
**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): May 2, 2012

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

36-4370966
(I.R.S. Employer
Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360
(Zip Code)

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 – Results of Operations and Financial Condition.

On May 2, 2012, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended March 31, 2012, and providing financial guidance for the second 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 March 2, 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 Mark L. Kuna, the Company’s Senior Vice President, Finance and Controller, discussed the Company’s consolidated financial results for the quarter ended March 31, 2012, provided financial guidance for the second quarter of 2012 and described certain business developments. A copy of the prepared remarks of Messrs. Michels and Kuna is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

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

Item 9.01 – Financial Statements and Exhibits.**(d) Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated May 2, 2012, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2012, and providing financial guidance for the second quarter of 2012.
99.2	Prepared Remarks of Douglas A. Michels and Mark L. Kuna for OraSure Technologies, Inc. First Quarter 2012 Analyst/Investor Conference Call Held May 2, 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: May 2, 2012

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

Index to Exhibits

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OraSure Technologies, Inc.

Company Contact:

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www.orasure.com

OraSure Announces 2012 First Quarter Financial Results

BETHLEHEM, PA – May 2, 2012 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the first quarter of 2012.

Financial Highlights

- Consolidated revenues were \$20.9 million for the first quarter of 2012, a 20% increase from the comparable quarter of 2011. Revenues for the current quarter included \$3.3 million in revenues from the Company's molecular diagnostic collection subsidiary, DNA Genotek Inc. ("DNAG"), acquired in August 2011.
- Consolidated net loss for the first quarter of 2012 was \$3.3 million, or \$0.07 per share, which compares to a net loss of \$2.6 million, or \$0.06 per share, for the first quarter of 2011.

"We are pleased to deliver first quarter financial results that are in line with expectations," said Douglas A. Michels, President and CEO of OraSure Technologies. "Our molecular collection systems business was an important contributor for the quarter and we are starting to see some positive impact on sales of our OraQuick® HCV test resulting from the CLIA waiver received in late 2011. We are also pleased that the FDA's Blood Products Advisory Committee will consider our OraQuick® At-Home HIV test submission at its upcoming meeting on May 15."

Financial Results

Product revenues for the quarter increased 16% primarily as a result of the \$3.3 million of molecular collection system sales and higher sales of the Company's cryosurgical systems products. These increases were partially offset by lower sales of the Company's infectious disease testing, substance abuse testing and insurance risk assessment products. Licensing and product development revenues for the first quarter of 2012 increased by \$842,000 primarily as a result of the receipt of a \$1.0 million milestone payment received under the terms of the Company's HCV collaboration agreement with Merck. Licensing and product development revenues for the current quarter also reflect a decrease in royalties received under a Settlement and License Agreement with Merck related to the Company's cryosurgical patents.

Consolidated gross margin for the three months ended March 31, 2012 was 66% compared to 65% for the three months ended March 31, 2011. The increase in gross margin in the current quarter was largely due to the benefit of the \$1.0 million milestone payment, partially offset by an increase in product support costs and a decline in the absorption of labor costs when compared to the first quarter of 2011.

Consolidated operating expenses increased \$3.6 million to \$17.4 million in the first quarter of 2012 from \$13.8 million in the comparable period of 2011. This increase reflects the inclusion of \$3.1 million of DNAG operating expenses, increased sales and marketing spending associated with the preparation for commercialization of the Company's HIV-OTC product and increased consulting and staffing costs. These increases were partially offset by a decrease in spending on clinical trials related to the Company's OraQuick® HIV-OTC product.

For the quarter ended March 31, 2012, the Company also recorded an income tax benefit of \$0.5 million associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits.

Cash totaled \$22.8 million at March 31, 2012 compared to \$23.9 million at December 31, 2011. Working capital remained relatively flat at \$30.8 million at March 31, 2012 compared to \$30.9 million at December 31, 2011.

Second Quarter 2012 Outlook

The Company expects total consolidated revenues for the second quarter of 2012 to range from \$22.0 to \$22.5 million and is projecting a consolidated net loss of approximately \$0.09 - \$0.10 per share for the second quarter of 2012.

