

**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): October 30, 2007**

---

**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))
-

---

**Item 7.01 – Regulation FD Disclosure.**

On October 30, 2007, 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, 2007, described certain business developments and provided an update on financial guidance for the fourth quarter and full year 2007. 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 2007 Analyst/Investor Conference Call Held October 30, 2007.

**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: October 30, 2007

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

**Index to Exhibits**

---

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2007 Analyst/Investor Conference Call Held October 30, 2007.

**OraSure Technologies, Inc.**

**2007 Third Quarter Analyst/Investor Conference Call**

**October 30, 2007**

**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 Eileen,

Good afternoon everyone and welcome to our third quarter 2007 earnings conference call.

For today's call, Ron Spair will begin with a review of our financial performance for the third quarter of 2007. As you can see from our earnings release, our third quarter financial results were in line with expectations and the nine months ended September 30, 2007 were strong. Following Ron's remarks, we will open the floor for your questions on these items.

During the remainder of the call we will update our progress against our principal strategic initiatives and provide some brief additional business updates. We will also discuss our financial guidance for the rest of 2007. We will conclude by again opening the floor for your questions.

Now let's turn to Ron's financial overview.

**Financial Overview – Ron Spair**

Thanks, Doug, and good afternoon everyone.

**2007 Third Quarter Results – Ron Spair**

Our third quarter results, on both the top and bottom lines, were consistent with our most recent guidance. When combined with our results for the first half of the year, we are pleased with the Company's financial performance.

**Revenues – Ron Spair**

Total revenues for Q3 were \$21.4 million, a 21% increase over the same period in 2006 and a record for OraSure. Increased sales of the Company's OraQuick ADVANCE<sup>®</sup> test and its international and domestic over-the-counter ("OTC") cryosurgical wart removal products were the primary revenue drivers for the quarter.

In the infectious disease market, we booked sales of \$8.2 million, a 9% increase over the third quarter of 2006. The primary reasons for continued growth in the infectious disease testing business were a 31% increase in sales to Abbott Labs for distribution in the U.S. hospital market, a 17% increase in direct sales of OraQuick® to the public health market and higher international OraQuick® sales, primarily to Africa.

In substance abuse testing, sales were \$4.1 million, which is slightly lower than Q3 of 2006. Included are \$3.2 million in sales of our Intercept® drug testing system, which represents a 3% increase over 2006. Our workplace testing business was up 7% over 2006 which was partially offset by decreases in our criminal justice business and international sales which were down 4% and 20% from 2006, respectively. Our direct sales grew 56% for the quarter.

Cryosurgical systems sales were \$6.7 million, an increase of 67% compared to the same period in 2006. Higher sales of our U.S. and Mexican OTC cryosurgical products were the main reasons for this increase, partially offset by lower sales of Histofreezer® to physicians' offices and lower sales of our European OTC product. During the third quarter, we had approximately \$2.5 million in sales of our U.S. OTC product to Prestige Brands. However, Prestige purchased no product in Q3 of 2006, which included the period just prior to their acquisition of the competing Wartner® brand in September of that year. As a result of the arbitration decision and the termination of our agreement with Prestige at the end of this year, we do not expect further revenues from Prestige in 2008.

Sales of our OTC cryosurgical product to SSL, our European distributor, were lower primarily because SSL is working off its existing inventory in anticipation of launching a product with an enhanced configuration and labeling next year. Finally, the launch of our OTC cryosurgical product in Mexico continues to exceed our expectations.

During the third quarter, we recorded \$727,000 of funded R&D work pursuant to our agreement with Schering-Plough for the development of a rapid hepatitis C ("HCV") test on the OraQuick® platform.

Finally, insurance risk assessment sales in the third quarter were \$1.6 million, compared to \$1.7 million in the comparable period of 2006.

**Gross Margin – Ron Spair**

Turning to Gross Margin, our margin for Q3 of 2007 was 60%, a decrease from 64% for Q3 of 2006. This decline was primarily due to increased scrap and spoilage, higher product support costs and an unfavorable product mix versus the year ago period.

**Operating Expenses – Ron Spair**

Research and Development expenses for Q3 were up approximately \$1.9 million over 2006, primarily as a result of costs associated with the clinical development work for our OraQuick ADVANCE<sup>®</sup> HIV-1/2 OTC test and product development costs for our OraQuick<sup>®</sup> HCV test.

