 2011 results included $813,000 in domestic and international OraQuick® HCV revenues compared to $107,000 in the fourth quarter of the prior year. In addition, our OraQuick® HCV revenues increased sequentially from the third quarter by $388,000. The increases in HCV revenues were partially offset by a decrease in domestic and international HIV revenues of $363,000, largely due to changes in customer ordering patterns.

In substance abuse testing, revenues increased from $2.9 million in the fourth quarter of 2010 to $3.5 million in the comparable period of 2011, primarily as a

result of increased Intercept® sales caused by the timing of orders placed by one of our laboratory customers. QED sales also increased as we fulfilled an order backlog created by a disruption in production earlier in the year.

Fourth quarter 2011 cryosurgical revenues increased 10% compared to the fourth quarter of 2010. Professional sales in the U.S. increased 12% and international professional sales decreased 21%. OTC sales were up 26%.

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 decreased in the current quarter due to customer ordering patterns.

OTC cryosurgical sales during the quarter increased $217,000 when compared to 2010, largely as a result of higher sales to our European distributor.

Our insurance risk assessment sales decreased from $1.4 million in 2010 to $1.1 million in 2011. This was largely due to continued softness in insurance underwriting and the adoption by some underwriters of a "Simplified Issues" policy. This is a policy where lab based testing is replaced by having applicants respond to a questionnaire about their behaviors. We had two customers adopt this policy.

Gross Margin – Ron Spair

Turning to gross margin, our overall margin for Q4 of 2011 was 62% compared to 64% reported for the fourth quarter of 2010. The decrease in gross margin in the quarter was largely due to an unfavorable change in product revenue mix. In addition, 2011 gross margin included $102,000 of increased costs of products sold caused by the turnover of finished goods inventory subject to the "stepped-up value" adjustment recorded in connection with the DNA Genotek acquisition.

Operating Expenses – Ron Spair

Our total operating expenses for the fourth quarter increased $2.0 million compared to the fourth quarter of 2010. Fourth quarter 2011 expenses included $3.1 million of DNA Genotek expenses. Research and development expenses decreased by approximately $751,000, reflecting lower clinical trial costs associated with our OraQuick® HCV program, partially offset by the inclusion of DNA Genotek expenses. General and administrative expenses increased primarily as a result of higher accounting and legal fees. Sales and marketing expenses increased for the quarter primarily due to the inclusion of the DNA Genotek expenses.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of $115,000, or $0.00 earnings per share for the fourth quarter of 2011. This compares to a net loss of $1.0 million, or $0.02 per share, for the same period of 2010. In the fourth quarter of 2011, we recorded an income tax benefit of $553,000 on a loss before taxes of $438,000. The income tax benefit is associated with the DNA Genotek loss before income taxes and certain Canadian research and development and investment tax credits.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, our cash balance at December 31, 2011 was $23.9 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 fourth quarter, we generated $1.1 million in cash from operations compared to $3.6 million generated from operations in the fourth quarter of 2010.

First Quarter 2012 Financial Guidance – Ron Spair

Turning to guidance for the first 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 $0.08 to $0.09 for the quarter. Expenses in Q1 of 2012 are expected to be higher than in Q4 of last year as a result of approximately $1.7 million in pre-launch prep costs for our OraQuick HIV OTC test. Additionally, we are in the process of conducting a refresh of our overall corporate strategy and this will run through mid year. The costs associated with this activity will also impact Q1. Some of these costs were expected to be expended in Q4 of last year but were deferred to 2012, and this contributed to the over performance last quarter.

And now back to Doug.

Program and Business Update – Doug Michels

Thanks, Ron. During the fourth quarter, we achieved two significant milestones in our principal clinical programs. I would like to briefly comment on these as well as certain other developments in our business.

OraQuick HCV – Doug Michels

The first milestone relates to our OraQuick® HCV test. In November, we announced the receipt of a CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver for this product. Our OraQuick® HCV test is now FDA approved and CLIA waived for both venous and fingerstick whole blood applications. This is the only FDA approved rapid HCV testing product available for sale in the U.S.

Receipt of the CLIA waiver has always been an important strategic objective as it substantially increases the potential market reach and broadens the public health benefit of this new product. Our test can now be used by more than 180,000 sites in the United States, where previously the test could only be performed in laboratories certified under CLIA to perform “moderately complex” tests. With the waiver, our test can now be used in a variety of settings including health clinics, community-based organizations and physician offices.