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

	Unaudited	
	Three months ended	
	March 31,	
	2012	2011
Results of Operations		
Revenues	\$20,944	\$17,414
Cost of products sold	7,212	6,147
Gross profit	13,732	11,267
Operating expenses:		
Research and development	3,444	4,420
Sales and marketing	7,874	4,932
General and administrative	6,066	4,468
Total operating expenses	17,384	13,820
Operating loss	(3,652)	(2,553)
Other expense	(121)	(45)
Loss before income taxes	(3,773)	(2,598)
Income tax benefit	(521)	—
Net loss	<u>\$ (3,252)</u>	<u>\$ (2,598)</u>
Loss per share:		
Basic and Diluted	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>
Weighted average shares:		
Basic and Diluted	<u>47,807</u>	<u>46,518</u>

Market	Three Months Ended March 31,				
	Dollars		% Change	Percentage of Total Revenues	
	2012	2011		2012	2011
Infectious disease testing	\$ 9,776	\$ 9,962	(2)%	47%	57%
Substance abuse testing	2,087	3,061	(32)	10	18
Cryosurgical systems	3,478	2,710	28	16	15
Molecular collection systems	3,298	—	N/A	16	0
Insurance risk assessment	1,099	1,317	(17)	5	8
Product revenues	19,738	17,050	16	94	98
Licensing and product development	1,206	364	231	6	2
Total revenues	<u>\$20,944</u>	<u>\$17,414</u>	20%	<u>100%</u>	<u>100%</u>

OraQuick® Revenues	Three Months Ended March 31,		
	2012	2011	% Change
Domestic HIV	\$8,148	\$8,867	(8)%
International HIV	660	698	(5)
Domestic HCV	536	34	1,476
International HCV	282	48	488
Total OraQuick® revenues	<u>\$9,626</u>	<u>\$9,647</u>	0%

Intercept® Revenues	Three Months Ended March 31,		
	2012	2011	% Change
Domestic	\$1,523	\$1,877	(19)%
International	46	519	(91)
Total Intercept® revenues	<u>\$1,569</u>	<u>\$2,396</u>	(35)%

<u>Cryosurgical Systems Revenues</u>	Three Months Ended		
	March 31,		
	<u>2012</u>	<u>2011</u>	<u>% Change</u>
Professional domestic	\$ 1,371	\$ 1,342	2%
Professional international	287	339	(15)
Over-the-Counter	<u>1,820</u>	<u>1,029</u>	77
Total cryosurgical systems revenues	<u>\$ 3,478</u>	<u>\$ 2,710</u>	28%

Consolidated Balance Sheets (Unaudited)	March 31, 2012	December 31, 2011
<u>Assets</u>		
Cash	\$ 22,814	\$ 23,878
Accounts receivable, net	13,292	17,159
Inventories	10,818	9,621
Other current assets	3,013	2,178
Property and equipment, net	19,376	19,855
Intangible assets, net	29,988	30,383
Goodwill	25,318	24,740
Other non-current assets	53	47
Total assets	<u>\$ 124,672</u>	<u>\$ 127,861</u>
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 7,167	\$ 7,292
Accounts payable	3,529	4,142
Accrued expenses	8,430	10,542
Other liabilities	8	—
Deferred income taxes	5,249	5,636
Stockholders' equity	<u>100,289</u>	<u>100,249</u>
Total liabilities and stockholders' equity	<u>\$ 124,672</u>	<u>\$ 127,861</u>

Additional Financial Data (Unaudited)	Three months ended	
	March 31,	
	2012	2011
Capital expenditures	\$ 306	\$ 882
Depreciation and amortization	\$ 1,809	\$ 829
Stock based compensation	\$ 1,192	\$ 973
Cash used in operating activities	\$ 1,356	\$ 2,049
Accounts receivable – days sales outstanding	58 days	63 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2012 first quarter financial results, business developments and second 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 Mark L. Kuna, Senior Vice President, Finance and Controller. 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 #71939275, 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 May 9, 2012, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #71939275.