Sales and Marketing expenses increased approximately \$1.4 million, primarily due to increased staffing and related charges such as travel, recruiting and relocation expenses.

General and Administrative expenses increased approximately \$1.7 million, because of higher legal fees related to the Prestige arbitration and increased staffing related charges. Pursuant to the arbitration decision, we expect to recover our legal fees and certain costs incurred in the Prestige matter in an amount to be determined by the arbitrators.

**Net Income – Ron Spair**

From a net income perspective, we were at break even on the bottom line for Q3 and within the guidance announced during the last quarterly investor conference call. This compares to net income of \$2.1 million, or \$0.05 per share for the same period of 2006.

**Cash Flow from Operations and Liquidity – Ron Spair**

Our cash balance remained strong with \$92.3 million at the end of Q3. During the first nine months of the year, we generated \$7.8 million in cash flow from operations. Accounts receivable increased partially as a result of higher revenues. Days sales outstanding held steady at 52 days compared to 53 days in the prior year. Importantly, this represents a reduction of 11 days from the June 30, 2007 days sales outstanding metric.

And with that, we would now like to open the floor for questions regarding our third quarter financial results.

**[Q&A Session – 2007 Q3 Financial Results]**

**Business Update – Doug Michels**

Thank you for the questions. We will now discuss the progress we are making against our strategic initiatives and certain other business developments.

**HIV-OTC – Doug Michels**

First, let me start with our ongoing efforts to obtain FDA approval to sell the OraQuick *ADVANCE*<sup>®</sup> HIV test over the counter.

During the last earnings call, I indicated we would be starting a more robust label comprehension study. This study has now been completed. During the quarter, we also initiated our Phase 2 interpretive studies which evaluate an individual's ability to properly interpret test results without having to actually perform the test. These studies are ongoing and we expect them to conclude during the fourth quarter.

We expect to submit the IDE amendments for the Phase 2b and Phase 3 user studies in the next few weeks. As previously discussed, Phase 2b will assess an individual's ability to use the test properly in an observed setting, and Phase 3 will do the same in an unobserved, at home setting. These studies are scheduled to begin next year. The results of the robust label comprehension study and the Phase 2, 2b and 3 studies will all be included in our FDA submission for OTC approval.

Work also continues on the development of a 24 hours per day, 7 days a week customer resource and medical referral system. As previously reported, The Constella Group, a leading global provider of professional health services and a long-term HIV/AIDS-related services provider for the CDC, is helping us with the design and implementation of this system. Draft call center scripts have been completed and a prototype system is nearing completion. Training on the system is planned for December and a fully developed system will be operational in time for the Phase 2b user studies next year.



So, in summary, the schedule I announced during the last earnings call remains intact. There is still a great deal of clinical work to be accomplished that we expect will take us to mid 2008. We have requested a meeting with the FDA to review clinical progress to date and our plans for completion of the clinical study effort in 2008. We hope that meeting will occur before year end. We still plan to submit a PMA application with the FDA for OTC approval upon completion of our studies as soon as possible in 2008.

#### **OraQuick® HCV – Doug Michels**

Turning to the development of our rapid HCV test on the OraQuick® platform, this project also continues to progress nicely.

Previously we reported the completion of our product design and the generation of clinical performance data equivalent to existing laboratory-based HCV tests. We have since made good progress in establishing and verifying the manufacturing specifications for production of the OraQuick® HCV device. As a result, this product has now been transferred from R&D to manufacturing and is now being produced in our production facility. Following successful production of 3 clinical trial lots, we will begin the clinical studies to support product approval. These studies should begin before the end of the year and are expected to continue through the early part of next year.

#### **OraQuick Stability**

As you know, a critical project has been to extend the shelf life of our OraQuick® HIV test beyond 6 months. Real time stability studies are progressing and have gone well. We recognize this is an important issue for our infectious disease business and we are working to extend the shelf life of this product as quickly as possible.

#### **High Throughput Assays – Doug Michels**

Another key program is the development of homogeneous fully-automated drugs of abuse assays with Roche Diagnostics for use with our Intercept® oral fluid collection device.

The development work continues to go extremely well. In fact, three posters with preliminary performance data for prototype assays for cocaine, opiates, amphetamine and methamphetamine were presented at the Society of Forensic Toxicologists, or “SOFT”

meeting on October 18 of this year. These prototypes showed excellent correlation with current confirmatory methods for drugs of abuse. The performance of these prototype assays was very encouraging and indicated that we should be able to develop state of the art drugs of abuse assays using oral fluid on automated systems. Interest in the assays at the SOFT conference was tremendous, with customers specifically visiting the OraSure and Roche booths to inquire when they can anticipate using the assays in their labs.

