
**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 5, 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))
-
-

Item 7.01– Regulation FD Disclosure.

On May 5, 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 March 31, 2010, described certain business developments and provided financial guidance for the second quarter 2010. 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. First Quarter 2010 Analyst/Investor Conference Call Held May 5, 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: May 5, 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. First Quarter 2010 Analyst/Investor Conference Call Held May 5, 2010.

OraSure Technologies, Inc.
2010 First Quarter
Analyst/Investor Conference Call
May 5, 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.

I will start today’s call with an update on several recent developments, including our Q1 performance. Ron will then follow with a more detailed overview of our Q1 results and guidance for the second quarter. I will conclude the call with a brief discussion of our major clinical programs and certain other business developments. We will then open the floor for your questions.

Q1 Performance – Doug Michels

As indicated in our press release, revenues for the first quarter were \$17.9 million. This represents an increase over the comparable period of 2009, but fell below our top-line guidance for the quarter. Despite the lower than expected revenues, we exceeded our guidance on the bottom line. The revenue shortfall was driven primarily by lower than expected domestic sales of our OraQuick ADVANCE® HIV test and international sales of our over-the-counter (“OTC”) cryosurgical wart removal product.

Continuing economic challenges have had a greater than expected impact on some of our OraQuick® customers. Funding cuts at both the state and local levels

resulted in lower sales during the quarter, primarily in the public health segment which depends heavily on public funding. Reduced funding also impacted our OraQuick® sales to hospitals, but to a lesser degree.

Funding challenges are not new and we built our 2010 plan and first quarter forecast anticipating their impact. However, it is becoming more apparent that the extent and timing of the reductions and their impact on our business can be very difficult to predict with precision. For example, during the first quarter several large customers unexpectedly reduced their purchases from committed levels previously communicated to us. In fact, one state's reduction did not occur until after an early March meeting of the state legislature, which focused on reducing expenditures by the Department of Health. Several other jurisdictions were unable to expand their HIV testing programs in the first quarter as previously planned.

Funding issues were more pronounced where customers had accumulated higher levels of product inventory. As you may recall, we reported strong results in the third and fourth quarters of 2009 in part because several public health customers made large purchases of OraQuick® tests during those periods. This is not unusual as customers often try to spend unused funds prior to the September 30 or December 31 ends of their respective fiscal years. However, because of continued funding cuts associated with testing initiatives, some of these customers were unable to deploy their purchased inventory at normal or expected rates. This in turn adversely affected their Q1 purchases.

Reduced funding has also placed increased pressure on pricing for our OraQuick® HIV test. While we continue to maintain a premium on price compared to our competitors, and our 2010 forecast did reflect a lower average selling price, the price degradation during the first quarter was somewhat greater than expected.

Despite the state and local funding challenges, our OraQuick® HIV test continues to be a key tool in the fight against HIV/AIDS. HIV testing is strongly supported at the Federal level as evidenced by the CDC's funding decisions during the past few years, and we expect this to continue. In fact, on April 1, 2010, the CDC announced a \$31.5 million expansion of its program to fund HIV testing in healthcare settings. As a result, total funding of \$142.5 million is planned for the 3-year period beginning October 2010. We believe this will mitigate some of the funding issues currently being experienced by our public health and hospital customers.

With respect to our cryosurgical business, we experienced lower than expected sales of our OTC wart removal product in Latin America during Q1. As explained on prior calls, our distributor, Genomma, launched our product in Brazil beginning late last year. The launch has gone well and the product has been well received by retailers and consumers. However, late in Q1 Genomma decided to cancel two purchase orders which we had included in our forecast. These orders totaled more than \$500,000 and were cancelled in order to give Genomma more time to gauge the level of consumer purchases so as to avoid an inventory build up at retail outlets.

Looking forward, we believe the economic climate and funding challenges will continue to impact our business for the rest of 2010, particularly here in the U.S. While the exact impact is difficult to predict at this time, we believe revenues for the year may well be at or near the levels recorded in 2009. Ron will provide more detail on our specific expectations for the second quarter later in the call.

OraQuick® HCV – Doug Michels

Regarding some key accomplishments for the quarter, we recently completed a facility and quality systems audit performed by the FDA in connection with our premarket approval (“PMA”) application for the OraQuick® HCV test. This audit occurred during March and went well. We have submitted our formal response, which we believe satisfies all the FDA’s observations and clears the path for approval of our OraQuick® HCV test for use with whole blood.

The completion of the audit was the result of excellent work by a cross-functional group of employees from our Regulatory, Quality, Operations and R&D groups. Their efforts are very much appreciated.

Organizational Change

One final comment before Ron provides his update, relates to an organizational matter. Manuel Mendez, who joined OraSure last year and has led our Sales and Marketing group, will be leaving the Company to pursue another opportunity. We appreciate Manuel’s contributions and wish him well in his new endeavor. A search for his successor is underway. In the interim, I will directly manage the Sales and Marketing function as I have done at times in the past.

