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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): August 7, 2012**

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**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**

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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 August 7, 2012, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended June 30, 2012, and providing financial guidance for the third 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 August 7, 2012, the Company held a webcast conference call with analysts and investors, during which Douglas A. Michels, the Company’s President and Chief Executive Officer, and Ronald H. Spair, the Company’s Chief Financial Officer and Chief Operating Officer, discussed the Company’s consolidated financial results for the quarter ended June 30, 2012, provided financial guidance for the third 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated August 7, 2012, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2012, and providing financial guidance for the third quarter of 2012.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2012 Analyst/Investor Conference Call Held August 7, 2012.

**Signatures**

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

OraSure Technologies, Inc.

Date: August 7, 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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Chief Financial Officer  
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### **OraSure Announces 2012 Second Quarter Financial Results**

**BETHLEHEM, PA** – August 7, 2012 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the second quarter and six months ended June 30, 2012.

#### **Financial Highlights**

- Consolidated revenues were \$22.6 million for the second quarter of 2012, a 19% 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 revenues were \$43.6 million for the six months ended June 30, 2012, a 19% increase from the comparable period of 2011. Revenues for the current period included \$6.6 million in revenues from DNAG operations.
- Consolidated net loss for the second quarter of 2012 was \$3.6 million, or \$0.07 per share, which compares to a net loss of \$2.4 million, or \$0.05 per share, for the second quarter of 2011. The increase in the net loss for the quarter was largely the result of increased spending in sales and marketing associated with the commercialization of the Company's OraQuick® In-Home HIV Test.

- Consolidated net loss for the six months ended June 30, 2012 was \$6.8 million, or \$0.14 per share, which compares to a net loss of \$5.0 million, or \$0.11 per share, for the six months ended June 30, 2011.

“We are pleased with the Company’s second quarter financial results, which are in line with expectations and reflect revenues from DNA Genotek, our molecular collection systems business, and continued sales growth for our OraQuick® HCV test,” said Douglas A. Michels, President and CEO of OraSure Technologies. “We are also proud to have delivered one of the Company’s most important strategic objectives with the recent FDA approval of our OraQuick® In-Home HIV Test. We can now be the first to market the only rapid HIV test approved for sale into the U.S. consumer marketplace. We are continuing to implement a comprehensive commercialization plan and expect this exciting new product to be available for purchase by consumers beginning in October.”

### **Financial Results**

Product revenues for the quarter and the six month period ended June 30, 2012 increased 19% and 18%, respectively, primarily as a result of the 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 second quarter of 2012 decreased \$87,000, or 24%, reflecting lower royalties under a license related to the Company’s cryosurgical patents. Licensing and product development revenues for the six months ended June 30, 2012 increased by \$755,000, primarily as a result of a \$1.0 million milestone payment received under the terms of the Company’s HCV collaboration agreement with Merck, partially offset by lower royalties related to the Company’s cryosurgical patents.

Consolidated gross margin for the three and six months ended June 30, 2012 was 65% compared to 64% for the same periods of 2011. DNAG margins of 67% in both periods contributed to this improvement. The increase for the current six month period was also positively impacted by the \$1.0 million HCV milestone payment, partially offset by higher product support costs and a decline in the absorption of labor costs when compared to the first half of 2011.

Consolidated operating expenses increased to \$18.2 million in the second quarter of 2012 from \$14.6 million in the comparable period of 2011. For the six months ended June 30, 2012, consolidated operating expenses were \$35.6 million, an increase over the \$28.4 million reported for the six months ended June 30, 2011. These increases reflect the inclusion of DNAG operating expenses, increased sales and marketing costs associated with the preparation for commercialization of the Company’s OraQuick® In-Home HIV Test and higher consulting, legal and staffing costs. These increases were partially offset by lower clinical trial costs related to the Company’s OraQuick® In-Home HIV Test.