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, the Company is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, and commercial and industrial entities. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health. For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to obtain FDA approval of the OraQuick® HIV test for use in the over-the-counter market; 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, 2011, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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OraSure Technologies, Inc.
2012 First Quarter
Analyst/Investor Conference Call
May 2, 2012

Prepared Remarks of Douglas A. Michels and Mark L. Kuna

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.

Before we begin, I wanted to let you know that Ron Spair, our Chief Operating Officer and Chief Financial Officer, who normally joins me on these calls, has had to attend to an urgent and unexpected personal matter involving a family member and will not be able to participate today. Instead, Mark Kuna, our Senior Vice President, Finance and Controller, will fill in for Ron and present our financial results and assist me in responding to your questions at the end of the call.

With the first quarter under our belt, 2012 is off to a good start. We are in the final stages of the FDA review process for our OraQuick® HIV over-the-counter ("OTC") test, and we are gaining traction with sales of our OraQuick® HCV test.

Consolidated revenues for the first quarter, which included revenue from our recently acquired subsidiary, DNA Genotek, were up 20% compared to the first quarter of 2011. I am pleased to report that our consolidated results came in at the top of our guidance range for revenues and we exceeded our Q1 guidance on the bottom line.

Mark will start with a detailed review of our first quarter financial performance and then I will follow with some additional comments on our business. We will close by taking your questions.

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

First Quarter 2012 Financial Results – Mark Kuna

Thanks Doug, and good afternoon everyone.

Revenues – Mark Kung

Our first quarter 2012 revenues were \$20.9 million compared to \$17.4 million reported in 2011. Revenues for the current quarter included \$3.3 million from our molecular diagnostic collections subsidiary acquired in August 2011. Our product revenues increased 16% as a result of the molecular collection systems sales and higher sales of our cryosurgical systems products. These increases were partially offset by lower sales of our infectious disease, substance abuse and insurance risk assessment products. Our first quarter 2012 licensing and product development revenues included a \$1.0 million milestone payment received under our HCV collaboration with Merck.

Our infectious disease testing revenues were \$9.8 million in the first quarter of 2012 compared to \$10.0 million in the first quarter of 2011. The overall 2% decrease was primarily a result of lower OraQuick® HIV sales in the domestic and international markets, partially offset by higher OraQuick® HCV sales. Domestic HIV revenues were down \$719,000 year over year or 8% as a result of ordering patterns by one of our large public health customers who placed a large order during the first quarter of 2011 which was not repeated in the first quarter of 2012. HCV revenues were \$818,000 for the quarter and sequentially up from Q4 of 2011, largely as a result of receiving a CLIA waiver in November of 2011, which increased the number of customers to which we are able to sell the product. It is important to note that during the first quarter, we saw a substantial increase in the number of customers purchasing our HCV product, which contrasts with the large bulk purchases by a small number of customers experienced in the fourth quarter of 2011.

In substance abuse testing, revenues decreased from \$3.1 million in the first quarter of 2011 to \$2.1 million in the first quarter of 2012 primarily as a result of lower Intercept® sales. This decrease was the result of a reduction in purchases by our largest domestic laboratory distributor who began selling its own competitive

oral fluid drug testing system at the end of 2011, and lower international sales due to a reduction in our UK distributor's target inventory levels.

First quarter 2012 cryosurgical revenues increased 28% compared to the first quarter of 2011, primarily as a result of higher OTC sales.

OTC cryosurgical sales during the quarter increased \$791,000, or 77% when compared to 2011, largely as a result of higher sales to both our Latin American OTC distributor, Genomma, and our European distributor, Reckitt Benckiser. Genomma did not purchase from us during the first quarter of 2011 as a result of advertising restraints imposed by the Mexican government as well as changes required by the Brazilian government to our package inserts. Both of these issues were resolved by the end of the 2011. The increased sales to Reckitt Benckiser were the result of the timing of the orders placed.

Professional cryosurgical sales in the U.S. increased 2% and international professional sales decreased 15% from Q1 2011. The decrease in international professional sales was primarily due to lower sales in Europe, partially offset by higher sales in Australia and Africa.

