# **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): May 8, 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 May 8, 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 March 31, 2007, described certain business developments and provided an update on financial guidance for the second 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

Exhibit

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99

Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2007 Analyst/Investor Conference Call Held May 8, 2007.

# Signatures

Date: May 8, 2007

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.

By: /s/ Jack E. Jerrett

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

# **Index to Exhibits**

Exhibit No.

Description
Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2007 Analyst/Investor Conference 99 Call Held May 8, 2007.

#### OraSure Technologies, Inc.

#### 2007 First Quarter Analyst/Investor Conference Call

May 8, 2007

#### Prepared Remarks of Douglas A. Michels and Ronald H. Spair

<u>Please see "Important Information" at the conclusion of the following prepared remarks.</u>

#### Introduction - Doug Michels

Thanks Eileen,

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

Similar to the format we used for our last investor conference call, our call today will be divided into two sections. In the first section Ron Spair, our Chief Operating Officer and CFO, will review our outstanding financial results for the first quarter of 2007. We will then open the floor for any questions that you may have on the earnings press release issued earlier today and our first quarter performance.

The second half and majority of time on the call will focus on our future and the significant strategic initiatives we are pursuing. We will also provide additional business updates and discuss our financial guidance for both the second quarter and the full year of 2007. We will conclude by again opening the floor for questions on the information provided during the second half of the call.

Overall, we are off to a great start to 2007. Our first quarter financial results were excellent and we continue to make significant progress against our strategic initiatives, as I will describe further during today's call.

With that, let's get started with a financial overview from Ron.

#### Financial Overview - Ron Spair

Thanks, Doug, and good afternoon everyone.

#### 2007 First Quarter Results - Ron Spair

We are extremely pleased with the very strong financial results reported for the first quarter of 2007. We substantially exceeded expectations on both the top and bottom lines and our business performed very well.

#### Revenues - Ron Spair

Total revenues for Q1 were a record \$20.1 million, a 32% increase over revenues reported for the same period in 2006. This is the highest level of quarterly revenues recorded to date. Increased sales of the Company's OraQuick *ADVANCE*® test, Intercept® oral fluid drug test and cryosurgical systems products, as well as an increase in funded R&D activities during Q1 related to our rapid Hepatitis C ("HCV") test, drove these fantastic results.

In the infectious disease market, we booked record sales of \$8.9 million, 45% higher than the first quarter of 2006 and up 12% over Q4 of 2006. A revenue increase of 50% in our direct sales to the public health market and a 45% increase in sales to Abbott for hospital distribution were the primary reasons for the outstanding performance in the infectious disease testing business.

In substance abuse testing, sales were \$3.9 million, up 14% over Q1 of 2006. Our workplace testing and criminal justice businesses were each up 21% over 2006 as we continued to expand oral fluid drug testing and increase market share. Our direct sales, although compared to a modest base, were up 47%.

First quarter cryosurgical systems sales were \$5.7 million, a 27% increase over 2006. The primary growth drivers were higher sales of our international over-the-counter ("OTC") cryosurgical product in both Europe and Mexico. Our business in Mexico is off to a great start and we will share more specifics later in the call.

During the first quarter, we recorded \$679,000 of funded R&D work pursuant to our agreement with Schering-Plough for the development of a rapid HCV test on the OraQuick® platform.

Rounding out the revenue picture, insurance risk assessment sales of \$890,000 in the quarter were down \$200,000, or about 18% when compared to the comparable quarter in 2006.

#### Gross Margin - Ron Spair

Gross margin for Q1 of 2007 was 62%, down slightly from 2006's first quarter gross margin of 63%, resulting primarily from increased product support costs partially offset by higher funded R&D.

### <u>Operating Expenses – Ron Spair</u>

Research and Development expenses for Q1 were up approximately \$1.3 million over 2006, primarily as a result of increased staffing related charges of approximately \$700,000 and an increase of approximately \$600,000 in product development costs.

