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 4, 2009

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 4, 2009, 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, 2009, described certain business developments and provided financial guidance for the fourth quarter 2009. 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 2009 Analyst/Investor Conference Call Held November 4, 2009.

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 4, 2009

By: /S/ JACK E. JERRETT

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

Index to Exhibits

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EXHIBIT 99

OraSure Technologies, Inc.

2009 Third Quarter

Analyst/Investor Conference Call

November 4, 2009

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**,**

Good afternoon everyone and welcome to the call.

I am pleased to report we had a strong third quarter, exceeding our guidance on both the top and bottom lines, largely as a result of record revenues and lower R&D expenses. The higher revenues were driven primarily by the continued strong performance of our infectious disease testing business along with a rebound in sales of our international cryosurgical over-the-counter ("OTC") products.

Importantly, during the quarter we eliminated a $2.2 million backlog in orders for our OraQuick ADVANCE® rapid HIV test. As you will recall, we experienced manufacturing issues during the second quarter and were unable to meet demand for our OraQuick® HIV test. These issues were resolved during the third quarter when we resumed full-scale production and restored our inventory levels for this product. It is worth noting that if this backlog were excluded, our infectious disease testing business would still have increased by a double digit rate over the prior year quarter. So, we are very pleased with these results. The reduced R&D spending in the quarter was the result of lower clinical trials costs associated with our OraQuick® Hepatitis C ("HCV") test and our OraQuick® HIV OTC product.

Ron is going to provide a more complete description of our financial performance for the quarter and will follow that with an update on financial guidance for Q4. Following Ron's remarks, I will review the progress on our major clinical development programs and provide some more general business updates. We will conclude by opening the floor for your questions.

And with that, I will turn things over to Ron for his financial review.

Third Quarter 2009 Financial Results – Ron Spair

Thanks Doug and good afternoon everyone.

Revenues – Ron Spair

Third quarter 2009 revenues were $21.6 million, representing a 28% increase from the $16.9 million reported in 2008.

Overall infectious disease revenues increased 39% in the third quarter of 2009. Excluding $1.8 million in backlog dollars for public health customers, our public health sales would have increased 11% as a number of our customers have expanded their HIV testing programs.

Hospital sales increased 75% in the third quarter of 2009. This increase is a result of the elimination of $400,000 in backlog orders from June 30 and the higher average selling price realized under the direct sales model which began at the beginning of 2009.

Lastly, sales of OraQuick® to our International customers increased 48% primarily as a result of a 28% increase in sales to Africa, as well as increased sales activity in various countries in Europe and Latin America.

Third quarter 2009 cryosurgical revenues increased 61% compared to the third quarter of 2008 with revenue increases realized in the international OTC market as well as the U.S. professional market.

International OTC sales were $1.2 million in the third quarter of 2009 compared to $367,000 in the third quarter of 2008 as a result of increased sales to our Latin American OTC distributor, Genomma, and higher European OTC sales to our distributor, SSL. Genomma has successfully worked through their excess inventory levels from 2008 and has resumed purchasing product from us.

We shipped $564,000 of product to Genomma during the third quarter of 2009. In addition, Genomma recently received approval to sell our OTC cryosurgical product in Brazil. We made our first shipment to Brazil in Q3 in preparation for a product launch this quarter.

During the first half of 2009, we experienced a decline in purchasing volume from SSL as a result of slower than expected outsales in the European market combined with excess inventory levels built at the end of 2008. However, sales to SSL rose to $683,000 in the third quarter 2009 compared to $367,000 in 2008. We believe this increase was largely the result of SSL having worked through its excess inventory.

As previously discussed, during the first quarter of 2009 we launched our own nationally branded cryosurgical wart removal product in the U.S. OTC market, which generated gross revenues of $467,000 in the third quarter. We also participated in several promotional and advertising programs in order to create initial awareness and implement the launch of our product within the OTC marketplace. As a result, and in accordance with US GAAP, we netted the cost of these promotion and advertising programs, which approximated $589,000, against our revenues.

On the professional side, our combined cryosurgical sales increased by 19% compared to the third quarter of 2008. Sales of our Histofreezer® product to U.S physician offices increased 35% in the third quarter of 2009 largely due to fluctuations in distributor ordering patterns, price increases enacted in certain distributor contract renewals, and a decrease in product diversion from international sources. We believe we have identified all sources of the diversion and have cut off sales of Histofreezer® to all involved parties in an effort to finally remedy the situation. The 16% decrease in international sales reflects the discontinuance of sales to one of these foreign distributors.

