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 4, 2011

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 – Regulation FD Disclosure.

On May 4, 2011, 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, 2011, described certain business developments and provided financial guidance for the second quarter of 2011. 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

Exhibit Number	Description
99	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2011 Analyst/Investor Conference Call Held May 4, 2011.

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 4, 2011

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 2011 Analyst/Investor Conference Call Held May 4, 2011.

Exhibit 99

OraSure Technologies, Inc.

2011 First Quarter

Analyst/Investor Conference Call

May 4, 2011

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.

2011 has gotten off to a solid start as our results for the first quarter were better than expected. We exceeded our guidance for both revenues and the bottom line. We also continue to make good progress on our major clinical programs. Our manufacturing improvements are yielding results and our balance sheet remains strong. As you will hear in the next 20 minutes, the OraSure team is executing effectively against our goals and objectives. Although the economy remains a challenge with funding and employment trends still under pressure, I am pleased with the response by our management team during these challenging times.

For the call today, Ron will start with some financial highlights, and then I will address some factors affecting our business and provide an update on our major clinical programs. We will then open the floor for your questions.

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

First Quarter 2011 Financial Results – Ron Spair

Thanks Doug and good afternoon everyone.

Revenues – Ron Spair

First quarter 2011 revenues were $17.4 million compared to $17.9 million reported in 2010. Our product revenues increased 3% as increased sales of our infectious disease and substance abuse testing products were partially offset by lower sales of our cryosurgical systems products and lower insurance risk assessment revenues. The increase in product revenues was offset by lower licensing and product development revenues caused by the absence of a $1.0 million milestone payment received in the first quarter of 2010 under our HCV collaboration with Merck.

Infectious disease testing revenues were $10.0 million in the first quarter of 2011 compared to $9.5 million in the first quarter of 2010. The overall 5% increase was primarily a result of higher OraQuick® HIV sales in international markets. Domestic OraQuick® sales rose 2%. International OraQuick® revenues increased 115% largely because certain private and government customers were able to make purchases for HIV testing.

In substance abuse testing, revenues increased from $2.7 million in the first quarter of 2010 to $3.1 million in the first quarter of 2011 as a result of a 17% increase in sales of our Intercept® drug testing system. This increase was the result of an improvement in pre-employment testing rates when compared to the first quarter of 2010 and the return by our primary drug testing laboratory customer to a more normal ordering pattern. In 2010, this customer changed its inventory management model and this change negatively impacted Intercept® sales during the year ago period.

First quarter 2011 cryosurgical revenues decreased 9% compared to the first quarter of 2010.

OTC sales decreased $485,000 when compared to 2010 largely as a result of the absence of sales to our Latin American OTC distributor, Genomma. One reason

for the reduction was the absence of an initial pipeline fill by Genomma required for the commercial launch of our product in Brazil during the first quarter of 2010. Genomma's purchases during the first quarter of 2011 were also negatively impacted by regulatory issues in Mexico and Brazil. The decrease in sales to Genomma was partially offset by higher European OTC sales to our distributor, Reckitt Benckiser, during the first quarter.

On the professional side, combined domestic and international sales increased 14% as a result of improved distributor focus on our products, the continued impact of our manufacturer's sales representative organizations, increased pricing, and some economic recovery.

Our insurance risk assessment sales decreased from $1.4 million in 2010 to $1.3 million in 2011 due to the issuance of fewer new insurance policies.

Gross Margin – Ron Spair

Turning to Gross Margin, our overall margin for Q1 of 2011 was 65% compared to 64% reported for the first quarter of 2010. Margins in the first quarter of 2011 benefited from increased manufacturing efficiencies and a more favorable product mix. Product gross margins increased 340 basis points when compared to last year primarily as a result of the manufacturing efficiencies. These benefits were partially offset by the decrease in licensing and product development revenues that I mentioned previously. The $1.0 million HCV milestone we received during the first quarter of 2010 accounted for approximately 210 basis points of margin for that period.