Sales and Marketing expenses increased approximately \$700,000, due to increased staffing related charges, and increased advertising reimbursement expense for our OTC cryosurgical product. As we discussed previously, we are adding to our field sales force and have agreed to reimburse a portion of the advertising expenditures incurred by SSL, our European OTC cryosurgical distributor.

General and Administrative expenses increased approximately \$1.3 million, because of increased staffing related charges, higher consulting fees related to our successful enterprise resource planning system ("ERP") implementation, and higher legal fees.

#### Net Income - Ron Spair

Net income for Q1 was \$1,487,000 or \$0.03 per share on a fully-diluted basis, compared to \$900,000 or \$0.02 per share for the same period of 2006. This increase was due to a gain from the January sale of our investment in our UK Intercept® distributor. Operationally, our increased gross margin generated during the first quarter was reinvested in the business.

#### Cash Flow from Operations and Liquidity - Ron Spair

Our cash balance remained strong with \$86.5 million at quarter end. In the quarter, we expended \$4.0 million for intellectual property licenses and used \$1.0 million for operating cash flows. Accounts receivable increased as days sales outstanding rose to 66, as a result of intra quarter revenue distribution and a decrease in the timeliness of customer remittances.

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

#### [Q&A Session – 2007 Q1 Financial Results]

#### Business Update - Doug Michels

Thank you for your questions. At this point, let's move on to a discussion of our many strategic initiatives and other business developments.

During the last conference call, we provided a fairly detailed description of the significant initiatives, programs and projects planned for 2007 and beyond. We continue to make very good progress toward the successful completion and delivery of these priorities and we remain extremely enthusiastic about these initiatives. We believe these projects and programs represent very substantial business opportunities for our Company.

# HIV-OTC - Doug Michels

As you know, one of our most important objectives is to obtain FDA approval to sell our OraQuick *ADVANCE*® HIV test in the retail or over-the-counter market. We continue to be very pleased with the significant progress on this initiative.

We are now conducting several more extensive operational or "flex" studies in a non-laboratory or clinical setting. These studies are designed to determine the impact of environmental and common household factors on the performance of the OraQuick® test. These studies are more than half way complete and, so far, there have been no surprises. We expect these studies to be wrapped up in the next few months.

Initial label comprehension studies performed in an observed setting have also been completed, and we have filed an amendment to our Investigational Device Exemption with the FDA to initiate more extensive label comprehension studies in a non-laboratory or clinical setting. We expect these more extensive studies to be conducted in the next couple of months.

The results of the initial label comprehension studies have generated very helpful information. We have used these results to refine and improve our packaging and the content of our labeling for use with consumers. As a result, we are now close to finalizing our packaging and labeling, which is a major milestone in obtaining FDA approval.

Progress has also been made in the development of a resource and medical referral system which will be available 24 hours per day, 7 days a week for our customers. We recently announced the signing of an agreement with the Constella Group, a leading global provider of professional health services. Constella brings a wealth of experience to this project and is an ideal partner. Constella has provided HIV/AIDS-related services for the Centers for Disease Control and Prevention ("CDC") for nearly a decade, including operating an HIV/AIDS call and resource center for the CDC. We intend to take advantage of Constella's expertise to develop a resource and referral system that is fully portable and compliant with FDA and quality standards. The system will offer phone and website access to assist consumers using our test and provide referral information to help consumers obtain HIV/AIDS prevention, treatment and care services.

We will continue to perform the required clinical work for an FDA submission throughout 2007 and into 2008. We plan to submit a PMA application with the FDA for OTC approval upon completion of our studies in 2008.

#### OraQuick® HCV - Doug Michels

A second very important project is the development of a rapid Hepatitis C or HCV test using our OraQuick® platform, which will be sold into the professional market once FDA approval is obtained. I am proud to report that development of this rapid HCV test is progressing nicely.

The final test design is nearing completion and our R&D group is collecting final data to be sure the test is fully optimized. We expect this design work to be completed within the next 30 to 60 days.