For the three and six months ended June 30, 2012, the Company recorded an income tax benefit of \$91,000 and \$611,000, respectively, associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits. The income tax benefit recorded in the second quarter of 2012 was negatively impacted by an adjustment to the Company's Canadian deferred tax liability to reflect a change in enacted Canadian provincial income tax rates.

Cash totaled \$23.3 million at June 30, 2012 compared to \$23.9 million at December 31, 2011. Working capital was \$31.5 million at June 30, 2012 compared to \$30.9 million at December 31, 2011. On July 11, 2012, the Company completed a public equity offering of 6.1 million shares of its common stock, resulting in net proceeds of approximately \$70 million after expenses of the offering.

### **Third Quarter 2012 Outlook**

The Company expects total consolidated revenues to range from \$22.0 to \$22.5 million and is projecting a consolidated net loss of approximately \$0.07 - \$0.08 per share for the third quarter of 2012.

## Condensed Consolidated Financial Data

(In thousands, except per-share data)

	Unaudited			
	Three months ended		Six months ended	
	June 30,	2011	June 30,	2011
2012		2012	2011	
<b>Results of Operations</b>				
Revenues	\$22,616	\$19,064	\$43,560	\$36,477
Cost of products sold	7,917	6,803	15,129	12,949
Gross profit	<u>14,699</u>	<u>12,261</u>	<u>28,431</u>	<u>23,528</u>
Operating expenses:				
Research and development	3,113	5,143	6,557	9,563
Sales and marketing	9,014	5,352	16,887	10,284
General and administrative	6,112	4,125	12,178	8,593
Total operating expenses	<u>18,239</u>	<u>14,620</u>	<u>35,622</u>	<u>28,440</u>
Operating loss	(3,540)	(2,359)	(7,191)	(4,912)
Other expense	(113)	(79)	(234)	(124)
Loss before income taxes	(3,653)	(2,438)	(7,425)	(5,036)
Income tax benefit	(91)	—	(611)	—
Net loss	<u>\$ (3,562)</u>	<u>\$ (2,438)</u>	<u>\$ (6,814)</u>	<u>\$ (5,036)</u>
Loss per share:				
Basic and Diluted	<u>\$ (0.07)</u>	<u>\$ (0.05)</u>	<u>\$ (0.14)</u>	<u>\$ (0.11)</u>
Weighted average shares:				
Basic and Diluted	<u>48,235</u>	<u>46,814</u>	<u>48,021</u>	<u>46,667</u>



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

Market	Three Months Ended June 30,				
	Dollars		%	Percentage of Total Revenues	
	2012	2011	Change	2012	2011
Infectious disease testing	\$10,387	\$11,284	(8)%	46%	59%
Substance abuse testing	2,888	3,185	(9)	13	17
Cryosurgical systems	4,503	2,802	61	20	15
Molecular collection systems	3,341	—	N/A	15	N/A
Insurance risk assessment	1,220	1,429	(15)	5	7
Product revenues	22,339	18,700	19	99	98
Licensing and product development	277	364	(24)	1	2
Total revenues	<u>\$22,616</u>	<u>\$19,064</u>	19%	<u>100%</u>	<u>100%</u>

Market	Six Months Ended June 30,				
	Dollars		%	Percentage of Total Revenues	
	2012	2011	Change	2012	2011
Infectious disease testing	\$20,164	\$21,246	(5)%	47%	58%
Substance abuse testing	4,974	6,246	(20)	12	17
Cryosurgical systems	7,981	5,512	45	18	15
Molecular collection systems	6,638	—	N/A	15	N/A
Insurance risk assessment	2,320	2,745	(15)	5	8
Product revenues	42,077	35,749	18	97	98
Licensing and product development	1,483	728	104	3	2
Total revenues	<u>\$43,560</u>	<u>\$36,477</u>	19%	<u>100%</u>	<u>100%</u>

