
**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 5, 2008

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission File Number)

36-4370966
(I.R.S. Employer
Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360
(Zip Code)

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 – Regulation FD Disclosure.

On November 5, 2008, 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, 2008, described certain business developments and provided an update on financial guidance for the fourth quarter of 2008. A copy of the prepared remarks of Messrs. Michels and Spair is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--|
| 99 | Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2008 Analyst/Investor Conference Call Held November 5, 2008. |

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 5, 2008

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

Index to Exhibits

Exhibit No.

99

Description

Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2008 Analyst/Investor Conference Call Held November 5, 2008.

OraSure Technologies, Inc.

2008 Third Quarter

Analyst/Investor Conference Call

November 5, 2008

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 Kathy,

Good afternoon everyone, and welcome to our third quarter 2008 earnings conference call.

In a press release issued earlier today, we announced our Q3 results and provided financial guidance for the fourth quarter. Our third quarter revenues and bottom line results exceeded the guidance provided for the quarter. Ron Spair will provide a further overview in a few minutes.

Following Ron's remarks, I will discuss additional business developments, including the progress we are making in our major clinical and development projects. We will then conclude the call by opening the floor for your questions.

Before Ron provides his financial update, I would like to briefly discuss two very exciting and recent developments – the filing of our FDA pre-market approved ("PMA") application for a rapid Hepatitis C ("HCV") test and the transition of our hospital distribution arrangement with Abbott to a direct sales model which we announced through a press release within the past hour.

OraQuick® HCV – Doug Michels

As you know, we have been conducting clinical trials for use of an OraQuick® HCV Rapid Antibody test on five specimen types - - oral fluid, fingerstick whole blood, venous whole blood, plasma and serum. Our clinical studies included data from over 3,000 participants and generated results consistent with the encouraging pre-clinical data that we previously announced publicly.

We continue to believe there is a substantial opportunity for a rapid HCV test. On a worldwide basis, there are an estimated 180 million people who are chronically infected with HCV, with an estimated three to four million individuals newly infected each year. The prevalence of Hepatitis C infection is estimated to be four times that of HIV around the world. According to the World Health Organization, as many as 50% of persons infected with HCV are undiagnosed, and up to 80% who have HCV show no signs or symptoms. In the U.S., there are an estimated 4 million Americans, or 1.2 percent of the entire population, that are or have been infected with HCV.

Hepatitis C is a curable disease. Existing treatment therapies can result in viral clearance ranging from as high as fifty percent to up to eighty percent, and new therapies are under development which may improve these treatment rates. We believe that the key to improving public health with respect to HCV is early diagnosis through expanded testing and screening initiatives.

While we cannot predict if or when we will receive FDA approval, generally PMA submissions take ten to twelve months before approval. The ultimate timing will depend on the extent of any FDA questions or requests for additional information and the results of an FDA inspection of our facilities, which is part of the process for PMA submissions of this complexity.

Additionally, we intend to file for a CLIA waiver as soon as our PMA submission is approved. CLIA waived tests are simple laboratory tests and procedures that are cleared by the FDA for use outside of a laboratory. These tests are so simple and accurate as to render the likelihood of erroneous results negligible and pose no reasonable risk of harm to the patient if the test is performed incorrectly. Gaining a CLIA waiver for the HCV rapid test, as we have done for the HIV rapid antibody test, would thus substantially expand the available market for the product to include outreach settings, physicians' offices and other non-laboratory organizations. We are now wrapping up some additional studies required to obtain a CLIA waiver. As I mentioned, we will file an application for a CLIA waiver as soon as FDA approval of the HCV test is obtained.

We are also finishing up some additional clinical work needed to complete our submission for a CE mark. This is required to sell the test in Europe, and we expect to make the filing in the next several months.

The completion of the HCV clinical trials and submission of our FDA application is a significant milestone. Our R & D, Regulatory and Operations groups have done an excellent job, and their significant efforts on this project are greatly appreciated.

Abbott Transition

The second announcement which we issued in a press release about an hour ago, is the termination of our distribution agreement with Abbott Laboratories and expansion of our direct OraQuick® HIV business. For the past several years, Abbott has distributed our OraQuick ADVANCE® HIV test on an exclusive basis to U.S. hospitals and reference laboratories and on a nonexclusive basis to the U.S. physician office market. We

recently entered into an agreement with Abbott pursuant to which our distribution arrangement will terminate at the end of this year, and we will begin to distribute our OraQuick® HIV test directly to both U.S. hospitals and reference laboratories beginning in 2009. Physicians' offices will continue to be served through distributors.

