
**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): August 4, 2010

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 7.01 – Regulation FD Disclosure.

On August 4, 2010, OraSure Technologies, Inc. (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 financial results for the quarter ended June 30, 2010, provided financial guidance for the third quarter 2010 and described certain business developments. A copy of the prepared remarks of Messrs. Michels and Spair is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

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

<u>Exhibit Number</u>	<u>Description</u>
99	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2010 Analyst/Investor Conference Call Held August 4, 2010.

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 4, 2010

By: /s/ Jack E. Jerrett

Jack E. Jerrett
Senior Vice President, General Counsel
and Secretary

Index to Exhibits

Exhibit No.

Description

99

Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2010 Analyst/Investor Conference Call Held August 4, 2010.

OraSure Technologies, Inc.
2010 Second Quarter
Analyst/Investor Conference Call
August 4, 2010

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.

As indicated in our press release, both revenues and our bottom line exceeded our guidance and each of our business lines performed well during the second quarter. Our results also reflect a \$1 million milestone payment under our Hepatitis C ("HCV") collaboration with Merck, which we earned one quarter ahead of schedule.

Today, Ron will start the call with a detailed overview of our second quarter financial results and will provide guidance for the third quarter. I will then review several recent regulatory approvals, and provide an update on our major clinical programs and certain other business matters. We will then conclude by opening the floor for your questions.

And with that, I will turn things over to Ron.

Second Quarter 2010 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Q2 Discussion – Ron Spair

Before I get into the details, I would like to put our Q2 results in context with the guidance provided during the first quarter call. Revenues for the second quarter of 2010 were \$19.2 million, exceeding our guidance range of \$17.0 to \$17.5 million. As Doug noted, our current quarter revenues include a \$1.0 million payment received from Merck as a result of our achievement of commercial objectives pursuant to our collaboration agreement for the development and promotion of our OraQuick® rapid HCV test in Europe. After backing out the earlier than expected milestone payment, we still exceeded the high end of our guidance. In addition, we experienced sales growth across all of our product lines.

From a bottom line perspective, we reported a net loss of \$553,000, or \$0.01 per share in Q2 2010, compared to a forecasted loss of \$0.07 to \$0.08 per share. The higher revenues and lower than projected operating expenses helped to reduce our net loss for the quarter. R&D expenses came in lower due to the timing of clinical trial spend for our OraQuick® HCV test and for other R&D projects. Sales and marketing and general and administrative expenses were also lower than expected due to timing of recruiting and staffing expenses.

Revenues – Ron Spair

Second quarter 2010 revenues of \$19.2 million represented an 11% increase from the \$17.3 million reported in 2009. As you may recall, our second quarter 2009 revenues were negatively impacted by a manufacturing issue related to our OraQuick® HIV test, which resulted in a backlog at June 30, 2009 of \$2.2 million.

Infectious disease testing revenues were \$10.0 million in the second quarter of 2010 compared to \$9.4 million in the second quarter of 2009. This also represents an approximate \$493,000 increase from the first quarter of 2010. The overall 6% increase in our infectious disease revenues in the second quarter of 2010 compared

to 2009 was the result of a 12% increase in OraQuick® HIV sales in the domestic market, partially offset by a 36% decrease in international sales. Domestic OraQuick® sales during the second quarter of 2009 were negatively impacted by the OraQuick® manufacturing issue. Had the \$2.2 million backlog been filled in the prior year period, we would have experienced a decline in sales for the second quarter of 2010 when compared to the second quarter of 2009, primarily as a result of decreased sales volume resulting from reduced public health funding by state and local governments and slightly lower average selling prices. International OraQuick® HIV revenues declined largely as a result of some customer losses caused by price competition, changes in government testing algorithms and the non-recurrence of one-time customer orders from the prior year period.

Moving to substance abuse testing, revenues increased 4% from \$2.9 million in the second quarter of 2009 to \$3.1 million in the second quarter of 2010, as increased sales of our Intercept® drug testing system in the domestic market were partially offset by decreased sales of Intercept® in the international market.

Second quarter 2010 cryosurgical revenues increased 8% compared to the second quarter of 2009 due to a 95% increase in professional sales in the domestic market. The higher U.S. professional sales were caused by the continued elimination of the diversion issue, the introduction of a newly reconfigured Histofreezer® product line in the U.S., an overall price increase implemented in April 2010, and the impact of adding our new manufacturer's sales representative organizations. International sales partially offset this increase with a 58% decline, largely due to decreases in the European and Latin American markets.

OTC cryosurgical sales decreased 13% to \$1.3 million when compared to the same period of 2009, primarily as a result of decreased sales to our Latin American OTC distributor, Genomma, which were partially offset by higher sales to our European OTC distributor, SSL.