During our last call, I mentioned that we were planning to conduct studies in human subjects. These studies are in process and include all five specimen types for which we intend to seek FDA approval for use with this test device — oral fluid, fingerstick whole blood, venous whole blood, plasma and serum. All samples are being collected at the same time from the same

subjects. Our OraQuick® HCV test has performed well in these studies and the initial data is consistent with the prior feasibility data generated with this test. The studies have met our expectations and we believe the data will demonstrate that this test has the sensitivity and specificity required to obtain FDA approval. Our Chief Science Officer, Dr. Stephen Lee, will be presenting this additional data on all specimen types at the July meeting of the American Association of Clinical Chemistry in San Diego.

Our collaboration with Schering-Plough on the development of our OraQuick® HCV test has been productive. We have been in discussions with Schering's clinical and R&D groups and have provided them with our plan for conducting clinical trials in support of FDA approval. Schering is actively involved in the selection of suitable clinical trial sites. Overall, the relationship is going very well and we expect to collaborate further as we move into the clinical trial phase for this product.

On the regulatory front, we had a very productive meeting with the FDA at the end of March, during which we presented our high level plans for conducting the OraQuick® HCV clinical trials and the timeline for our submission to the agency. We are now incorporating the FDA's feedback from the meeting into our clinical protocols and are in the process of selecting a contract research organization (CRO) to support these studies. We expect the studies will begin soon and will last through most of this year. Our objective is to file our FDA submission by year end or early next year.

I should also point out that we expect to sell our OraQuick® HCV test in international markets. So our clinical work is designed to satisfy the quality and regulatory requirements for the European Union and other international standards.

#### High Throughput Assays - Doug Michels

Another initiative that we have discussed is the development of homogeneous fully-automated drugs of abuse assays for use with our Intercept® oral fluid collection device. The initial development work with Roche Diagnostics is underway and is going extremely well. We expect to continue to make significant progress in this development effort during the rest of this year.

As explained on our last call, development of these assays for use with our Intercept<sup>®</sup> device is a key initiative that we believe will bring significant benefits to our laboratory customers and allow us to more effectively compete against the urine products that currently dominate the drug testing market.

We are engaged in active discussions with Roche to finalize the formal legal contracts for the development and commercialization activities. We are working against a detailed development plan and discussions on commercial terms are progressing nicely. We hope to have the final terms worked out shortly and the legal contracts negotiated and prepared for execution in the next month or so. In the meantime, both parties continue the development work in a very collaborative manner.

#### <u>Cryosurgical Product Extensions - Doug Michels</u>

The final initiatives I want to share with you relate to our cryosurgical systems products.

Our work to add at least one new indication other than common or plantar warts to our OTC cryosurgical product continues. Since the last call, we decided to further examine the market opportunity for this product. After that analysis is completed, we will determine how best to proceed with clinical development and obtain FDA approval for this product.

We completed the clinical work for use of our OTC cryosurgical product in combination with salicylic acid and our submission is pending before the FDA. We recently received some feedback from the FDA on our submission and we are gathering data for a response.

#### **Operations Update - Doug Michels**

One final area I would like to address is operations.

During the quarter we completed an extensive, consultant driven effort in capacity and facility planning designed to address the current and future production requirements of our recently completed long range plan. This involved assessing the use of automated manufacturing, semi-automated production and offshore manufacturing.

I am pleased to report that the Company has in place the plans to insure sufficient capacity to meet the forecasted demand for OraQuick *ADVANCE*® in both the professional and OTC markets, the projected requirements for our HCV rapid test on the OraQuick® platform and the production needs associated with the continued growth in our Intercept® product line. During the

quarter, we made substantial progress towards our goal of validating our automated manufacturing equipment in advance of filing with the FDA and in construction of an additional semi-automated manufacturing space for OraQuick® devices that will need to be validated and approved by the FDA. We are laying the foundation to support a much larger business in the years to come.

#### Summary - Doug Michels

As you can see, the first quarter was a busy one for us with significant progress being made on all of our major development initiatives. We continue to be very excited about these programs and the business opportunities they represent for our future. We will continue to provide updates as additional progress is made and milestones are achieved.

Now I would like to review some additional steps that we are taking under each of our product lines to grow our business.