Our insurance risk assessment sales decreased from \$1.3 million in 2011 to \$1.1 million in 2012 as a result of the loss of one of our larger customers who changed its underwriting methodologies in 2011.

As mentioned earlier, our molecular collection systems revenues were \$3.3 million for Q1 and primarily represent sales of the Oragene® product line. These first quarter revenues include a large initial order from a prominent new customer.

Gross Margin – Mark Kuna

Turning to Gross Margin, our overall margin for Q1 of 2012 was 66% compared to 65% reported for the first quarter of 2011. Gross margin in the current quarter benefited from the \$1.0 million HCV milestone payment. This is partially offset by increased product support costs and a decline in the absorption of labor costs when compared to the first quarter of last year.

Operating Expenses – Mark Kuna

Our total operating expenses for the first quarter increased \$3.6 million, or 26%, compared to the first quarter of 2011. The first quarter 2012 expenses included \$3.1 million from our molecular diagnostic collections subsidiary. Research and development expenses decreased from \$4.4 million to \$3.4 million for the quarter due to lower clinical trial costs associated with our OraQuick® HIV-OTC program. Sales and marketing expenses were \$7.9 million for the first quarter, an increase of \$2.9 million over 2011 due to the inclusion of \$1.6 million of DNA Genotek expenses and higher spending as we prepare for the commercialization of our HIV-OTC product. General and administrative expenses increased by approximately \$1.6 million as a result of \$773,000 of DNA Genotek expenses and higher consulting and staffing costs.

Net Loss – Mark Kuna

From a bottom line perspective, we reported a net loss of \$3.3 million, or \$0.07 per share, compared to a net loss of \$2.6 million, or \$0.06 per share, for the same period of 2011. In the first quarter of 2012, we recorded an income tax benefit of \$521,000 associated with our operations in Canada.

Cash Flow from Operations and Liquidity – Mark Kuna

Turning briefly to our balance sheet and cash flow, our cash balance at March 31, 2012 was \$22.8 million compared to \$23.9 million on hand at December 31, 2011. Cash used in operating activities in the first quarter of 2012 was \$1.4 million, an improvement over the \$2.1 million used during the first quarter of 2011.

Second Quarter 2012 Financial Guidance – Mark Kuna

Turning to guidance for the second quarter of 2012, we are projecting consolidated revenues of approximately \$22.0 to \$22.5 million and a consolidated net loss per share of approximately \$0.09 to \$0.10 for the quarter.

And now back to Doug.

Business Update – Doug Michels

Thanks, Mark.

HIV-OTC – Doug Michels

A major priority has been the pursuit of FDA approval of our OraQuick® HIV-OTC test. As you will recall, we submitted the third and final module to our pre-market approval (“PMA”) application to the FDA at the end of 2011. Our PMA submission is under active review by the agency and we are preparing for a Blood Products Advisory Committee (“BPAC”) review of our clinical data at a public meeting to be held on May 15 of this year.

We are very pleased to be on the schedule and look forward to presenting our data to the Committee. Under the BPAC’s rules, our presentation for the meeting, as well as presentations by the FDA and others, will be made public about two days before the meeting. Our BPAC presentation will include a summary of our clinical study results, including the most recent phase 3 unobserved user study, a risk-benefit analysis of the product and our rationale for why an HIV-OTC test should be approved by the FDA.

As we have discussed previously, the CDC estimates that there are about 1.2 million people in the U.S. infected with HIV, approximately 240,000 of which are unaware of their status. 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. Unfortunately, this is occurring despite the widespread availability of both laboratory-based and rapid point-of-care HIV testing options.

We believe these data clearly demonstrate that additional HIV testing options are urgently needed, and 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.

With the BPAC meeting close at hand, we are more focused than ever on planning for commercial launch. We have been working closely with our advertising and public relations firms to develop creative materials and finalize our marketing plans. To the extent permitted under applicable FDA regulations, we are communicating with the major retail outlets through which we intend to sell the product, and we are completing preliminary work to qualify OraSure as an approved vendor for these outlets. We are also finalizing the logistics and order-to-cash procedures for this product. Our call center operator has begun initial staffing and personnel training so that this key consumer support service is in place when we can launch the product.