Our insurance risk assessment sales increased to \$1.6 million in 2010 from \$1.5 million in 2009.

Gross Margin – Ron Spair

Turning to Gross Margin, our overall margin for Q2 of 2010 was 63%, a significant increase over the 57% reported for the second quarter of 2009. Gross margin in the current quarter benefited from the higher licensing and product development revenues, a more favorable product revenue mix, and an improvement in scrap and spoilage expense levels when compared to the second quarter of 2009. These benefits were partially offset by an increase in unabsorbed overhead costs due to lower product production and severance costs related to a reduction in force during the second quarter.

Operating Expenses – Ron Spair

Our total operating expenses for the second quarter decreased \$2.5 million compared to 2009. Second quarter 2009 operating expenses included a \$3.0 million impairment charge related to license payments for certain HCV patents, which we previously capitalized.

Research and Development expenses for Q2 increased 25% or approximately \$596,000 from the second quarter of 2009, primarily as a result of increased staffing costs, increased laboratory supplies expense related to new product development, and increased clinical trial spending associated with our OraQuick® HIV OTC program. These increases were partially offset by lower clinical costs for our OraQuick® HCV test.

Sales and Marketing expenses increased 6% or approximately \$321,000, as a result of increased consulting and advertising expenses, partially offset by decreased staffing costs.

General and Administrative expenses decreased approximately 8% or by \$361,000, primarily due to lower legal expenses, partially offset by an increase in staffing costs.

Net Loss – Ron Spair

On the bottom line, we reported a net loss of \$553,000, or \$0.01 per share, for Q2 2010. This compares to a net loss of \$5.2 million or \$0.11 per share in the second quarter of 2009.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, our cash balance remained strong with cash and short-term investments increasing during the quarter to \$74.5 million. Our working capital of \$77.0 million at June 30, 2010 is down compared to the working capital balance at December 31, 2009 of \$89.4 million, largely due to the reclassification of our long-term debt to a current liability as a result of its maturity date in June 2011 and a reduction in cash and cash equivalents.

During the second quarter of 2010, we generated \$1.9 million in cash flow from operations compared to \$1.0 million generated during the second quarter of 2009. The increase is largely the result of our lower net loss coupled with a decrease in prepaid expenses and other assets of \$1.3 million largely due to the collection of a federal tax refund of \$673,000, a decrease in inventories and an increase in accrued expenses and other liabilities. Offsetting these increases in cash was an increase in accounts receivable and a decrease in accounts payable. Day sales outstanding was 62 days at June 30, 2010 compared to 58 days at June 30, 2009.

Third Quarter 2010 Financial Guidance – Ron Spair

Turning to guidance for the third quarter of 2010, we are projecting revenues of approximately \$17.5 to \$18.0 million and a loss per share of approximately \$0.03 to \$0.04.

And with that, I will turn things back over to Doug.

Second Quarter Regulatory Developments – Doug Michels

Thanks Ron. During the second quarter, we received several important regulatory approvals.

The most important of these was the FDA approval of our OraQuick® Hepatitis C test for use with venous whole blood specimens, which we previously announced. It is the first rapid HCV test to be approved by the FDA, and we formally launched this product at the annual meeting of the American Association for Clinical Chemistry (“AACC”) at the end of July. We are now actively selling this product to our customers. We expect sales of this product during the second half of 2010, but sales of any magnitude will likely require approval of one or more additional specimen types, along with receipt of a CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver.

A second important approval we received relates to the shelf life for our OraQuick® HIV test. During the second quarter, the FDA approved a dating extension for this product from 12 to 18 months. We also received approval from our notified body to extend dating to 18 months in Europe. As a result, we will soon be selling our OraQuick® HIV test both domestically and around the world with this longer dating. Real time stability studies are ongoing and, assuming the product continues to meet our stability criteria, we would expect to seek approval of further shelf life extensions in the future.

A final regulatory approval received during the second quarter relates to our manufacturing operations. As you may know, some time ago we decided to invest in automated manufacturing equipment for our OraQuick *ADVANCE*[®] HIV product. This equipment has now been validated and approved by the FDA for use in the manufacture of our OraQuick[®] HIV test. This equipment will enable us to produce larger quantities at lower cost and will be critical to our ability to meet future demand for this important product. The first automated production lot will come off the line this week.

Clinical Programs Update – Doug Michels

Turning to our major clinical programs, there are several important developments to report.

OraQuick[®] HCV – Doug Michels

Now that we have received venous whole blood approval for our OraQuick[®] HCV test, we are focusing our efforts on gaining approval for additional specimen types and implementing our CLIA waiver studies.