Development of the assays for PCP and THC, or marijuana, also continues to progress. Once all tests have been developed and optimized, Roche will initiate the clinical studies with our assistance, and the data generated will be used as the basis for a 510(k) submission to the FDA.

#### **Operations Update – Doug Michels**

A final area I would like to address is operations.

During the quarter, we completed the qualification of our new fully-automated manufacturing equipment for OraQuick®. The Team is in the process of completing validation activities and compiling the final data set for an FDA submission. Since our last investor call, an additional assembly station was added to the line to increase capability of the system.

In addition, equipment installation and validation was completed in a recently constructed semi-automated manufacturing space for OraQuick® devices. Data and documentation for an FDA submission have been compiled and the submission should be filed in the fourth quarter.

Once FDA approval is obtained for both the new semi-automated assembly space and our fully-automated assembly system, we will have completed a major expansion in our manufacturing capacity for OraQuick® HIV and HCV. These additions to capacity are important steps in the execution of our 5-year facility and manufacturing plan, designed to insure our infrastructure can support the future growth of the Company.

Now I would like to provide additional details regarding each of our businesses.

**Efforts to Grow Business – Doug Michels**

**Infectious Disease – Doug Michels**

In our infectious disease testing business:

- The primary driver will continue to be, in our view, the increasing support for and adoption of the CDC’s revised recommendations for routine HIV screening in healthcare settings. To help implement these recommendations, the CDC previously announced that it had identified \$35 million in additional funding to increase HIV testing opportunities among populations disproportionately affected by HIV, primarily African Americans.
- In September, the CDC awarded this funding to 23 states and major metropolitan areas. We have been working closely with many of the grantees and because many are already OraQuick® customers, we believe we are in a strong position to capture a significant portion of these incremental funds.
- In addition to financial support, the CDC is providing implementation and communication support for the funded jurisdictions. For example, the CDC has completed strategic planning workshops to help grantees implement the recommendations in Los Angeles, Chicago, Boston and Miami, and additional workshops are currently scheduled for Washington, D.C., New York and San Antonio. Eight additional workshops are planned for other funded jurisdictions.
- The CDC recommendations have received broad support from the American College of Emergency Physicians, the AMA, the NMA and others, and a

number of states have adopted legislative changes since last year designed to increase HIV testing, including eliminating the requirement for written informed consent and requiring opt out prenatal testing. These are all positive developments.

- At a recent meeting of the President's Advisory Commission on HIV/AIDS, or PACHA, data was provided for the CDC's hospital emergency department demonstration projects and several public health testing programs. This data showed that adoption of the CDC's revised guidelines is resulting in increased HIV screening and identification of new HIV infections.
- Earlier this month, we participated in a two-day meeting convened by the National Black Leadership Commission On AIDS, or NBLCA, which brought together many of the nation's most prominent African American clergy, representatives of the National Medical Association, the Congressional Black Caucus and other organizations to discuss a plan to fight HIV/AIDS within the African American community. At this meeting, there was overwhelming support for increased testing, education and treatment and to prioritize these efforts.
- In partnership with the Latino Commission on AIDS, OraSure also participated in a rapid HIV testing initiative on National Latino Awareness Day 2007. We donated OraQuick HIV tests and educational materials to the Commission, which in turn distributed the test kits to more than 100 community testing sites and events nationwide.
- During the quarter, we continued our efforts to expand HIV testing initiatives in cities that have launched major campaigns. Washington, D.C.'s program continues to expand. The District is one of 23 jurisdictions awarded CDC funding for expansion of its program. Philadelphia also continues to grow its program, expanding into traditional public health and corrections settings and partnering with hospitals to deliver rapid HIV testing. Finally, our work continues with the city of Los Angeles on the development of their testing initiative. We anticipate a more formal announcement will be issued in the near future.