#### Efforts to Grow Business - Doug Michels

# Infectious Disease - Doug Michels

During the first quarter, our infectious disease business continued its strong growth, and we expect continued growth for a number of reasons:

- Our direct sales to the public health market grew 50% in Q1 and should continue to fuel substantial growth throughout the rest of the year.
  - We continue to make good progress assisting our customers in planning for and implementing city-wide testing initiatives. Washington DC remains committed to establishing a city-wide routine HIV screening program, as evidenced by an additional purchase order from the city. In addition, the program in Philadelphia, where testing is being conducted in underserved communities, is going well and we expect this program to continue to expand. We are also in discussions with several other large cities that intend to launch broad scale testing initiatives in the near future.
  - We continued our efforts to sell OraQuick® outside of the traditional public health setting. For example, during the National Week of Prayer, we worked with a number of faith-based organizations to offer testing programs, one of which was the Enon Baptist Tabernacle Church in Philadelphia, which tested nearly 1,000 people in just one day.

- In February, we announced that we were donating OraQuick® tests to more than 20 community-based organizations and testing sites around the country who were offering free HIV testing in observance of National Black HIV/AIDS Awareness Day. The primary goal of this day was to encourage African Americans to get tested and know their HIV status, get educated about the transmission modes of HIV and AIDS, get involved in their local community, and get treated if they are currently living with HIV or are newly diagnosed. Along these lines, the CDC announced in early March its mobilization effort in response to Fighting HIV Among African Americans. This announcement included several strategies focused on expanding investments and access to HIV testing for African Americans.
- We expect that sales of OraQuick ADVANCE® to Abbott Laboratories for further distribution to hospitals will also continue to grow.
  - During the first quarter we added 73 new hospitals and 9 new emergency room departments as OraQuick® customers. Not surprisingly, we recorded a record level of sales to Abbott during Q1. This is a clear indication that rapid HIV screening in hospitals is expanding.
  - We have been participants in a series of CDC-sponsored workshops that are taking place throughout the country with some of the nation's largest hospitals and emergency rooms to support the adoption of the new CDC recommendations for routine HIV screening.
  - As discussed during our last call, Abbott Laboratories recently announced that it was selling its diagnostics division, which includes its rights to our OraQuick® test, to General Electric. That transaction has not yet closed, so we have not yet been able to discuss the impact of that transaction with management at General Electric. Our understanding is that the transaction is expected to close in the next couple of months, at which time we plan to engage GE management to discuss how our relationship will move forward.
- In the physician office market, we have added a new significant distributor with the signing of an agreement with Henry Schein. We are also in discussions to add several other physician office distributors later in the year.
- On the international front:

- We have some long-awaited great news to share with you regarding a CE mark for the OraQuick *ADVANCE*® test. In March and April our Notified Body completed two facility inspections as a final step towards granting our CE mark. These inspections were important milestones. After the second inspection, which ended last Wednesday, May 2, we were told by our auditors that we are being recommended for CE mark approval. We have been preparing final labeling and packaging for the European Union in anticipation of officially receiving our CE mark. After receipt, we will move to actively pursue the required country approvals.
- As previously disclosed, there are several sites in Europe currently conducting investigational or pilot studies with our OraQuick *ADVANCE*® test. One prominent hospital in the UK has given us some very positive feedback on the performance of our test and has indicated that it is very pleased with the use of OraQuick® in oral fluid testing. We believe studies like this will help facilitate the European launch of OraQuick after the CE mark is obtained.
- As we recently announced, we have been working closely with the government of Madagascar in support of their plans for a major HIV screening initiative in that country. To date, we have sold approximately \$300,000 of OraQuick® tests to the Madagascar government. Last month I traveled to meet with the Prime Minister and Minister of Health to formally kickoff their mother and child wellness week, which is intended to provide free healthcare for women and children and promote expanded HIV screening program with oral fluid testing using the OraQuick® device. Approximately 15,000 individuals were screened for HIV in Madagascar in 2005 and this increased to nearly 140,000 in 2006, primarily due to the adoption of oral fluid testing with OraQuick® in the latter part of that year. Because of the success of the testing program with OraQuick®, the government is expanding its testing program and has indicated that it expects to test more than 400,000 individuals in 2007. A major component of that testing program will be a door-to-door campaign that will utilize teams of individuals traveling throughout the most populated areas of the country. Currently approximately 70% of all HIV screening in Madagascar is done with the OraQuick® test, and we expect OraQuick® to play a major role in future testing in that country.
- During the first quarter, we successfully registered OraQuick® in both South Korea and Singapore and we recently learned that our registration in Indonesia has been approved. We expect to obtain several additional registrations later this year. In addition, our OraQuick test has been validated for use with oral fluid in several African countries.