As disclosed previously, the FDA required additional clinical studies to support claims for fingerstick whole blood and oral fluid. We completed these studies and were prepared to submit a pre-market approval (“PMA”) supplement seeking approval of both claims once we received venous whole blood approval. However, prior to submitting the PMA supplement, we shared our data with the FDA as part of our discussions on the CLIA waiver study protocols. The FDA recently provided feedback on our data.

The FDA’s primary comments related to the lower sensitivity of our test in oral fluid and fingerstick whole blood when compared to venous whole blood. As a result of these comments, and in consultation with the FDA, we have decided to separate the submissions for fingerstick whole blood and oral fluid. A PMA supplement was recently sent to the FDA for the fingerstick claim.

We still intend to pursue an oral fluid claim for our OraQuick® HCV test. However, the filing of a PMA supplement for oral fluid has been delayed pending additional discussions with the FDA. It is likely that more clinical data will be needed to support our oral fluid PMA submission. We will provide updates at appropriate times as to the timing and additional requirements for our oral fluid submission once they are clarified.

With respect to a CLIA waiver, we are working to finalize our protocols with the FDA. In light of the feedback on the fingerstick whole blood and oral fluid clinical data, our current plan is to pursue a CLIA waiver initially for fingerstick and venous whole blood. Our filing with the FDA will be timed to occur if and when approval for the fingerstick claim is received. We would expect to pursue the CLIA waiver for oral fluid once our path forward on the PMA supplement for this specimen type is clarified and we are in a position to make a submission and obtain approval.

HIV OTC – Doug Michels

With respect to our rapid HIV over-the-counter test, we have continued to test our product labeling and we have finalized our protocol for the final phase of clinical testing. We still expect to submit our labeling validation data and final clinical study protocol for approval by the FDA later this year.

We have also initiated site selection for the final clinical studies. We expect to begin the final phase of clinical testing once the FDA approves our protocol. Assuming a timely approval of our labeling and final protocol, we still expect clinical testing to commence later this year and extend into 2011.

High Throughput Assays and Substance Abuse Testing Business – Doug Michels

In substance abuse testing, submissions for FDA 510(k) clearance remain pending for the high throughput oral fluid assays for opiates, PCP, amphetamines, methamphetamines and cocaine developed under our collaboration with Roche Diagnostics. Our initial expectation was that we would receive FDA clearance for these assays by year end. However, the FDA has requested some additional data. Our expectation is that the data will be supplied prior to the end of this year. The likely impact of these additional requirements is that any FDA 510(k) clearance would not be expected until 2011.

Other Business – Doug Michels

Finally, before we take your questions, I would like to comment on several aspects of our major business lines.

OraQuick® HIV

As discussed during the last call, continuing economic challenges have had an adverse impact on some of our OraQuick® HIV customers. Funding cuts at both the state and local levels have resulted in lower purchases, primarily in the public health market. These economic conditions have also increased pressure on pricing. Although we will continue to aggressively address these challenges in the marketplace, we believe these difficult conditions will continue to affect our business until such time as we see some improvement in the broader economy.

Despite these challenges, HIV testing and treatment continues to be a priority for the Federal government. As you know, earlier this year the CDC announced an expansion of its program to fund HIV testing and prevention in healthcare settings. More recently, President Obama released his National HIV/AIDS Strategy, which reaffirms the Administration's focus on HIV/AIDS through increased testing and treatment, especially in communities where the disease has had the greatest impact. We continue to believe that the Federal government's ongoing support will help mitigate somewhat the impact of the current economic climate on our customers.

Substance Abuse

During the past several calls we have indicated that our substance abuse testing business appears to be stabilizing. Our second quarter performance, particularly in the domestic workplace and criminal justice markets, provides further evidence of this, as revenues were up slightly in both markets compared to the second quarter of 2009. Our major workplace laboratories have also reported that the number of oral fluid specimens processed during the first half of 2010 is slightly ahead of the comparable period of 2009. This is a nice improvement from the substantial declines in testing volumes these laboratories experienced during 2009 compared to 2008.

Cryosurgical Systems

Finally, with respect to cryosurgical systems, our business performed well during the quarter, particularly in the domestic professional market. As Ron explained, this part of the business benefitted from our efforts to eliminate diversion by certain foreign distributors into the U.S., the deployment of two manufacturers' sales representative organizations and the launch of a newly designed Histofreezer[®] product for the U.S. market. We believe these factors will continue to positively impact our business for the remainder of 2010. On the OTC front, sales were up for the quarter primarily due to the strong performance of our product in Europe.

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

[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 press release 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; 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; 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; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; 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; 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; 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; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; 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; ability to identify, complete and realize the full benefits of potential acquisitions; 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, 2009, 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 these prepared remarks and OraSure Technologies undertakes no duty to update these statements.