Operating Expenses – Ron Spair

Our total operating expenses for the first quarter increased $240,000 or 2%, compared to the first quarter of 2010. Research and development expenses increased by approximately $1.3 million due to higher clinical trial costs associated with our OraQuick® HIV OTC program, partially offset by an decrease in clinical trial costs associated with our OraQuick® HCV test. Sales and marketing expenses

decreased by approximately $762,000 as a result of lower staffing, recruiting and market research costs. General and administrative expenses decreased by approximately $311,000 as a result lower consulting and staffing costs, partially offset by higher legal expenses.

Net Loss – Ron Spair

From a bottom line perspective, we reported a net loss of $2.6 million, or $0.06 per share, which exceeded our guidance. This compares to a net loss of $2.2 million, or $0.05 per share, for the same period of 2010.

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 $72.4 million at March 31st.

Cash used in operating activities in the first quarter of 2011 was $2.0 million, a $3.0 million improvement when compared to the $5.0 million used during the first quarter of 2010.

Second Quarter 2011 Financial Guidance – Ron Spair

Turning to guidance for the second quarter of 2011, we are projecting revenues of approximately $17.75 to $18.25 million and a loss per share of approximately $0.07 to $0.08.

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

Business Outlook – Doug Michels

Thanks Ron. In looking at our business, several points should be kept in mind.

- We were certainly pleased to see higher sales of our OraQuick® HIV product during the first quarter, especially given the difficult economic environment. However, ongoing economic and funding

challenges are likely to continue to affect our business, particularly in the domestic public health market. Although some improvement seems to be occurring in certain areas of the U.S. and in some international markets, it is difficult to predict with certainty whether, and to what extent, these conditions will continue over the long term.

- With respect to our OraQuick® HCV test, we believe a number of factors will affect the commercial success of the product. Of most significance for the U.S. is the receipt of a waiver under the Clinical Laboratory Improvement Amendments of 1988, or CLIA. This approval is critical to our ability to penetrate both the physician office and public health markets. As you know, we have submitted an application for a CLIA waiver and I will provide an update on our HCV clinical program in a few minutes. On the international front, we are still working to raise awareness, particularly in the European market. As we have discussed in the past, adoption of point-of-care diagnostics remains challenging in Europe, where laboratory testing is entrenched and healthcare delivery systems are structured around centralized testing models.
- As you may know, there was a meeting of the FDA's Antiviral Drugs Advisory Committee in late April at which the Committee recommended that the FDA approve Merck's new pharmaceutical for HCV, a protease inhibitor called boceprevir. The Committee also recommended FDA approval of a second protease inhibitor manufactured by Vertex, called telaprevir. As a result of the Committee's recommendations, there is an expectation that both of these drugs will be approved by the FDA in the near future. The expected approval of these drugs represents a major landmark in HCV therapy. By adding this new class of drug to the existing regimen, physicians will likely

achieve cure rates in two-thirds to three quarters of their patients. Also, many patients will likely be able to achieve a cure after a substantially shorter treatment duration than currently required. We believe this will help drive awareness and demand for increased HCV testing, including our OraQuick® HCV product.

- We are encouraged by the improved performance of our substance abuse business. As Ron indicated, this appears to be the result, in part, of improving employment conditions here in the U.S. However, these conditions may not continue on a sustained basis. Overall, employment has not returned to robust levels. In addition, the substance abuse area is likely to experience increased competition in the future. For example, there are at least two firms that are selling high throughput fully-automated oral fluid drug testing products in non-regulated markets. We believe that one of these competitors has also received FDA clearance for a NIDA-5 panel. These products will obviously compete with our Intercept® business and with the high throughput assays we intend to commercialize jointly with Roche.

Clinical Programs Update – Doug Michels

Turning to our clinical programs — Let me start with HCV.

OraQuick® HCV – Doug Michels

During the first quarter, there were two significant developments related to our OraQuick® HCV product. First, in February we received FDA approval for use of the test on fingerstick whole blood samples. This was the second application approved by the FDA — the first being venous whole blood which was approved in June 2010.

The second development was our submission in March of an application for a CLIA waiver for the OraQuick® HCV product for use with both venous whole blood and fingerstick whole blood samples. Under its current approvals, the OraQuick® HCV test can be used by laboratories certified or accredited under CLIA as being able to perform “moderately complex” tests. However, with a CLIA waiver, we will be able to sell our test to substantially more sites nationwide that currently hold a waiver, including outreach clinics, community-based organizations and physician offices. As previously mentioned, the receipt of a CLIA waiver is critical to fully realizing the market potential for this product.