- Sales to Abbott increased 31% and during the third quarter, and Abbott's outsales increased 30% compared to 2006. OraQuick® is now being used in almost 2000 hospitals and is now on contract with seven major hospital group purchasing organizations. As you may know, the initial term of our agreement with Abbott ends at the end of this year and there are provisions governing the renewal of this agreement. We are in renewal discussions with Abbott at this time, and expect the Abbott agreement to continue for 2008.
- We are also making good progress on the international front.
  - Since our OraQuick *ADVANCE*® HIV test is CE marked, we have been aggressively pursuing distributors in the European Union. We have signed distributors in the UK and Ireland and are close to signing a distributor in Spain. We are also making progress in Italy and France as well.
  - Several sites in Europe are currently conducting investigational studies with the OraQuick *ADVANCE*® test. We believe studies like this will help facilitate the European launch of this product.
  - OraQuick® sales to Africa during Q3 more than doubled, compared to 2006. Sales to the Government of Madagascar remain strong as that country's testing program continues to expand. We are also making significant progress in other African countries which we believe will help fuel future growth.

---

### **Substance Abuse – Doug Michels**

There were several important developments in our substance abuse testing business in Q3:

- Intercept® sales in the workplace testing market grew 9% and 41 new accounts were closed in the third quarter across both workplace and criminal justice. Two of the closes were large criminal justice accounts.
- We also recently reached agreement to extend our Intercept® contract with Quest Diagnostics.

### **Cryosurgical Systems – Doug Michels**

In the cryosurgical systems market, apart from the Prestige arbitration, the most important developments were in the international arena.

- Significantly, we are close to signing agreements to distribute our OTC cryosurgical product in a number of additional Latin American countries.

### **Litigation Update – Doug Michels**

Last week we received the decision in our pending arbitration with Prestige Brands, the distributor of our U.S. over-the-counter cryosurgical product.

The arbitrators found that Prestige had breached the non-compete provision of our distribution agreement when it acquired the competing Wartner® product. The arbitrators also concluded that we were entitled to an award of our legal fees and share of the arbitrators' costs. To receive payment, we have to submit proof of our legal fees for approval by the arbitrators.

The panel also concluded that the agreement with Prestige will terminate on December 31, 2007. As a result, we have been evaluating alternative product and distribution strategies for the domestic OTC cryosurgical market. The domestic OTC cryosurgical market is important and we intend to participate in the future.

With respect to the Schering Plough litigation, this matter remains pending. We look forward to bringing this litigation to a conclusion as well.

I will now turn it back over to Ron to update our financial guidance.

**Fourth Quarter and Full Year 2007 Financial Guidance – Ron Spair**

Thanks, Doug.

Starting first with our fourth quarter guidance, we are now expecting revenues to range from \$19.5–\$20.0 million and earnings per share to approximate breakeven. We do expect R&D expenses to increase as we progress our clinical development activities. To the extent we can accelerate spending to achieve our desired outcomes sooner, we will do so with a corresponding impact on EPS.

With respect to guidance for the full year 2007, we are reiterating our revenue forecast of approximately \$83 million, representing a 22% increase over 2006. As we close out the year, we intend to aggressively advance our clinical development plans on OraQuick® HIV OTC, our rapid HCV test on the OraQuick® platform, a product line extension for our cryosurgery product line and the automated assays under development with Roche, all of which are running concurrently. We believe that there is nothing more important to securing our future than the successful completion of this work and obtaining final approval of our next generation of products. As a management team, we are focused on executing each required step as rapidly as possible.

As we have discussed previously, forecasting the exact timing of clinical trial expenses is a difficult task and the actual timing of these costs will have a significant impact on our EPS. In addition, in Q4 we have our Schering Plough litigation and the pending

resolution and quantification of our legal fee recovery in the Prestige dispute. It is against this background of difficult to predict variables, some of which are outside of our control, that we feel comfortable with leaving full-year earnings guidance at \$0.05 per share.

With respect to 2008 guidance, we will be providing estimates on our fourth quarter earnings call in early February 2008.

In closing, I continue to believe that our activities in 2007 will position us for future growth in the years to come.

Now we will again open the floor to questions regarding our business update.

**[Q&A session regarding business update]**

**Conclusion – Doug Michels**

I want to thank everyone for participating in this call. We are looking forward to finishing a successful 2007. I look forward to updating you again on our progress during our next conference call.

Have a good afternoon and evening, everyone.

**Important Information**

The foregoing "Remarks" contain certain forward-looking statements, including with respect to revenues, net income, products, markets, clinical testing, and 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: 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 our products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other new products or technology; 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 projects 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 approval 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 our stock price; uncertainty relating to patent protection; 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; 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 complete consolidation or restructuring activities; 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, 2006, 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 the Remarks were made and OraSure Technologies undertakes no duty to update these statements.