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): February 9, 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 February 9, 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 and full year ended December 31, 2010, described certain business developments and provided an update on financial guidance for the first 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.

The information in this Current Report 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

Exhibit Number	Description
99	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2010 Analyst/Investor Conference Call Held February 9, 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: February 9, 2011

By: *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. Fourth Quarter and Full Year 2010 Analyst/Investor Conference Call Held February 9, 2011.

Exhibit 99

OraSure Technologies, Inc.

2010 Fourth Quarter and Full Year

Analyst/Investor Conference Call

February 9, 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.

We ended 2010 on a strong note by exceeding our fourth quarter guidance for both revenues and the bottom line. We are also generally pleased with our full year performance, especially given the difficult economic conditions and funding challenges encountered by our customers.

Ron Spair will begin today's discussion with some financial highlights. I will then discuss our major clinical programs and comment on other developments in our business.

We will conclude by opening the floor for your questions.

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

Fourth Quarter 2010 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone. As Doug mentioned, our fourth quarter performance exceeded our prior guidance, on both the top and bottom lines. In addition, I am pleased to say we generated $3.6 million in cash flow from

operating activities for the quarter which brings us to a total of $3.9 million for the whole year.

Revenues – Ron Spair

Turning to revenues. Our total revenues for Q4 2010 were $18.8 million, compared to $20.9 million for Q4 2009.

Overall infectious disease revenues decreased 10% in the fourth quarter of 2010 primarily as a result of our performance overseas. OraQuick® HIV revenues in the international market declined during the fourth quarter as a result of price competition, changes in the use of our test within government testing algorithms and lower funding for HIV testing initiatives. Domestic OraQuick® HIV revenues increased slightly as a result of higher volume partially offset by a lower average selling price which was forecasted.

In substance abuse testing, revenues decreased 8% from $3.1 million in the fourth quarter of 2009 to $2.9 million in the fourth quarter of 2010, as a result of lower sales of our Intercept® drug testing system in the criminal justice market, lower sales of our Q.E.D.® rapid saliva alcohol test and an absence of laboratory equipment sales.

Fourth quarter 2010 cryosurgical revenues decreased 10% compared to the fourth quarter of 2009 primarily due to lower sales to our Latin American OTC distributor, Genomma. In the fourth quarter of 2009, Genomma increased its orders to prepare to launch our product in the Brazilian OTC market at the end of the year. We did not have a similar pipeline fill in the fourth quarter of 2010. Offsetting this decrease were increases in professional sales in both the domestic and international markets. The higher U.S. professional sales were caused primarily by elimination of the diversion issue and the impact of our manufacturer's sales representative organizations, which we added earlier in 2010.

International sales increased largely as a result of fluctuations in ordering patterns of our customers.

Gross Margin – Ron Spair

Turning to Gross Margin, our overall margin for Q4 of 2010 was 64% compared to 59% reported for the fourth quarter of 2009. Margins in the fourth quarter 2010 benefited from a reduction in royalty expense related to our OraQuick HIV product as a result of a royalty buy-out earlier in the year. Year to date margins increased to 63% compared to 61% for the full year of 2009, largely due to milestone payments received from Merck related to our HCV test.

Operating Expenses – Ron Spair

Total operating expenses for the quarter were $12.9 million compared to $15.8 million in the fourth quarter of 2009. 2009 operating expenses included a $1.5 million expense related to a litigation settlement. Research and development expenses decreased by approximately $613,000 due a decrease in clinical trial costs associated with our OraQuick® HCV test, partially offset by an increase in clinical trial costs associated with our OraQuick® HIV OTC program. Sales and marketing expenses decreased by approximately $854,000 as a result of lower market research and travel costs. General and administrative expenses remained flat in Q4 of 2010 at approximately $4.0 million compared to $3.9 million in Q4 of 2009.

Net Loss – Ron Spair

On the bottom line, we reported a net loss of $1.0 million, or $0.02 per share, for Q4 of 2010. This compares to a net loss of $2.8 million, or $0.06 per share, in the fourth quarter of 2009. Our bottom line performance exceeded our previously issued Q4 guidance for a number of reasons. Revenues exceeded the high end of the range and our gross margin came in higher as well. R&D costs were lower than projected largely as a result of slower than expected patient accrual into the

HIV-OTC trial over the holidays. Finally, severance payments related to our Q4 reduction in force were lower than originally projected.