Moving to substance abuse testing, revenues decreased 9% in the third quarter of 2009 compared to the third quarter of 2008 as a result of lower sales in the forensics toxicology market and reduced sales of our Intercept® drug testing system for workplace testing caused by much lower pre-employment testing due to the continuing adverse economic conditions. These decreases were partially offset by higher sales in the U.S. criminal justice and international markets.

Finally, our insurance risk assessment sales of $1.4 million for the third quarter increased 22% from $1.2 million in 2008, primarily due to variable laboratory ordering patterns, while licensing revenues for the quarter remained flat at $702,000.

Gross Margin – Ron Spair

Turning to Gross Margin, our overall margin for Q3 of 2009 was 64%, compared to 58% for Q3 of 2008. Gross margin was favorably impacted by increased absorption of our fixed costs as a result of the return to full-scale production of our OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and replenishment of finished goods inventories. Gross margin also benefited in the current quarter by our switch in January 2009 to a direct sales model in the U.S. hospital market.

Operating Expenses – Ron Spair

Our total operating expenses for the third quarter were down $928,000 or 7% compared to 2008.

Research and Development expenses for Q3 were down 30% or approximately $1.2 million, primarily due to a decrease in clinical trial spending associated with our OraQuick® HCV and OraQuick® HIV OTC programs and a decrease in staffing costs. The additional clinical testing and studies required by the FDA in order to obtain approved claims for use of our OraQuick® HCV test with venous whole blood, oral fluid, and fingerstick whole blood specimen types did not start to ramp up until September of this year.

Sales and Marketing expenses decreased slightly from $5.3 million in the third quarter of 2008 to $5.2 million in the third quarter of 2009. This decrease was the result of lower staffing-related costs for the quarter.

General and Administrative expenses for the quarter increased approximately 12% or by $413,000, primarily due to higher staffing-related costs.

Net Income (Loss) – Ron Spair

From a bottom line perspective, we reported pre-tax income of $1.8 million, or $0.04 per share. This compares to a net loss of $1.8 million or $0.04 per share reported for the same period in 2008.

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 $83.0 million at the end of the third quarter. Our working capital was $92.1 million at September 30, 2009, which is an increase from the balance at December 31, 2008 of $90.9 million. And our current ratio improved from 6.95 at December 31, 2008 to 7.6 at September 30, 2009.

During the third quarter of 2009, we generated positive cash flow from operations of $4.3 million resulting in a year-to-date cash provided by operations of $2.7 million compared to $3.7 million used during the first nine months of 2008. This represents an improvement of $6.4 million for the current nine month period.

Accounts receivable collections also improved as we collected a large outstanding balance due from one of our international customers. Day sales outstanding improved from 63 days at September 30, 2008 to 60 days at September 30, 2009.

Financial Guidance – Ron Spair

Turning to our guidance – For the fourth quarter of 2009, we are projecting revenues of approximately $19.0 to $19.5 million and a loss per share of approximately $0.08 to $0.09. We expect substantially higher clinical trial costs during the fourth quarter, as spending increases for the additional OraQuick® HCV studies. Sales and marketing expenses are also expected to increase due to costs associated with preparation for the launch of our OraQuick® HCV test in Europe and additional market research studies to be completed in the fourth quarter.

And with that, I will turn things back over to Doug for an update on our major clinical programs.

OraQuick® HCV – Doug Michels

Thanks Ron. There has been good progress with our efforts to obtain regulatory approval of an OraQuick® HCV test.

First, on the international front, we recently received feedback from our notifying body who is actively reviewing our application for CE mark approval, which is required to sell the OraQuick® HCV test in Europe. We are responding to requests for additional information which we do not believe are significant. An inspection by our notifying body is scheduled for early December, at which time we hope to close out any open issues on our submission. It is therefore possible that approval could be obtained by the end of the year. This would be an important development and would enable us to begin implementing our European launch of this product in the near future.

As previously discussed, here in the U.S., we are conducting supplemental clinical testing to obtain approval for a venous whole blood claim and an additional clinical study to obtain approval of claims for both oral fluid and fingerstick whole blood.

Enrollment for the venous whole blood testing was completed in October, and we are on schedule to complete testing and data analysis by the end of the year. The additional study for oral fluid and fingerstick whole blood is also well under way and we expect to add a few additional clinical sites this month in order to advance this study as quickly as possible. All testing and data analysis should be completed and our submission filed with the FDA during the first half of next year. We are also preparing for a pre-approval facility inspection by FDA. We hope to schedule that inspection in the next several months so that there is no hold up in obtaining one or more approvals once the additional clinical work is completed and submitted to the agency.