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

First Quarter 2010 Financial Results – Ron Spair

Thanks Doug and good afternoon everyone.

Revenues – Ron Spair

First quarter 2010 revenues were \$17.9 million, representing a 4% increase from

the \$17.3 million reported in 2009. Increased licensing and product development revenues and increased sales of our cryosurgical systems products were partially offset by a decline in infectious disease testing and insurance risk assessment revenues.

Our first quarter 2010 licensing and product development revenues include a \$1.0 million milestone payment received from Merck as a result of our achievement of certain regulatory objectives pursuant to our collaboration agreement for the development and promotion of our OraQuick® rapid HCV test.

Infectious disease testing revenues were \$9.5 million in the first quarter of 2010 compared to \$10.5 million in the first quarter of 2009. As we discussed during the previous call, we have observed that an increasing number of our public health customers are supplying hospitals with OraQuick® HIV tests purchased from us. This overlap makes it difficult to separately track OraQuick® sales to these markets. Since this trend is likely to continue, we began reporting public health and hospital sales as a combined domestic market beginning with the first quarter.

The overall 9% decline in our infectious disease revenues in the first quarter of 2010 was a result of decreased OraQuick® HIV sales in both the domestic and international markets. Domestic OraQuick® sales were down 6% primarily due to lower average selling prices and lower volumes. International OraQuick® revenues declined 27% largely as a result of some customer losses caused by increased price competition as well as the non-recurrence of customer orders from the prior year period.

Moving to substance abuse testing, revenues remained flat at \$2.7 million in the first quarter of 2010 compared to the first quarter of 2009 as lower sales of our Intercept® drug testing system were offset by increased sales of the Q.E.D.® rapid saliva alcohol test.

First quarter 2010 cryosurgical revenues increased 40% compared to the first quarter of 2009. International OTC sales increased \$952,000 when compared to sales in the same period of 2009 largely as a result of \$1.1 million of sales to our Latin American OTC distributor, Genomma, in support of the launch of our product in Brazil. This was partially offset by lower European OTC sales to our distributor, SSL, during the first quarter.

On the professional side, a 28% increase in sales of Histofreezer® in the United States was offset by a 57% decrease of Histofreezer® sales in the international market. Domestic sales were up largely due to increased purchases by our distributors in anticipation of price increases implemented in January and April 2010. The decline in international sales is largely due to a discontinuance of sales to certain foreign distributors that had been diverting product to the U.S. market.

We believe our efforts to stop diversion by certain foreign distributors along with the addition of two manufacturer's sales representative organizations ("MROs"), are having a positive impact on our domestic Histofreezer® business. On the OTC front, we expect additional orders from Genomma for Brazil despite the first quarter cancellations and we expect that sales this year to SSL for Europe will be higher than last year.

Our insurance risk assessment sales decreased from \$1.6 million in 2009 to \$1.4 million in 2010 due to variations in laboratory ordering patterns and a decrease in the issuance of new insurance policies.

Gross Margin – Ron Spair

Turning to Gross Margin, we are pleased that our overall margin for Q1 of 2010 remained at 64%, essentially unchanged from Q1 of 2009. Gross margin in the

current quarter benefited from the increase in licensing and product development revenues as well as a decrease in royalty and licensing expenses. However, these benefits were offset by an increase in unabsorbed overhead costs due to lower product production in light of existing inventory levels as well as the lower selling price realized by our OraQuick® product.

Operating Expenses – Ron Spair

Our total operating expenses for the first quarter increased \$747,000 or 6%, compared to 2009. Lower Research and Development costs were offset by higher Sales and Marketing and General and Administrative spending.

Research and Development expenses for Q1 declined 7% or approximately \$246,000 from the first quarter of 2009, primarily due to a decrease in clinical trial spending associated with our OraQuick® HCV and OraQuick® HIV OTC programs as well as a decrease in validation and vendor qualification costs for those same programs.

Sales and Marketing expenses increased 13% or approximately \$672,000, as a result of additional market research activities, increased recruiting and consulting costs and commissions paid to the two new manufacturer's sales representative organizations that we retained during the first quarter to support sales of our Histofreezer® product in the U.S. physician office market.

General and Administrative expenses also increased approximately 7% or by \$322,000, primarily due to increased consulting costs, partially offset by a decrease in legal expenses.

Net Loss – Ron Spair

From a bottom line perspective, we reported a net loss of \$2.2 million, or \$0.05 per share, which exceeded our guidance. This compares to a net loss of \$1.6 million, or \$0.04 per share for the same period 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 of \$73.4 million at the end of the first quarter. Our working capital of \$86.6 million at March 31, 2010 is down somewhat compared to the working capital balance at December 31, 2009 of \$89.4 million. Our current ratio improved from 6.81 at December 31, 2009 to 8.48 at March 31, 2010.

