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): November 9, 2010

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 November 9, 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 September 30, 2010, provided financial guidance for the fourth 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

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

Exhibit 99

OraSure Technologies, Inc.

2010 Third Quarter

Analyst/Investor Conference Call

November 9, 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 am pleased to announce that we delivered a solid third quarter and that both our revenues and bottom line exceeded our previously issued guidance. Ron Spair will begin today's discussion with some highlights from our third quarter financial results, followed by guidance for the rest of 2010.

I will then discuss our major clinical programs and certain other business matters.

We will conclude by opening the floor for your questions.

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

Third Quarter 2010 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Before discussing our sales performance for the third quarter, I believe we need to take a brief look back at the prior year. As you may recall, our third quarter 2009 revenues included the elimination of a $2.2 million backlog for OraQuick® HIV orders existing at June 30, 2009. Had the backlog been fulfilled in the second quarter of 2009, we would have reported an increase in the third quarter of 2010 in overall infectious disease revenues when compared to the third quarter of 2009. This growth was largely due to higher domestic OraQuick® sales volume as the cautionary spending we saw in the early part of the year by our public health customers subsided somewhat and led to an increase in spending during the third quarter of 2010 as certain of these customers approached their fiscal year end. Internationally, OraQuick® HIV revenues declined during the third 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.

In substance abuse testing, revenues decreased 8% from $3.3 million in the third quarter of 2009 to $3.0 million in the third quarter of 2010, as a result of lower domestic sales of our Intercept® drug testing system and the absence of laboratory equipment sales, partially offset by a 17% or $83,000 increase in international Intercept® sales due to variability in ordering patterns experienced with our largest customer.

Third quarter 2010 cryosurgical revenues increased 12% compared to the third quarter of 2009 due to a 39% increase in professional sales in the domestic market. The higher U.S. professional sales were caused by elimination of the diversion issue and the impact of adding our new manufacturer's sales representative organizations.

OTC cryosurgical sales decreased 12% to $992,000 when compared to the same period of 2009, primarily as a result of the ordering patterns of our Latin American OTC distributor, Genomma.

Gross Margin – Ron Spair

Turning to Gross Margin, our overall margin for Q3 of 2010 was 62% compared to 64% reported for the third quarter of 2009. As you may recall, OraQuick® HIV production during the third quarter of 2009 had increased significantly in order to fill the backlog of orders existing at June 30, 2009. This increased production allowed for a higher absorption of overhead costs and consequentially drove a higher gross margin for the prior year quarter. Gross margin in the current quarter is more representative of normalized production levels and benefited from an improved product mix and lower scrap.

Operating Expenses – Ron Spair

Our total operating expenses for the third quarter decreased $603,000 compared to 2009 primarily as a result of a decrease in sales and marketing expenses of 12% or approximately $635,000, as a result of decreased staffing, consulting, and market research expenses.

Net Loss – Ron Spair

On the bottom line, we reported net income of $274,000, or $0.01 per share, for Q3 of 2010. This compares to net income of $1.8 million, or $0.04 per share, in the third 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 at $73.7 million.

During the current quarter, we generated $3.3 million in cash flow from operations compared to $4.3 million generated during the third quarter of 2009.

Fourth Quarter 2010 Financial Guidance – Ron Spair

Turning to guidance for the fourth quarter of 2010, we are projecting revenues of approximately $18.0 to $18.5 million. When preparing our projections, we took note of the increase in funding at the federal level to supplement the state and local funding available to test and treat HIV. While we believe these grants will positively impact our results by stimulating product purchases by grant recipients, the timing and extent of these purchases over the next few quarters is hard to predict.

From a bottom line perspective, we expect to be spending heavily during Q4 on research and development activities related to the CLIA waiver studies for our OraQuick® HCV test, the initiation of our final OraQuick® HIV over-the-counter clinical trial and the development of our next generation OraQuick® HIV test. These expenditures, together with the revenues projected for Q4, will produce a loss per share in the $0.08 to $0.09 range.

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

Clinical Programs Update – Doug Michels

Thanks, Ron. During the third quarter, there were a number of positive developments in our major clinical programs.

OraQuick® HCV – Doug Michels

As you know, last quarter we received FDA approval of our OraQuick® HCV test for use with venous whole blood specimens. Since that approval, we have been focused on gaining approval for additional specimen types and executing our CLIA waiver studies.

During the third quarter, we filed our premarket approval (“PMA”) supplement for fingerstick whole blood with the FDA. We have been in regular dialogue with the agency regarding our submission, and we were advised that audits were recently conducted at two of our clinical sites. These audits are a routine part of the PMA review process that is designed to verify the quality and integrity of our clinical data. This activity confirms that our fingerstick submission is under active review by the FDA.