Finally, we have added some new personnel in-house who are specifically assigned to the HIV-OTC initiative in order to support sales, marketing and call center activities. In short, we are doing all that we can to ensure that we support our OTC product and the consumers that use it in a comprehensive and professional manner. Our extensive preparation should enable us to launch this product as quickly as possible if and when we receive FDA approval.

OraQuick® HCV – Doug Michels

With respect to our OraQuick® HCV test, our focus in Q1 was on expanding sales. As you know, late in 2011, we received a CLIA waiver for this product. As a result, our test can now be more widely used in a broad variety of settings, including health clinics, community-based organizations and physician offices.

During the first quarter, we started to see some benefits from the CLIA waiver as well as a more focused sales and marketing effort. As Mark explained, domestic OraQuick® HCV sales in Q1 increased over the fourth quarter of last year. During 2011, when most of our sales occurred without the benefit of the CLIA waiver, we sold product to 21 state and local health departments. During the first quarter of this year alone, we have sold product to 14 health departments, 9 of which are first-time customers. We expect the number of new HCV customers and the level of sales during the rest of the year to grow substantially.

We are particularly focusing our direct sales efforts on public health departments that already have the infrastructure in place to conduct rapid testing with our OraQuick® HIV product. We have now also finalized contracts with three major med-surg distributors that will focus largely on physician offices and federally-funded community health centers. These distributors include McKesson, Henry Schein and PSS. Sales training and launch activities have either occurred or are well underway with each of these organizations.

With respect to our Merck collaboration, now that we have received a CLIA waiver, our detailing activities in the U.S. physician office market have begun. During the first quarter, over 600 calls were made to primary care physicians, and over 1,000 calls to gastroenterologists were conducted. The objective of those calls was to build awareness and begin the sales process. The primary care physician is the individual most likely to conduct HCV testing. Out of the 600 physician

contacts, about 70% expressed an interest to move forward in the sales process with 13% expressing a strong interest to begin testing after the initial call. We expect these activities to increase as the year progresses.

As you may know, May is National Hepatitis Awareness Month, and this May 19th will be the first ever National Hepatitis Testing Day. We believe these and other activities will continue to focus attention on hepatitis as a public health issue and the need for additional testing and treatment.

DNA Genotek Acquisition – Doug Michels

Turning now to our newest business line — DNA Genotek exceeded our expectations for the first quarter. As previously explained, one of DNA Genotek's strengths is strong customer loyalty and repeat business. Of DNA Genotek's top 25 customers for the first quarter, 23 were repeat customers and accounted for over 80% of revenues for that period. The company also acquired several new customers, including one significant customer that made a substantial initial purchase during Q1 and is expected to join the list of repeat customers in the future.

During the first quarter, DNA Genotek also announced that Complete Genomics, an outsourced whole genome sequencing company, had begun accepting DNA samples collected with the Oragene collection kit for full sequencing. This is a significant development, as genome sequencing historically has been performed primarily with blood samples.

2012 Annual Meeting of Stockholders – Doug Michels

One final area I would like to address is our upcoming Annual Meeting of Stockholders, scheduled for May 15. As you may have noted, this is the same date on which we have been invited to present our OraQuick® HIV-OTC test to the BPAC. Because we only confirmed recently that we were scheduled for the May 15th BPAC meeting, we were unable to change the Annual Meeting to accommodate a different schedule.

Since Ron Spain and I will be at the BPAC meeting, we will not be able to attend our Annual Meeting as we have in past years. Doug Watson, the Chairman of our Board, will preside and all other members of the Board will participate either in person or by phone. Because I will not be attending, we will not make the usual management presentation. However, Doug Watson will briefly comment on the business and answer questions for those present at the meeting with assistance as needed from the other members of the management team in attendance.

* * * *

Conclusion

So in summary, we delivered solid financial results for the first quarter and continued to advance our primary clinical program and business objectives. This is an exciting time of great opportunity for OraSure, and we look forward to continued success in 2012 and beyond.

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 obtain FDA approval of the OraQuick® HIV test for use in the over-the-counter market; 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, 2011, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.