#### Substance Abuse - Doug Michels

Turning to Substance Abuse testing, this business grew 14% in Q1 and we expect continued growth for a number of reasons:

- During the first quarter of 2007, 23 new Intercept® accounts were closed and the number of specimens processed in the workplace testing market hit an all-time high of over 300,000 specimens for the quarter. This is indicative of the continued penetration of our Intercept® test in the drug testing market. We will continue to focus on closing new accounts and implementing recently-signed accounts as rapidly as possible.
- During the first quarter, we also added two new criminal justice laboratories that are both up and running and processing Intercept® specimens. We are driving the adoption of oral fluid drug testing and we hope to add several additional labs yet this year.
- Also in the first quarter, we added five new third party administrators or TPAs, who are now actively offering Intercept® oral fluid drug testing as part of their overall employee screening programs that they deliver to their workplace customers.

#### Cryosurgical Systems - Doug Michels

In the cryosurgical systems market, several developments are in process to strengthen our business.

- Overall, our relationship with SSL has developed nicely. During the first quarter, we saw a 28% increase in sales to SSL compared to 2006, and we
  expect sales to continue to increase throughout this year. We recently announced an amendment to our agreement with SSL for the distribution of our
  over-the-counter cryosurgical product in Europe, Australia and New Zealand. The purpose of this amendment was to restructure the agreement
  somewhat to create a greater incentive for SSL to expand sales and accelerate the commercialization of this product in new countries.
- Genomma, our distributor in Mexico who sells our OTC cryosurgery product under the POINTTS brand name, had an outstanding product launch in March. Fueled by a robust national media campaign, Genomma purchased approximately \$500,000 during the first quarter.

With that as an overview, I will now turn it back over to Ron to update our financial guidance.

#### Second Quarter and Full Year 2007 Financial Guidance - Ron Spair

Thanks, Doug.

Starting first with the second quarter guidance, we are expecting revenues to approximate \$20 million and earnings per share to approximate breakeven to \$0.01 per share. We do expect expenses to increase as we progress our clinical development activities.

With respect to guidance for the full year 2007, I am pleased to report that we are increasing our revenue forecast to \$81 million, which would represent a 19% increase over 2006. As explained during our last call, our previous full year guidance did not include any additional governmental bulk orders for OraQuick *ADVANCE*® or orders from Prestige Brands for our over-the-counter cryosurgical product, beyond those received at the time we initially announced our guidance. Based on the Company's performance in the first quarter and the receipt of an additional order of approximately \$1.0 million from Prestige for delivery in the second quarter, we are taking up our revenue guidance. We currently expect our full year earnings per share to remain within the \$0.03 to \$0.05 per share range.

We will continue to monitor developments in our business so that we can provide an update on guidance as necessary after each quarter.

In closing, we continue to believe that 2007 will be an exciting year and will position us for future growth.

Now, I will turn it back over to Doug.

#### Conclusion - Doug Michels

Thank you Ron.

We're pleased once again to open the floor to questions regarding our business update.

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

I want to thank everyone for participating in this call. I believe we are off to a very good start for the year, and I look forward to updating you again on our progress during our next conference call.

Have a good evening.

#### **Important Information**

The foregoing "Remarks" contain certain forward-looking statements, including with respect to revenues, net income and products. 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; 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 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; 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, patent infringement, 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.