During the first quarter of 2010, we used \$5.0 million in cash flow from operations compared to \$2.7 million used during the first quarter of 2009. The increase is largely the result of our increased net loss coupled with payments of our 2009 accruals and accounts payable as well as increases in inventories and other assets. These uses of cash were partially offset by a decrease in accounts receivable of \$1.6 million as a result of timely collection of amounts due and the decrease in product revenues experienced in the first quarter of 2010 compared to the fourth quarter of 2009.

Day sales outstanding was 61 days at March 31, 2010 compared to 59 days at March 31, 2009.

Second Quarter 2010 Financial Guidance – Ron Spair

Turning to guidance for the second quarter of 2010, we are projecting revenues of approximately \$17.0 to \$17.5 million and a loss per share of approximately \$0.07 to \$0.08.

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

Clinical Programs Update – Doug Michels

Thanks Ron. We have continued to progress all of our major clinical programs.

OraQuick® HCV – Doug Michels

With the FDA audit behind us, we believe there is very little left to do before we receive a first U.S. approval of our OraQuick® HCV test for a whole blood claim. We are in discussions with the FDA on our labeling, and we expect this approval shortly.

With respect to the other applications, as you know, the FDA has required an additional clinical study to support claims for fingerstick whole blood and oral fluid. This study is now complete and within the next 30 days we expect to submit our final data to the FDA.

With respect to a CLIA waiver, our protocols for the required studies were submitted to the FDA in the form of a pre-Investigational Device Exemption (“IDE”) submission. We are waiting for feedback from the agency and once received we will finalize the protocols as quickly as possible. As stated previously, our plan is to submit the clinical data from our CLIA studies and request a CLIA waiver as soon as possible after we receive approval of our fingerstick whole blood and oral fluid claims.

Finally, you will recall that we received CE mark approval for the OraQuick®

HCV test in 2009, which allows us to sell the product in Europe. In April, we formally launched the OraQuick® HCV test at a meeting of the European Association for the Study of the Liver, or EASL. The launch went well, and we are now focused on building awareness and acceptance for this product in a number of European countries.

HIV OTC – Doug Michels

Since the last call, we have prepared and filed with the FDA an amendment to our IDE which contains a proposed protocol for the final phase of clinical studies related to our rapid HIV OTC test. The FDA has reviewed the protocol and we are incorporating their feedback. We have also made some further revisions to our product labeling, which we believe will further improve the performance of the product in users' hands. We are in the process of testing these changes in several small validation studies. This will then be followed by a larger study demonstrating the efficacy of our final product labeling. After completion of these studies, we intend to submit the labeling validation data, along with the revised clinical study protocol, for final approval by the FDA.

Once this approval is received, we will initiate subject enrollment for the final phase of clinical testing. We remain on schedule for this project with clinical testing still expected to extend into 2011. We also continue to believe that an additional Blood Products Advisory Committee meeting will be needed before final approval would be issued by the FDA.

High Throughput Assays and Substance Abuse Testing Business – Doug Michels

In the Substance Abuse testing area, we continue to prepare for the commercialization of fully automated homogeneous drugs of abuse assays developed with Roche Diagnostics.

Submissions for FDA 510(k) clearance were filed at the end of 2009 for the opiates, PCP, amphetamines and methamphetamines assays, and a submission for cocaine was filed in late April. Once 510(k) clearance is received for each of these assays, which is expected later this year, OraSure and Roche will launch a partial NIDA-5 panel in the workplace testing and other markets. The assay for THC is expected to be filed later this year. We have also started development on a second group of assays, which will continue into 2011. Overall, we are pleased with our collaboration with Roche on these important products.

As discussed on the last call, we believe our Intercept® business is stabilizing despite the ongoing adverse employment conditions. To supplement this part of the business, we intend to launch some new drug testing products later this month. These include a group of microplate assays for the detection of various prescription medications, which will expand our offerings in the forensic toxicology, criminal justice and pain management markets. We will also start offering a rapid urine drug screening test into the criminal justice, drug treatment and workplace testing markets, which will allow us to more effectively compete for customers that use urine as their sole or primary drug testing matrix.

OraQuick® HIV Shelf Life – Doug Michels

Finally, before we take your questions, I want to update you on the shelf life for the current OraQuick® HIV test. Our ongoing real time stability studies have now reached the 20-month mark. A submission requesting a dating extension to 18 months is being finalized and is expected to be filed within the next few weeks.

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 document contains certain forward-looking statements, including with respect to revenues, net income/loss, earnings/loss per share and products. Actual results could be significantly different. Factors that could affect results include the 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 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 and ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's 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 changes in international funding sources; 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 Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2009, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. Although forward-looking statements help to provide complete 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 document and OraSure Technologies undertakes no duty to update these statements.