Per the agreement with Abbott, we will pay a one-time, lump sum termination fee, and Abbott will assist in transitioning its OraQuick® customers to us. Once the termination fee is paid, which will be early next year, we will have no further financial obligations to Abbott as a result of the termination of the distribution agreement.

This transition is an important and necessary step for our Company for many reasons. We believe taking this business direct will help us maximize sales by taking greater control of an important market - U.S. hospitals. It will also help lay a foundation to sell future products in this same channel, in particular our OraQuick® Rapid HCV Test once FDA approval is obtained.

We have been calling on hospital accounts with our Abbott counterparts for the past five years and, in so doing, have developed close ties with these customers. Knowing for a couple of months now that this transition was a possibility, we have already begun the expansion of our hospital sales team and related support services, and we are confident that the transition will be a smooth one. We are very pleased with the interview flow and we are hiring experienced and high achieving sales managers and reps that understand the hospital market. With these additions, we are expanding a very strong sales force to serve our hospital customers.

As you know, we announced some organizational changes during our last earnings call, several of which were in the sales and marketing department. The expansion of our sales force as a result of the Abbott transition is now part of this reorganization, as was

the addition of Brian Reid, our new Vice President, International Sales, which we announced several weeks ago. As you may recall, Brian joined OraSure with more than thirty years of experience, the majority of which was in international markets working for companies such as Axis-Shield Diagnostics and Ortho-Clinical Diagnostics. We expect all of these changes, including my continued involvement in leading the sales and marketing activities, to begin to have a more significant impact on our business in the months to come.

And with that, let's move on to Ron's financial overview.

2008 Third Quarter Financial Results – Ron Spair

Thanks Doug and good afternoon everyone. I will start with a brief review of the third quarter results.

Revenues – Ron Spair

Total revenues for Q3 were \$16.9 million compared to \$21.4 million in the prior year. Increased sales of our OraQuick *ADVANCE*[®] test were offset primarily by an expected decrease in revenue from our cryosurgical systems category.

An 18% growth in our infectious disease revenues was the result of continued strong performance by our OraQuick *ADVANCE*[®] HIV test. Sales to public health during the quarter increased 37% over 2007, as a result of continued growth in our base business and incremental sales driven by the Centers for Disease Control and Prevention's ("CDC") efforts to increase HIV testing. International sales of OraQuick[®] increased 13% compared to the same period in 2007, largely as a result of an increase in revenues from Latin America. Our sales to Abbott decreased 17% as a result of their ordering patterns for the U.S. hospital market driven in part by the decision to go direct next year. We expect this trend in Abbott sales to continue in Q4 as they effectively drive their inventory position to zero in anticipation of the transition.

Our cryosurgical revenues during Q3 experienced an overall decrease of 75% compared to 2007. This was expected because of the absence of U.S. and Mexican over-the-counter (“OTC”) sales in the current quarter together with reduced OTC sales in Europe. As we explained earlier in the year, our Latin American distributor, Genomma, reduced its purchasing levels this year in response to an increase in returned product from retailers due to overstocking during the winter months. The decrease in U.S. OTC sales is a result of the termination of our domestic distribution relationship with Prestige Brands at the end of 2007, while Europe OTC sales declined due to lower revenues experienced by SSL in key markets outside of the United Kingdom.

Third quarter cryosurgical sales to the international and domestic professional markets experienced decreases of \$125,000 and \$173,000, respectively. This business continues to be affected by the diversion of some lower priced Histofreezer[®] product from several international distributors into the U.S. professional market. We are addressing this diversion by increasing our international pricing, changing product labeling and packaging, and enforcing contractual rights against certain international distributors.

In substance abuse testing, sales were \$3.6 million for the third quarter, a 12% decrease compared to 2007. Sales of our Intercept[®] drug testing system totaled \$2.6 million, a 20% decrease from 2007. Our total workplace testing business was down 35%, our international sales were down 8% and our criminal justice sales declined 1%. Our direct sales grew 11% for the quarter. The Company’s workplace testing business continues to be directly impacted by adverse economic conditions resulting in a decline in employment rates in some of the markets that buy our Intercept[®] product.