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 $75.7 million at year end.

As mentioned earlier, during the current quarter, we generated $3.6 million in cash flow from operations compared to $3.0 million used during the fourth quarter of 2009. Our full year cash flow from operations totaled $3.9 million as we improved collections of our outstanding receivable balances, more effectively controlled our inventory levels and reduced the amount of our prepayments.

First Quarter 2011 Financial Guidance – Ron Spair

Turning to guidance for the first quarter of 2011, we are projecting revenues of approximately $16.75 to $17.25 million and a net loss per share of approximately $0.08.

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

Clinical Programs Update – Doug Michels

Thanks, Ron. During the fourth quarter and the first few weeks of the new year, we have continued to make good progress on our major clinical programs.

OraQuick® HCV – Doug Michels

Last year as you may recall, we filed for FDA approval of our OraQuick® HCV test for use with fingerstick whole blood specimens. Based on our discussions with the FDA, we expect to see something on this approval very soon. Assuming things proceed as expected, fingerstick whole blood would be the second approved application for our test. This approval would also be another significant milestone which, along with a CLIA waiver, will be critical to fully realizing the market potential for this product here in the U.S.

Now that a fingerstick approval appears to be imminent, we are finalizing our strategy for obtaining FDA approval of an oral fluid claim. Our plan is to conduct some additional testing on oral fluid specimens, which we believe will provide further support for an oral fluid approval. We intend to meet with the FDA to discuss our oral fluid submission during the second quarter.

In December of last year, we completed the studies required for a CLIA waiver for both fingerstick and venous whole blood, and we are pleased with the study results. Analysis of the resulting data and preparation of a final report for the FDA is nearing completion. Assuming the fingerstick approval is received shortly, we would expect to file our formal request for CLIA waiver in the near future. We also plan to request a CLIA waiver for oral fluid once a PMA supplement for that claim is filed and FDA approval is received.

HIV OTC – Doug Michels

Since our last earnings call, we received an investigational device exemption (“IDE”) for the final phase of clinical testing for our rapid HIV over-the-counter test. As a result, this final study was commenced at the end of 2010. Our call center is up and running, and we are in the process of adding the additional clinical sites required to complete the study.

This final phase of testing will likely require 4,000-5,000 participants, and we will need to identify at least 100 newly-infected HIV individuals in order to meet the parameters specified by the FDA. This study is on track and, as previously disclosed, we expect study enrollment to close in the third quarter of this year. After the study is completed, we will analyze the data and complete our submission for filing with the FDA, which we will pursue as aggressively as possible. As discussed on prior calls, the results of our final clinical phase will need to be reviewed by an FDA advisory board, the Blood Products Advisory Committee. We will continue to provide you with appropriate updates as this

exciting and important program progresses.

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

In the area of substance abuse testing, I am pleased to report that the FDA recently issued a 510(k) clearance for use of a high throughput oral fluid PCP assay with our Intercept device. This is the first such clearance resulting from our joint collaboration with Roche Diagnostics. We believe the FDA clearance process is in the final stages for several of the other NIDA-5 assays that have been developed, and we would expect the FDA to issue additional 510(k) clearances in the near future.

As you know, the submission for the THC assay is progressing on a somewhat later schedule. Since the last call, Roche completed a pre-IDE review of the study protocol for THC. As a result, the THC clinical studies have now been started, and we expect that a submission for this assay will be filed with the FDA later this year.

The PCP approval is an exciting development for many of our laboratory customers who have expressed interest in utilizing integrated instrument platforms that can consolidate urine and oral fluid testing. By integrating oral fluid and urine samples on a single, random access workstation, labs can streamline workflow, decrease turnaround times, increase capacity and reduce costs.

OraQuick® HIV Shelf Life – Doug Michels

During our last call, I mentioned that we had requested FDA approval of a shelf life extension for our OraQuick® HIV test from 18 months to 24 months. I am pleased to report that our request was granted in November of last year. We will likely seek further extensions in the future when the required stability data is available.