As previously discussed, we still plan to pursue an oral fluid claim for this product, although the filing of a PMA supplement remains on hold pending further discussions with the FDA. Our strategy is to further progress our fingerstick submission before we move forward on oral fluid.

With respect to a CLIA waiver, the studies required for fingerstick and venous whole blood have been started and are progressing on schedule. We expect the CLIA studies to wrap up by the end of this year. Our plan is to file a CLIA waiver request as soon as possible after approval of a fingerstick claim is granted by the FDA. We also expect to pursue CLIA waiver for oral fluid once our PMA supplement for this claim is filed and approval is received.

HIV OTC – Doug Michels

With respect to our rapid HIV over-the-counter test, final validation of our labeling is complete. We have submitted a formal investigational device exemption, or IDE, to the FDA containing this validation data and we are anticipating final approval of our study protocol for the final phase of clinical testing.

Site selection, training and preparation and IRB review for the final clinical studies is well underway. We have also been working with our call center contractor to update and finalize call scripts and prepare for operation of the call center in connection with the final clinical studies. We still plan to begin the final phase of clinical testing this quarter. As previously indicated, we expect enrollment will continue through mid-2011 and, of course, we will continue to provide updates as appropriate.

Drugs-of-Abuse High Throughput Oral Fluid Assays – 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. In response to requests from the FDA for more data, additional studies are now being executed for these assays. We expect the studies to be completed and the data submitted to the FDA in the next couple of months.

The most likely timing for FDA 510(k) clearance of the initial panel five assays is the first half of 2011. Commercial launch of these assays would occur as soon as possible after final FDA clearance is received. We would also expect to complete testing and submit for 510(k) approval for the THC assay during the early part of 2011.

OraQuick® HIV Shelf Life – Doug Michels

As you know, an important objective of the Company has been to extend the shelf life for our OraQuick® HIV test. This is important for several reasons:

- A longer shelf life helps both OraSure and customers manage their inventory levels more effectively;
- In international markets, extended dating is needed to accommodate the additional time required to ship and deliver product through our distributor network; and
- Most importantly, a longer shelf life enhances our ability to sell our OraQuick® HIV test in the OTC market, after FDA approval is obtained.

Data from our real time stability studies indicate that the product is extremely stable, and we recently filed a request to extend our dating from 18 months to 24 months. Given the FDA's approval of similar extensions in the past, we expect to hear something back from the agency in the relatively near future.

OraQuick® Manufacturing Automation – Doug Michels

Another ongoing program has been to automate manufacturing for our OraQuick® HIV test. As discussed in prior calls, the validation of our manufacturing process was approved by the FDA, and I am pleased to report that we have begun manufacturing our test using this fully-automated equipment. We expect that automation will reduce costs and improve our gross margin, particularly as sales volumes increase for this important product line.

Organizational Change – Doug Michels

On the organizational front, Tony Bernardo recently joined OraSure as our new Senior Vice President, Business Development. Tony has over 30 years of healthcare experience including general management, business development, operations, and research and development. He has nearly 20 years experience in the diagnostics field with companies such as Inverness Medical, Dade International and Instrumentation Laboratory. We are very happy that Tony has joined our management team and believe he will be a significant contributor to our company's future success.

Other Comments – Doug Michels

Finally, before we take your questions, I would like to provide an update on an important issue affecting our business—- the status of government funding for HIV testing.

As previously discussed, ongoing economic challenges have caused funding cuts at both the state and local levels, resulting in lower purchases in the public health market, primarily during the first half of this year. Although we believe these difficult conditions will continue for the foreseeable future, the third quarter benefitted from the need by some customers to fully spend their HIV testing budgets before the September 30 end of their fiscal year. This same pressure to complete year-end spending may also benefit our fourth quarter results as well.

While state and local HIV/AIDS budgets have been impacted by the economy and in some cases jurisdictions have curtailed HIV testing activity, on the federal funding side, there continue to be favorable developments.

- Earlier this year, the CDC announced an expansion of its program to fund HIV testing and prevention in healthcare settings. This program was increased to provide up to $60 million annually over a 3-year period beginning in October of this year.
- More recently, the CDC announced $9.6 million in one-time supplemental funding to support HIV prevention programs. The purpose of this supplemental funding is to enable state and local health departments to address funding gaps in their HIV prevention and testing programs. Several of the 59 eligible jurisdictions have competed for this supplemental funding, which is required to be spent by the end of 2010.
- The National Institutes of Health also announced funding for the prevention and treatment of HIV among people in the criminal justice system. Funding for the NIH's "test and treat" program in the prison system is set at $10 million per year for a 5-year period.
- Finally, as previously discussed, earlier this year 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 priority and support for HIV testing and prevention will help mitigate somewhat the negative economic conditions adversely affecting our public health customers at the state and local levels.

* * * *

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.