Finally, insurance risk assessment sales in the third quarter were \$1.2 million, down 28% compared to \$1.6 million in the comparable period of 2007. This decrease is largely a result of the ordering patterns of two of our largest laboratory distributors coupled with an overall decrease in life insurance policies as a result of current economic pressures.

Third quarter 2008 licensing and product development revenue included \$702,000 in royalties from Schering-Plough related to sales of their OTC cryo-product in the U.S. market. Third quarter 2007 revenues included \$754,000 of funded research and development under our domestic HCV collaboration agreement with Schering-Plough.

Gross Margin – Ron Spair

Turning to Gross Margin, our margin for Q3 of 2008 was 58%, a decrease from 60% for Q3 of 2007. The margin decline for the current quarter was primarily due to an unfavorable change in product mix versus the year ago period partially offset by a decline in certain overhead costs, decreased production scrap and spoilage expense and lower product support costs.

Operating Expenses – Ron Spair

Research and Development expenses for Q3 were up 13% or approximately \$495,000 over 2007, largely as a result of costs associated with our ongoing OraQuick® HIV OTC and HCV clinical development programs.

Sales and Marketing expenses increased 7%, or approximately \$348,000, mostly due increased staffing and related charges as well as increased marketing expenses.

General and Administrative expenses decreased approximately \$1.5 million, largely as result of a decrease in legal costs compared to the third quarter of 2007.

Net Loss – Ron Spair

From a bottom line perspective, we reported a net loss of \$1.8 million, or \$0.04 per share, which is better than our guidance as some of our research and development expenses associated with our OraQuick® HIV OTC and HCV clinical development shifted to the fourth quarter. This compares to \$4,000 in net income or breakeven earnings per share for the third quarter of 2007.

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 \$85.4 million and working capital of \$99.5 million at September 30, 2008. During the first nine months of 2008, we used \$3.7 million in cash flow from operations, compared to \$7.8 million provided from operations during the first nine months of 2007. The use of cash in 2008 was largely due to decreased net income and payments of royalty obligations and legal expenses that were accrued at the end of 2007, as well as an increase in our inventory and accounts receivable balances and a decrease in accounts payable. Days sales outstanding was at 63 days compared to 52 a year ago. In addition, under the terms of our previously announced shares repurchase program we purchased 626,385 shares of stock at an average price of \$4.87 per share.

Now turning to our financial guidance update - -

Fourth Quarter Financial Guidance – Ron Spair

With respect to the fourth quarter, we project that revenues will be in the range of \$16.0 - \$16.5 million, and our loss per share will approximate \$0.10. Included in the fourth quarter loss per share are charges associated with the transition of our distribution agreement with Abbott and a \$1.0 million charge associated with a milestone payment required as a result of the filing of our OraQuick HCV pre-market approval application with the FDA.

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

Business Update – Doug Michels

Thanks, Ron. I will now provide an update on our product pipeline and other strategic matters.

HIV-OTC – Doug Michels

We continue to make progress in our clinical activities to obtain FDA approval for an OraQuick® Rapid HIV OTC test. As previously announced, we completed testing for the first 1,000 subjects in our observed user clinical study. This is a study where we assessed an individual's ability to interact with our packaging and comprehend the instructions for use, take the test and interpret the results while a trained professional observes those activities.

We stopped at 1,000 subjects because our clinical study met the stopping criteria under our protocol. By meeting the stopping criteria, we are permitted to examine the data to see if we have met the 95 percent confidence intervals for specificity and sensitivity initially established by the FDA for this phase of the trials. We believe the data shows this, and we have now submitted this data to the FDA for review.

We have also been granted a meeting with the FDA in December to review this data and discuss our draft protocol for the third and final clinical study for our submission. As previously discussed, this study is designed to test the device with consumers in an unobserved setting. In anticipation of moving to the next phase of our clinical trials, we have been identifying additional clinical sites to utilize in this final study.

We are encouraged by the results of our observed user trial and look forward to meeting with the FDA to discuss the continuation of this important project. We are doing everything within our control to advance this program as rapidly as possible. As additional progress is achieved, we will provide updates as appropriate.

OraQuick® Stability – Doug Michels

Our efforts to extend the shelf life of our OraQuick® HIV test have also progressed.

As previously announced, we submitted stability testing data to the FDA to support an extension of shelf life to twelve months. This improvement in stability is based on process changes in the manufacture and packaging of the OraQuick® device that were previously submitted to the FDA. During the next several weeks, we will be completing a small additional study requested by the FDA in support of these process changes, after which we will submit the data with the hope of getting final FDA approval to move to twelve months as quickly thereafter as possible.