OraQuick® Revenues	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Change	2012	2011	% Change
	Domestic HIV	\$ 8,432	\$10,069	(16)%	\$16,580	\$18,937
International HIV	744	714	4	1,403	1,412	(1)
Domestic HCV	742	98	657	1,279	133	862
International HCV	212	144	47	493	192	157
Total OraQuick® revenues	<u>\$10,130</u>	<u>\$11,025</u>	(8)%	<u>\$19,755</u>	<u>\$20,674</u>	(4)%

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Change	2012	2011	% Change
<b>Intercept® Revenues</b>						
Domestic	\$1,958	\$2,083	(6)%	\$3,482	\$3,962	(12)%
International	291	514	(43)	337	1,035	(67)
Total Intercept® revenues	<u>\$2,249</u>	<u>\$2,597</u>	(13)%	<u>\$3,819</u>	<u>\$4,997</u>	(24)%

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Change	2012	2011	% Change
<b>Cryosurgical Systems Revenues</b>						
Professional domestic	\$1,944	\$1,713	13%	\$3,316	\$3,055	9%
Professional international	371	247	50	657	587	12
Over-the-Counter	2,188	842	160	4,008	1,870	114
Total cryosurgical systems revenues	<u>\$4,503</u>	<u>\$2,802</u>	61%	<u>\$7,981</u>	<u>\$5,512</u>	45%

<u>Consolidated Balance Sheets (Unaudited)</u>	<u>June 30, 2012</u>	<u>December 31, 2011</u>
<u>Assets</u>		
Cash	\$ 23,273	\$ 23,878
Accounts receivable, net	15,413	17,159
Inventories	11,025	9,621
Other current assets	2,632	2,178
Property and equipment, net	18,975	19,855
Intangible assets, net	28,503	30,383
Goodwill	24,843	24,740
Other non-current assets	71	47
Total assets	<u>\$124,735</u>	<u>\$ 127,861</u>
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 7,042	\$ 7,292
Accounts payable	4,305	4,142
Accrued expenses	9,455	10,542
Other liabilities	30	—
Deferred income taxes	5,059	5,636
Stockholders' equity	98,844	100,249
Total liabilities and stockholders' equity	<u>\$124,735</u>	<u>\$ 127,861</u>
<u>Additional Financial Data (Unaudited)</u>		
	<u>Six months ended June 30,</u>	
	<u>2012</u>	<u>2011</u>
Capital expenditures	\$ 730	\$ 1,180
Depreciation and amortization	\$ 3,614	\$ 1,684
Stock based compensation	\$ 2,521	\$ 1,931
Cash used in operating activities	\$ 2,296	\$ 373
Accounts receivable – days sales outstanding	64 days	58 days

#### Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2012 second quarter financial results, business developments and third 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 #11264311, or go to OraSure Technologies' web site, [www.orasure.com](http://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 August 14, 2012, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #11264311.

### **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](http://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, including the OraQuick® In-Home HIV Test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to 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 Second Quarter**

**Analyst/Investor Conference Call**

**August 7, 2012**

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

**Please see "Important Information" at the conclusion of the following prepared remarks.**

**Introduction – Doug Michels**

Thanks Judy and good afternoon everyone. Thank you all for joining us on our call.

I am pleased to report that results for the second quarter exceeded our guidance range on both the top and bottom lines. Consolidated revenues were up almost 20% compared to the second quarter of 2011, primarily as a result of DNA Genotek.

As many of you know, the most significant development in Q2 was the receipt of FDA approval of our OraQuick® In-Home HIV Test, which was covered extensively in the media. I will provide an update on our commercialization efforts for this exciting new product as well as certain other developments in our business.

Before I do that, however, let me turn the call over to Ron for an overview of our financial results.

**Second Quarter 2012 Financial Results – Ron Spair**

Thanks Doug, and good afternoon everyone.