Not surprisingly, now that we have received the CLIA waiver, several sales and marketing initiatives can be implemented. For example, Merck can now begin detailing the product into the U.S. physician office market under our HCV

collaboration. These detailing activities have started and will be ramping up during the first quarter.

Additionally, we can now finalize and implement our distribution arrangements for physicians' offices and federally funded community health centers through several large distributors, including McKesson, Henry Schein and PSS. We will also be focusing our direct sales efforts on public health departments that already have the infrastructure in place to conduct rapid HIV testing, and we will continue to market this product directly to hospitals.

As discussed in prior calls, the difficult economic environment has created challenges for our business and has adversely affected funding available for our OraQuick® HIV product, particularly in the U.S. public health market and to some extent in hospitals. We expect those same headwinds to continue and have a similar impact on the OraQuick® HCV test.

As a result, in an effort to mitigate the impact of the tight funding environment, our sales and marketing teams have sought to assist customers in identifying funding for HCV testing efforts, and we are already starting to see results. We worked with Advocate Trinity Hospital in Chicago, where we were able to help locate grant money for HCV testing. This hospital is now the first in the nation to conduct rapid HCV testing using our OraQuick® product in its emergency room. This would not have been possible without the CLIA waiver and the experience of our sales team.

For the full year 2011, we generated $1.6 million in revenue from domestic and international sales of our OraQuick® HCV test. Although predicting future HCV revenues is somewhat difficult given that we are just now developing the market for a rapid test, we do expect to see growth in sales during 2012 compared to last year because of the CLIA waiver and the heightened profile HCV is receiving.

With the advent of new drug therapies for HCV, major pharmaceutical companies are eager to raise awareness of this condition. Furthermore, we believe HCV screening and treatment is likely to attract more significant attention in the future due in part to the efforts of government agencies.

- As you may recall, the Department of Health and Human Services issued its Viral Hepatitis Action Plan last year which lays out a strategy for expanding awareness, prevention, care and treatment of viral hepatitis, including HCV. This is a multi-year plan that includes revising the CDC's guidelines for HCV testing and linkage to care. In furtherance of this plan, the CDC is considering a new strategy for hepatitis screening that is broader in scope than the current screening approach. In particular, the CDC is now evaluating the use of a strategy expanded to include persons born from 1945 to 1965 in the definition of those "at risk" who should be screened for HCV. This age range includes 10's of millions of people. It is our expectation that revised CDC guidelines will be issued later this year.
- There have also been studies and support demonstrated by the community for the implementation of a broader testing strategy. According to a study published online this past November in the *Annals of Internal Medicine,* birth cohort screening for hepatitis C is cost effective in primary care settings and such a proactive screening strategy could identify over 800,000 currently unidentified cases, which could save many thousands of lives each year. Similarly, the Chronic Liver Disease Foundation, an organization comprised of our nation's leading hepatologists and gastroenterologists, earlier this year issued a position paper in support of broader HCV testing and recognizing the benefits associated with rapid HCV testing.

- The Viral Hepatitis Action Plan also indicates that hepatitis will continue to be nationally recognized through the designation of World Hepatitis Day on July 28th and the promotion of the month of May as “Hepatitis Awareness Month.” Additionally, beginning in 2012, the Plan provides for the designation of May 18th as “Hepatitis Testing Day” in the United States. This national designation is obviously important to our business and we have been invited to open the NASDAQ stock market to help recognize this date. We believe these activities will continue to focus attention on the need for greater levels of HCV testing, and the benefits and use of our OraQuick® HCV rapid testing product.

HIV-OTC – Doug Michels

Turning to our HIV-OTC clinical program, as previously announced, at the end of 2011 we submitted the third and final module to our application for FDA approval of an OraQuick® rapid HIV test for home use. This module contained the findings from the final phase of clinical testing, which involved the use of an investigational version of our product by subjects in an unobserved setting. Approximately 5,800 individuals were enrolled and tested in this phase across 20 sites nationwide. This work resulted in the identification of more than 100 previously undiagnosed HIV-infected individuals.

Our submission is under active review by the FDA, and we hope to participate in an FDA Blood Products Advisory Committee (“BPAC”) meeting this year. According to the FDA website, BPAC meetings are scheduled for May, July and December of 2012. Our hope is to be scheduled as soon as possible.