In order to extend the shelf life in Europe, we recently submitted stability data to our notified body with a requested extension to twelve months. Our notified body is scheduled to visit our Bethlehem facilities in early December as part of its normal annual inspection, and we would expect to discuss this request for shelf life extension with them at that time.

High Throughput Assays and the Substance Abuse Testing Business – Doug Michels

Our work with Roche Diagnostics to develop fully-automated homogeneous drugs of abuse assays for use with our Intercept® oral fluid collection device also continues to go extremely well.

At a recent meeting of the Society of Forensic Toxicologists, or SOFT, in late October, OraSure and Roche Diagnostics presented posters on automated homogeneous oral fluid assays for cannabinoids, or THC, and phencyclidine, or PCP. The data presented in these posters indicate that these assays demonstrate state of the art sensitivity for THC and PCP in oral fluid. What is significant about this is that feasibility and performance have now been demonstrated with oral fluid on automated equipment for all drugs in the initial NIDA-5 panel expected to be launched under our collaboration with Roche Diagnostics.

In addition, at the SOFT meeting, findings were presented from a recent large-scale study sponsored by the Substance Abuse and Mental Health Services Administration ("SAMHSA") of oral fluid drug testing results over a five-year period in the non-federally regulated workplace market. This large analysis demonstrated that oral fluid drug testing produces comparable outcomes to urine drug testing. Analysis of 650,000 oral fluid drug testing results, of which 98% were conducted with our Intercept® oral fluid drug testing system, also indicated that verified positive rates by Medical Review Officers (MROs) were higher with oral fluid specimens than with what is typically observed with urine drug tests.

The results of this analysis clearly reinforce the credibility and strong performance of oral fluid drug testing and in particular our Intercept® drug test.

OTC Cryosurgical Product Update – Doug Michels

As discussed in prior calls, we are planning to launch our own branded cryosurgical wart removal product in the U.S. OTC market beginning in the first quarter of 2009. Instead of using a distributor that already has a brand name, we will be launching a new national brand that we developed after conducting significant consumer testing. We will also sell our product directly to the retail market with assistance from a broker that specializes in consumer brands. Our plan is to start with a targeted launch, focusing on one or two major retailers. Once the product has entered the market, we will look to expand distribution to other major retailers in the OTC channel.

We are excited about introducing a new brand and reentering the domestic OTC cryosurgical market. In the long term, we look forward to expanding the number of branded cryosurgery products available to consumers.

New HIV Immunoassay – Doug Michels

A final development project that we have mentioned in prior calls is to obtain FDA approval of a new HIV lab-based enzyme immunoassay, or EIA, for use in testing oral specimens collected with our OraSure® collection device. The OraSure® device is used primarily in the insurance risk assessment testing and public health markets. As you may recall, last year bioMérieux indicated that it would cease manufacturing the only HIV-1 immunoassay approved for use with our OraSure® collection device.

We have identified another blood-based HIV-1 immunoassay which, with some optimization, we believe can be used with oral specimens collected with an OraSure® device to screen for HIV-1. The optimization is close to being finalized, and we are preparing to launch clinical trials to obtain FDA approval of this assay for use with the OraSure® device. These clinical trials will also incorporate the use of our oral fluid Western blot as the confirmatory test for oral specimens that initially screen positive with the new assay.

We expect these clinical trials to start in the first quarter of 2009. Our submission to the FDA will be made as soon as possible after they are concluded.

Litigation Update – Doug Michels

Finally, the lawsuit filed against OraSure by Inverness and Church & Dwight for patent infringement continues to move forward. Pursuant to a schedule adopted by the Court earlier this year, Inverness filed a motion for summary judgment on the issue of

infringement last month, and we plan to file our response to that motion at the end of this week on November 7. Inverness will have another seven days to reply under the current schedule, after which the Court will consider the motion with a decision expected either later this year or early next year. In the meantime, the discovery process is continuing and will continue through much of next year.

We remain confident in our position that our OraQuick *ADVANCE*[®] HIV test does not infringe the patent asserted in this lawsuit, that the Inverness and Church & Dwight patent is invalid and unenforceable and that we will successfully resolve this litigation. Additional updates on material developments will be disclosed as they occur.

And with that, we 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.

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; 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; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; 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; 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; 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, 2007, 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.