## **Revenues – Ron Spair**

Our second quarter 2012 revenues were \$22.6 million compared to \$19.1 million reported in 2011. Revenues for the current quarter included \$3.3 million from our molecular diagnostic collections subsidiary, DNA Genotek, acquired in August 2011. Our product revenues increased 19% 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 infectious disease testing revenues were \$10.4 million in the second quarter of 2012 compared to \$11.3 million in the second quarter of 2011. The overall 8% decrease was primarily a result of lower domestic OraQuick® HIV sales, partially offset by higher sales into the international market and by higher OraQuick® HCV sales. Domestic HIV revenues were down \$1.6 million year over year, or 16%, due to various factors, including changes in public health testing programs, reductions in government funding, some lost business due to price competition, and timing of certain orders. HCV revenues were \$954,000 for the quarter, a \$712,000 increase over the second quarter of 2011. HCV revenues were also sequentially up from Q1 of 2012.

In substance abuse testing, revenues decreased to \$2.9 million in the second quarter of 2012 from \$3.2 million in the second quarter of 2011, 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.

Second quarter 2012 cryosurgical revenues increased 61% compared to the second quarter of 2011, primarily as a result of higher OTC sales.

OTC cryosurgical sales during the quarter increased \$1.3 million, or 160%, when compared to 2011, largely as a result of higher sales to both our Latin American OTC distributor, Genomma, and our European distributor, Reckitt Benckiser. As discussed in previous calls, early in 2011 the Mexican government imposed restraints on the advertising Genomma could use for our product. At the same time, the Brazilian government required us to make changes to our package insert. Both of these issues negatively impacted our sales to Genomma during 2011 but were resolved by the end of that year. Resolution of those issues coupled with sales growth in Argentina and customer order patterns in Brazil all contributed to the increase in Latin American OTC revenues during the current quarter. The higher sales to Reckitt Benckiser were the result of increased advertising and promotional activities initiated by Reckitt Benckiser as well as expansion into additional European countries.

Professional cryosurgical sales in the U.S. increased 13% and international professional sales increased 50% from Q2 2011. The increase in domestic sales was due to the ordering patterns of one of our large distributors and the increased success of sales and promotional efforts by our distributors and manufacturers' representative organizations. The increase in international professional sales was primarily due to higher sales in Europe, Australia and Asia.

As mentioned earlier, our molecular collection systems revenues were \$3.3 million for Q2 and primarily represent sales of the Oragene® product line.

**Gross Margin – Ron Spair**

Turning to Gross Margin, our overall margin for Q2 of 2012 was 65% compared to 64% reported for the second quarter of 2011. A 67% margin at DNA Genotek contributed to the higher margin for the quarter.



### **Operating Expenses – Ron Spair**

Our total operating expenses for the second quarter increased \$3.6 million, or 25%, compared to the second quarter of 2011. The second quarter 2012 expenses included \$3.2 million from our molecular collection systems subsidiary. Research and development expenses decreased from \$5.1 million to \$3.1 million for the quarter due to lower clinical trial costs associated with our OraQuick® In-Home HIV test. Sales and marketing expenses were \$9.0 million for the second quarter, an increase of \$3.7 million over 2011 due to the inclusion of \$1.8 million of DNA Genotek expenses and higher spending of \$1.8 million associated with our preparation for the commercialization of our OraQuick® In-Home HIV test. General and administrative expenses increased by approximately \$1.9 million as a result of \$788,000 of DNA Genotek expenses and higher consulting, legal, and staffing costs.

### **Net Loss – Ron Spair**

From a bottom line perspective, we reported a net loss of \$3.6 million, or \$0.07 per share, compared to a net loss of \$2.4 million, or \$0.05 per share, for the same period of 2011.

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

Turning briefly to our balance sheet and cash flow, our cash balance at June 30, 2012 was \$23.3 million compared to \$23.9 million at December 31, 2011. Following the end of the second quarter, our cash balance increased by approximately \$70 million with the closing of our secondary stock offering.

Cash used in operating activities in the second quarter of 2012 was \$940,000 compared to \$1.7 million generated during the second quarter of 2011.