With respect to an oral fluid claim, we have initiated additional testing which we hope will provide further support for our oral fluid submission. We intend to meet with the FDA to discuss and finalize the structure of our oral fluid submission in the coming months.

Assuming a timely CLIA waiver, we expect domestic revenues for this product to increase later this year. We have been working with Merck under our collaboration agreement so that we are prepared to begin detailing the product in physician offices after the CLIA waiver is received.

HIV OTC – Doug Michels

Turning to our OraQuick® HIV OTC product, the final phase of clinical testing was started at the end of 2010. You will recall that this phase involves the use of our test in an unobserved setting. One of the study objectives specified by the FDA is to identify at least 100 HIV infected, but undiagnosed individuals. In order to meet this requirement, we expect that we will need to enroll and test approximately 4,000-5,000 participants in our study.

I am pleased to report that we have made substantial progress on the study, and it remains on time and on budget. All clinical sites have initiated testing and, in fact, we are now starting to close several of our initial sites to ensure we achieve the appropriate geographic diversity required by our protocol. We have enrolled over

2,500 patients, and we have identified over half of the required number of newly diagnosed HIV individuals. Assuming enrollment continues as expected and we meet our anticipated prevalence rates among those enrolled, we still expect to complete this study during the third quarter of this year.

OraQuick® HIV Shelf Life – Doug Michels

As discussed during our last call, we previously extended the shelf life for our OraQuick® HIV test to 24 months. We have continued our real time stability studies and now have stability data for this product that should support an extension to 30 months. We expect to file a formal request with the FDA in the next several weeks.

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

In the area of substance abuse testing, during the first quarter we announced several 510(k) clearances for the use of high throughput oral fluid assays with our Intercept® device. Specifically, clearances were received for phencyclidine (PCP), cocaine, opiates and methamphetamine. An application for amphetamines has also been filed, but remains pending with the FDA. We expect this assay to receive 510(k) clearance in the near future.

As discussed previously, the clinical work for the THC assay (marijuana) has followed a somewhat extended schedule. This work is continuing. Although the goal is to resolve all open issues and make an FDA submission as soon as possible, this will likely not occur until near the end of the year at the earliest.

In the meantime, we expect to launch this product line with Roche with a panel consisting of PCP, cocaine, opiates, methamphetamine and amphetamine beginning October. We are working with Roche to accelerate the availability of product in order to meet the competition expected in this market.

OraSure QuickFlu™ – Doug Michels

Earlier this year we announced the addition of a new infectious disease testing product to our portfolio, the OraSure QuickFlu™ rapid flu A+B test. Our focus with this product is primarily on the U.S. hospital market. During the first quarter, we trained our sales team and prepared marketing materials for a formal launch. A number of our customers are currently evaluating this product in anticipation of the 2011-2012 flu season. We expect sales of this test to begin to materialize during the second half of the year.

* * * *

So as you've just heard, we have been busy on multiple fronts and measurable progress is being made. Our team has been effectively managing many demands and I thank them for all their hard work. We are executing on our goals and objectives - on time and on budget. The Company is well funded to accomplish the tasks at hand and we have never been more optimistic about the future of the company. Although there is still much work that lies ahead, we believe 2011 is off to a good start, and we look forward to updating you as the year progresses.

New Director – Doug Michels

Finally, before we open the Q&A session, I would like to mention one final item regarding the recent change in our Board of Directors.

In April, we announced the addition of Dr. Stephen Tang as a member of the Company's Board. Steve has enjoyed a successful career in both the medical diagnostic and pharmaceutical industries and is currently the President and CEO of The University City Science Center, located in Philadelphia. We believe Steve will be a strong contributor, and we are very pleased that he has joined our Board.

Steve’s appointment follows the retirement of Dr. Jack Goldstein as a Director. As you may recall, Jack is the former President and Chief Operating Officer of Chiron Corporation, and he joined the Board in 2006. Jack made significant contributions to our Company, and we are grateful for his service. We thank Jack and wish him every success in his future endeavors.

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; 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; 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, 2010, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of these prepared remarks and OraSure Technologies undertakes no duty to update these statements.