To maximize the rapid HCV opportunity here in the U.S., we have been working closely with our legislators to increase the funding that will be available for HCV testing and treatment. A bill called the Viral Hepatitis and Liver Cancer Control and Prevention Act

of 2009, which is supported on a bipartisan basis, is currently pending in Congress. This bill highlights the need for increased testing and treatment for both Hepatitis C and Hepatitis B and, in its current version, would provide up to $90 million in funding for testing and treatment programs. While this bill has not yet been finalized or enacted, we believe it is an indication that both Congress and the current Administration support increased funding for HCV prevention.

When the OraQuick® HCV test is finally approved, we expect it will be launched with excellent shelf life and product dating. Our real time stability studies for this product continue to progress, with the most recent data indicating that the product has met the acceptance criteria for storage for 18 months at 30° Celsius. We will continue these studies in the hope of extending our product dating even further and we will use the results to support a final shelf life approval by the FDA.

HIV OTC – Doug Michels

Turning to our efforts to gain FDA approval to sell OraQuick® HIV OTC, as previously discussed the FDA plans to seek additional guidance from its Blood Products Advisory Committee ("BPAC") at a meeting scheduled for November 17th. We have been working closely with the agency to plan for this meeting. We expect this meeting will be productive and informative as to what will be required in order to obtain final approval.

After the meeting has occurred, we hope to be in a position to publicly disclose additional information on the next steps for this clinical program. The nature of our future disclosures will depend on the specific actions taken by the Advisory Committee and whether we need to engage in further discussions with the FDA. We will certainly keep you advised as soon as we are able on this important project.

High Throughput Assays and Substance Abuse Testing Business – Doug Michels

Our collaboration with Roche Diagnostics to develop and commercialize fully-automated homogeneous drugs of abuse assays for use with our Intercept® oral collection device continues to progress quite nicely.

As discussed in the past, we initially developed a NIDA-5 panel of assays for marijuana, cocaine, opiates, PCP, amphetamines and methamphetamines. The clinical studies remain largely on schedule, with the assays for opiates, PCP, amphetamines and methamphetamines expected to be submitted to the FDA for 510(k) clearance by the end of the year. The submission for a cocaine assay is likely to slip into early 2010 and, as previously communicated, the submission for THC, or marijuana, will not occur until later next year.

New HIV Immunoassay – Doug Michels

Another program that we have mentioned in prior calls was to obtain FDA approval of a new HIV-1 lab-based enzyme immunoassay, or EIA, for use in testing oral fluid specimens collected with our OraSure® collection device. Because bioMérieux ("BMX") has stopped manufacturing an HIV-1 immunoassay which was approved for use with our OraSure® device, we were planning to conduct our own clinical trials for approval of a third party's EIA.

Recently, and before the clinical trials had started, we learned that another third party had already obtained FDA approval of an EIA for use with our OraSure® device. This EIA was licensed by BMX to this other third party. As a result, it is no longer necessary that we conduct separate clinical trials, which is good news and also contributed to our lower clinical expenses during the third quarter.

Litigation Update – Doug Michels

Turning to litigation – the conference with the Court at which the Markman hearing will be scheduled has been delayed again until December 17th to accommodate the parties' schedules. We will provide further updates as this matter progresses.

Organization Changes – Doug Michels

On the organizational front, we have continued to strengthen our management team with the appointment of Dr. Robert Gregg as our new Vice President, Regulatory Affairs and Quality Assurance. Bob will have responsibility for the Company's regulatory, quality assurance and clinical affairs functions. He is joining OraSure with over 25 years of relevant regulatory experience in the medical device and diagnostics industries with organizations such as the FDA, Roche Diagnostics and Johnson & Johnson. We are

very pleased that Bob has joined OraSure He is already making a substantial contribution to our Company and the important clinical projects currently underway.

Business Update – Doug Michels

Finally, I would like to provide some perspective on various aspects of our business.

OraQuick® HIV

As Ron explained, our infectious disease testing business, and principally sales of our OraQuick® HIV test, remain strong. Sales to the public health market were the highest level reported in any quarter since we launched the product in late 2002. Despite the manufacturing challenges experienced earlier in the year, we were successful in not only retaining virtually all of our customers but we continued to deliver a high level of customer service and strengthened our customer relationships on several fronts. This is reinforced by the increase in sales during the third quarter.

During the third quarter, we also achieved substantial improvement in manufacturing. At June 30, 2009, we had a backlog for about $2.2 million in orders for our OraQuick® test. However, by the end of the third quarter that backlog was completely eliminated and we had built a finished goods inventory of about 500,000 units. All told, we produced about 1.7 million OraQuick® tests during the third quarter to meet both domestic and foreign demand. This is a record level of production for this product.