### **Third Quarter 2012 Financial Guidance – Ron Spair**

Turning to guidance for the third 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 \$0.07 to \$0.08 for the quarter.

And now back to Doug.

**Business Update – Doug Michels**

Thanks, Ron.

**HIV-OTC – Doug Michels**

Now that our OraQuick® In-Home Test has been approved, we are focused on delivering a successful commercial launch.

- We continue to implement our distribution and sales strategy and expect that the In-Home Test will be available in more than 30,000 retail outlets beginning in October. As previously explained, we anticipate achieving a greater than 85% all commodity volume for this initial placement. “All Commodity Volume,” or ACV, represents the dollar value share these stores represent out of the total market potential for our product.
- In addition to retailers such as Wal-Mart, Walgreens, CVS, Rite-Aid and Kroger, we have expanded our retail relationships to include Duane Reed, online retailers such as [drugstore.com](http://drugstore.com), large drug wholesalers such as McKesson and Amerisource Bergen, and certain regional food retailers. We are working closely with retailers to develop promotional plans for our product, including placement in advertising circulars, store and shelf signage, pharmacy displays and internet ads. While the retailers will have the final say on pricing for our product once it is available in October, we anticipate the retail price for an OraQuick® In-Home HIV Test to be approximately \$39.
- We have activated a temporary website, currently available at [www.oraquick.com](http://www.oraquick.com), to provide high level information about the product and its future availability. A more comprehensive website will be activated in late September, and will provide additional information about HIV/AIDS and our product and will offer consumers the opportunity to purchase our product online.

- We are now finalizing our advertising campaign, which will reach populations that have expressed high purchase intent, such as men who have sex with men (MSM), African Americans, Latino Americans and sexually-active adults 18-49 years old. Additionally, our media plans will enable our ads to be broadly seen by consumers outside of these populations who may also be interested in taking advantage of a simple and private HIV testing option.
- Closely aligned with our advertising campaign will be an extensive PR campaign. As you know, our OraQuick® In-Home HIV Test has generated extensive media coverage, with the FDA approval alone generating over 200 million media impressions. We are planning a variety of PR events through the rest of this year as part of a coordinated national and regional media outreach effort.
- Because pharmacists and medical professionals play a key role in educating consumers and driving the usage of medical products, an important part of our communications program will focus on these individuals. We are finalizing several educational tools to be used by retail pharmacists and in clinics and doctors' offices.
- In order to successfully execute our distribution and sales strategy, we need to be able to provide a sufficient quantity of product. Our manufacturing process is well underway, and we are on schedule to begin shipping product to retailers by mid-September, as initially planned and previously communicated.
- Finally, a very important component of our commercialization plan is the consumer support center. This center has been operating since July 6 and provides consumers with toll-free support on a 24/7, 365-day per year basis. As previously discussed, each of our support center representatives are bi-lingual and highly trained, and are prepared to answer questions about our test and to provide consumers with resource referrals for follow-up confirmatory testing, counseling and medical treatment.

So, in summary, the commercialization plans for our OraQuick® In-Home HIV Test are well developed and on schedule for an October launch. I look forward to providing additional updates as these plans progress.

**OraQuick® HCV – Doug Michels**

Turning now to our OraQuick® HCV test, we are pleased to see continued market acceptance and sales growth for this product. HCV sales for Q2 increased over both the second quarter of last year and the first quarter of this year. The primary drivers for this growth are the CLIA waiver we received in late 2011, the impact of our new distribution relationships with McKesson, Henry Schein and PSS, and other testing and awareness initiatives. Our direct sales efforts in the public health market are bearing fruit, as we saw numerous repeat customers and 34 new customers during the second quarter.