Organizational Change – Doug Michels

I am very pleased that we now have new leadership in the sales and marketing areas, with the addition of Tony Zezzo. As the Company's new Executive Vice President, Marketing and Sales, Tony will have overall responsibility for our global marketing and sales operations, including both the domestic and international sales teams for our infectious disease, substance abuse testing and insurance testing businesses. Our cryosurgical business will continue under the direction of Mike Formica.

Tony brings an extensive and very successful resume in sales and marketing, with almost 30 years of diagnostic sales and marketing experience with Johnson & Johnson, Dade International and Abbott Diagnostics. Tony has already hit the ground running, and we believe he will make a significant contribution to our Company.

Other Comments – Doug Michels

Finally, before we take your questions, I would like to comment on several other issues affecting our business.

- As discussed throughout 2010, the ongoing economic conditions and funding cuts have presented significant challenges for our OraQuick® HIV business, particularly in the domestic public health and international markets. We believe these conditions will continue in 2011, with some mitigation here in the U.S. as a result of ongoing Federal support for HIV testing. We are also attempting to aggressively address these circumstances through our sales and marketing initiatives.
- As you know, last year we launched our OraQuick® HCV test in Europe. Sales of this product are building, although adoption of point-of-care diagnostics continues to be challenging in European

markets where laboratory testing is entrenched and healthcare delivery systems are structured around centralized testing models. Nevertheless, we have generated the first commercial sales of our OraQuick® HCV test in 13 countries in Europe. Under our collaboration with Merck, training and physician call decks have been prepared for a total of 18 countries and Merck has now commenced detailing into physician offices in seven countries. This initiative is expected to raise awareness and drive preference for the OraQuick® HCV test.

- In the U.S., the commercial prospects for the OraQuick® HCV test will improve with the receipt of an approved claim for fingerstick whole blood. We expect domestic revenues for this product to materialize once this additional approval and a CLIA waiver are received.
- As you may have read, we recently announced the addition of a new infectious disease testing product, the OraSure QuickFlu™ Rapid Flu A+B Test. This test, which was recently approved by the FDA for the detection of influenza type A and B, including H1N1 viral infections, provides high precision results in just 10 minutes with a nasal swab. We are delighted to add another potentially lifesaving test to our list of marketed products. This test is being manufactured for us on a private-label basis by Princeton BioMeditech. We expect to aggressively compete in the domestic flu testing market in hospitals and public health. Since we did not obtain rights to this product until recently, we do not expect significant revenues until later this year when customers begin to purchase in advance of next year’s flu season. Our team did a fine job identifying and working out mutually favorable terms with Princeton BioMeditech for this product. Importantly, we were able to enter into this agreement without any upfront payments, and we also will be able to leverage our existing sales force to market the product without incurring

additional overhead expense.

- Finally, there are a number of factors we believe will have a positive effect on our substance abuse testing business.
  - During 2011, we expect to expand our drug testing product business. Assuming the additional 510(k) clearances are received in the next couple of months, our plan is to begin selling the newly developed high-throughput oral fluid drug assays as part of a new Intercept® drug testing system as early as this summer.
  - You may have seen that Quest Diagnostics, our largest laboratory customer, recently announced the issuance of its drug testing index, which contains a significant amount of data regarding the performance of oral fluid drug testing using our Intercept® device compared to urine testing. In particular, this data showed that oral fluid detected heroin use in the U.S. workplace at a rate five times higher than urine testing. This index is just the latest in a number of data sets confirming the accuracy and value of oral fluid drug testing.
  - Lastly, at the end of January, there was a meeting convened by the Drug Testing Advisory Board, or DTAB, which is part of the U.S. Substance Abuse and Mental Health Services Administration. One purpose of this meeting was for DTAB to consider whether oral fluid will be included as an approved matrix under the guidelines for Federal workplace drug testing programs. Based on the outcomes from that meeting, we believe the guidelines will be updated to include oral fluid. While these guidelines will likely not be issued for some time, this would be a significant development in that it would allow our Intercept® drug testing system to be used for Federal workers. In addition, there are other non-regulated industries which

may be influenced by the Federal guidelines, and thus open up even more markets to our oral fluid drug testing products.

* * * *

So overall, we are very encouraged by these positive developments and their potential impact on our business in the future. 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 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.