As you know, HIV/AIDS continues to be a major health issue both domestically and around the world. The CDC estimates that there are approximately 1.2 million people in the U.S. infected with HIV and that approximately 240,000 are unaware of their status. Unfortunately, this is occurring despite the widespread availability

of both laboratory-based and rapid point-of-care HIV testing options. According to the CDC, individuals who do not know their status are unknowingly responsible for up to 70% of the approximate 50,000 new HIV infections that occur each year in the U.S.

We believe these data are compelling and clearly demonstrate that the current state of HIV testing is inadequate. Additional options are urgently needed for identifying undiagnosed individuals. This is a major reason why we have invested so much time and resources into our OTC clinical program. We believe that our rapid HIV in-home test, if approved by the FDA, would be a significant step forward for HIV testing and a powerful addition to the HIV testing options currently available.

This view is not only supported by our market research and experience in the professional market, but also by other parties. For example, a new study conducted by researchers at the HIV Center at Columbia University Psychiatry and the New York State Psychiatric Institute, was recently published in the *Journal of Sex Research*. This study asked a group of gay men who habitually engage in risky sexual practices whether they would be willing to use a rapid HIV in-home test, such as our OraQuick® oral test, to screen their sexual partners. The study found that the vast majority of those individuals questioned would likely ask their partners to take the test and might engage in safer sexual practices if their partner's response raised doubts about his HIV status. We believe this study provides another piece of evidence supporting the benefits of an HIV OTC test.

As indicated in prior calls, we are focused on planning for the commercial launch of our HIV-OTC test, and we made good progress during the fourth quarter. We have now engaged advertising and public relations firms and have selected a firm to act as our sales representative to the retail trade and to provide logistics and order-to-cash services for our product. We have also created an integrated project plan and formed a cross-functional team to ensure we are prepared to launch this

product as quickly as possible once we receive FDA approval.

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

In substance abuse, I am happy to report the launch of the high throughput oral fluid drug assay program with Roche Diagnostics. We are pleased to add this new product line and expect these products to contribute to our overall growth. To date, assays for PCP, cocaine, opiates, methamphetamine and amphetamine have been FDA 510(k) cleared for use with our Intercept® oral fluid collection device.

To round out a complete NIDA-5 panel, we still need clearance for an assay for THC (marijuana). The final clinical studies are continuing, and we expect Roche to submit this assay for 510(k) clearance later this year.

DNA Genotek Acquisition – Doug Michels

Turning now to our newest business line, DNA Genotek — as previously noted, the fourth quarter of 2011 was the first for which we have reported consolidated results, and the business progressed largely as expected. DNA Genotek contributed over $4 million in revenues, which is consistent with our expectations. The integration process has also gone very smoothly, and this is a credit to the DNA Genotek team. DNA Genotek's senior management is continuing to build the business, and we are highly confident in their future success.

New Board Member – Doug Michels

A final point to mention is the appointment during the fourth quarter of Mr. Gerald Ostrov as a member of the Company's Board of Directors, which we previously announced. On numerous occasions over the past several years, our Board has discussed the value of adding a Director with strong experience and expertise in consumer products, especially as the clinical program for our HIV-OTC test has continued to progress. Jerry's addition to the Board fills this important need and comes at a very opportune time.

Jerry has much to offer from his extensive consumer experience at Bausch & Lomb, Johnson & Johnson and Ciba-Geigy and he is already providing wise counsel and important contributions to our efforts.

* * * *

Conclusion

So in summary, 2011 was a very successful year for OraSure as we made great strides on our clinical programs and added exciting new offerings to our product portfolio. This success has provided us the opportunity to transform the OraSure business in 2012 and beyond. I would like to thank all of our employees for their efforts and dedication towards the development of products that are critical tools in the battle against the spread of infectious diseases and substance abuse.

We have already had several of these important products approved, and we will not rest until the job is complete. We are working hard to maximize the HCV opportunity in the near term and remain very excited and optimistic about the prospects for offering the first ever rapid HIV test into the U.S. retail marketplace. With the progress of our clinical programs, the potential of new product offerings and entry into new markets, and the addition of DNA Genotek, we believe OraSure has never been better positioned for the future.

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.