On the legislative front, we were pleased to see the recent renewal of the Ryan White Care Act, pursuant to which the Federal government funds HIV/AIDS prevention, treatment and care programs. Under this latest renewal, the U.S. Department of Health and Human Services (HHS) has been directed to establish a national HIV/AIDS testing goal of 5 million tests annually. We believe this will have a positive impact on sales of our OraQuick® test, especially into the public health market, beginning in 2010.

OraQuick® HIV Hospital Sales

In the hospital market, the strong third quarter performance is attributable to the continued successful transition to a direct sales approach in this market, as well as the elimination of the second quarter backlog.

One of our strategic focal points for the hospital market has been to expand the number of contracts with large group purchasing organizations. In September, we were pleased to announce the execution of a 36-month agreement with Premiere Purchasing Partners, the group purchasing unit of Premiere, for our OraQuick® test. The new agreement became effective on November 1 and provides Premiere's more than 2,200 member hospitals with negotiated pricing and terms for the purchase of our OraQuick® test.

Although some of Premiere's customers were already OraQuick® customers, it is important to note that the OraQuick® test is the only rapid HIV test currently offered through Premiere's ASCEND™ (Accelerated Supply Chain Endeavor) program, which is designed to allow participating hospitals to achieve and sustain rapid improvements in supply chain performance. More than 90 participants, representing approximately $2.7 billion in supply chain purchasing volume and close to 24,000 hospital beds, currently participate in this program. Several of Premiere's hospital members purchase exclusively through their group purchasing organization, and we believe that our agreement represents the potential for significant new hospital business for our OraQuick® product line.

We also just recently signed a multi-year contract renewal with Health Trust Purchasing Group ("HPG"). HPG is one of the largest hospital group purchasing organizations in the country and its membership includes nearly 1,400 not-for-profit and for-profit acute care facilities, as well as ambulatory surgery centers, physician practices, and alternative care sites. Our OraQuick® test is one of only two rapid HIV tests that are currently available under the HPG contract.

Finally, as discussed during our last call, a regulatory change was announced in July by the U.S. Department of Veterans Affairs ("VA"), which eliminated the need for both written consent and mandated scripted pre- and post-test counseling for HIV testing. As a result, VA clinical providers can eliminate these cumbersome steps and simply obtain oral consent in order to implement HIV

testing for patients. This change brings the VA policy in line with the CDC's recommendations and enables VA providers to better implement routine HIV screening so that patients can be diagnosed earlier and receive treatment sooner. In August, the VA followed this change in law with the issuance of a directive to all VA hospitals and associated clinics that HIV testing be made a part of routine medical care and that providers should routinely offer HIV testing to all veterans. We believe this change represents a very attractive opportunity for our OraQuick® test, and we have been aggressively pursuing new business with the VA.

Cryosurgical Systems Business

Moving to cryosurgical systems, revenues from this business were up compared to the year ago quarter, primarily due to our international OTC business.

- Our Latin American OTC distributor, Genomma, and our European distributor, SSL, each ordered product in the third quarter this year.
- In addition, sales of our professional Histofreezer product in the U.S. increased over the prior year quarter. We believe that this is an indication that our efforts to eliminate diversion by foreign distributors into the U.S. market are working.

Substance Abuse Testing

Finally, in the substance abuse area, the economic downturn, rising unemployment and reduced funding continue to negatively impact sales of our Intercept® product line. Our Intercept® business is not likely to improve until we see significant changes in these conditions.

Conclusion – Doug Michels

So, in conclusion, our financial results were strong for the third quarter. We substantially improved our gross margin and posted record revenues, including strong growth in our core infectious disease testing business. Our public health sales force is doing a terrific job supporting our customers and winning new business, and we are expanding our relationship and business with large hospitals and group purchasing organizations. We resolved our OraQuick® manufacturing issues, returned to full scale production and completely eliminated the backlog in just one

quarter. Lastly, we have continued to advance our major clinical development programs. We look forward to our upcoming meetings with the BPAC and FDA in the next few weeks and will report back to you on the next steps for these important projects.

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

[Q&A session]

Conclusion – Doug Michels

I want to thank you all for participating in today's call and for your continued interest in OraSure Technologies.

Have a good afternoon and evening, everyone.

Important Information

This document contains certain forward-looking statements, including with respect to revenues, net income, 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 credit crisis; 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 and extended shelf life; 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 carryforwards 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 patent infringement, 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, 2008, 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.