Our new HCV distributors have been trained and their sales teams are now actively calling on physician offices, community health organizations and other potential customers. A big focus for these distributors is the education of medical professionals about the proposed new CDC guidelines on HCV testing. As previously discussed, the CDC has issued draft guidelines recommending that all persons born between 1945 and 1965 – or approximately 81 million people, according to the 2010 census—receive a one-time test for HCV. Our distributors are implementing extensive education and awareness campaigns to alert medical professionals that these guidelines are likely coming and, once adopted, can be met through the use of our OraQuick® HCV test. We are also supporting our distributors' sales efforts with the same manufacturer sales representative organizations that have helped to enhance sales of our Histofreezer® product line.

To further assist our distributors, we are collaborating with the Chronic Liver Disease Foundation by supporting an initiative to educate and certify physicians as HCV testing centers in anticipation of the adoption of the proposed CDC guidelines. Through education, training and promotional activities, this program will target approximately 6,000 physicians in 2,000 practices, and is expected to launch later this month.

We are also working with the National Medical Association (“NMA”) to implement an education, awareness and testing campaign. The NMA is the largest and oldest national organization representing African American physicians in the United States. Current NMA membership is estimated at 50,000 physicians. With assistance from OraSure, the goal of this campaign is to have NMA member physicians test thousands of individuals for HCV in 10 U.S. cities, including New York, Philadelphia, Washington DC, Newark, Durham, Chicago, Baltimore, Baton Rouge, Detroit, and Los Angeles.

Our awareness efforts have not been limited to the U.S. market. For example, we recently participated in several testing initiatives in recognition of World Hepatitis Day, which was founded by the World Health Organization and occurred this year on July 28. These initiatives took place in New York, Chicago and Washington DC, and in several foreign countries. In recognition of this date, we also closed the NASDAQ Stock Market and organized a publicly webcast panel discussion which included representatives from public health, hospitals and community-based organizations on best practices for incorporating HCV into testing programs. We believe all of these activities will encourage people to get tested for HCV, including the use of our OraQuick® test.

Finally, we have discussed our HCV collaboration with Merck on prior calls and particularly Merck’s detailing efforts directed at the physician office market. While these detailing efforts have been helpful, we now

believe it is in our best interests to focus on our new distribution relationships and the types of initiatives and collaborations described in my earlier remarks. As a result, our domestic agreement with Merck, which has an initial term expiring in September of this year, will not be renewed. As you may know, this agreement contains exclusivity restrictions which will terminate with this expiration. This will allow us more freedom to pursue potential collaborations with other companies in the HCV therapeutic marketplace. At this time, the international agreement with Merck will remain in place.

**DNA Genotek Acquisition – Doug Michels**

Now turning to molecular collection systems, the second quarter financial performance for this segment of our business also came in as expected. There was continued purchasing from a number of repeat customers, including a large reorder from a relatively new customer acquired during the first quarter. Several of DNA Genotek's commercial customers are starting to grow their businesses as their tests become more widely known in the marketplace, particularly in the U.S. There was also continued purchasing from DNA Genotek's worldwide academic customer base.

On the intellectual property front, in July DNA Genotek announced the issuance of a key U.S. patent covering the physical design of its Oragene® DNA sample collection kit. A similar patent has previously issued in several European countries, Mexico, Hong-Kong and China. In the second quarter, DNA Genotek also received notice that several key chemistry patents related to its product were issued in Canada, Australia and India. We believe these newly-issued patents further build what was already a strong IP portfolio.

\* \* \* \*

**Conclusion**

So in conclusion, we are well prepared for the commercial launch of our OraQuick® In-Home HIV Test, the first and only FDA approved rapid HIV test for consumers. This is an exciting time for our Company, and we intend to build on our performance during the first six months of 2012 as we finish the year and move into 2013.

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

**[Q&A session]**

**Conclusion – Doug Michels**

Thank you for participating on today's call and for your continued interest in OraSure. Have a good afternoon and evening.

**Important Information**

This document contains certain forward-looking statements, including with respect to expected revenues, 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, including the OraQuick® In-Home HIV Test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to 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.