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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 6, 2009**

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**OraSure Technologies, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**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**

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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 May 6, 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 March 31, 2009, described certain business developments and provided financial guidance for the second 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**

<u>Exhibit Number</u>	<u>Description</u>
99	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2009 Analyst/Investor Conference Call Held May 6, 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: May 6, 2009

By: */s/ Jack E. Jerrett*

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Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

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**Index to Exhibits**

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OraSure Technologies, Inc.

2009 First Quarter

Analyst/Investor Conference Call

May 6, 2009

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

**Please see "Important Information" at the conclusion of the following prepared remarks. The following remarks include a discussion of certain non-GAAP financial measures. Non-GAAP reporting is provided to help you better understand the Company's business and certain items which impacted the Company's results. However, non-GAAP financial results are not meant to be considered as a stand-alone measurement of performance, or as a substitute for, or as superior to, GAAP results. You should be aware that non-GAAP measures have inherent limitations and should be used only in conjunction with OraSure's consolidated financial statements prepared in accordance with GAAP. The Company issued a press release on May 6, 2009 which includes a table detailing the non-GAAP measures together with the corresponding GAAP results and a reconciliation to GAAP. You are encouraged to review these items.**

**Introduction – Doug Michels**

Thanks Judy,

Good afternoon everyone. Welcome to our first quarter 2009 earnings conference call.

Ron Spair will begin with a review of our financial performance for the quarter. As you will see, both our top and bottom line results exceeded the guidance provided during the last earnings conference call. Ron will also provide financial guidance for the second quarter of 2009.

After that, I will describe the progress we are making on the Company's major clinical development programs and provide some more general business updates. We will conclude by opening the floor for your questions.

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

**First Quarter 2009 Financial Results – Ron Spair**

Thanks Doug and good afternoon everyone.

**Revenues – Ron Spair**

First quarter 2009 revenues were \$17.3 million, representing a 5% decrease from the \$18.1 million reported in 2008. Increased sales in infectious disease and insurance risk assessment testing were offset by a decline in sales of our cryosurgical systems and substance abuse testing products.

The overall 10% growth in our infectious disease revenues in the first quarter of 2009 was a result of strong sales of our OraQuick *ADVANCE*<sup>®</sup> Rapid HIV-1/2 Antibody Test. Sales to public health increased 5% over the first quarter of 2008. In addition, and as you may recall, we switched to a direct sales model for U.S. hospitals on January 1, 2009. We are very pleased with the smooth transition from Abbott selling our OraQuick *ADVANCE*<sup>®</sup> product to using our own direct sales force to serve the U.S. hospital market. Direct sales to hospitals are off to a great start with a 41% increase over prior year sales levels to Abbott. This increase is due to the higher average selling price realized under the direct model. Offsetting these increases in infectious disease revenues was a 29% decline in International OraQuick<sup>®</sup> revenues as a result of lower sales into Africa. Sales volumes were up in all other international markets, including Europe, Asia and Latin America.

First quarter 2009 cryosurgical revenues decreased 36% compared to the first quarter of 2008. International over-the-counter (“OTC”) sales were down 67% when compared to sales in the same period of 2008. European OTC sales to our distributor, SSL, are tracking below 2008 levels, with a 55% decrease. This reduction was the result of lower unit selling prices and volatility in SSL’s ordering patterns.

In addition, during the first quarter of 2008 we had approximately \$400,000 of sales to our Latin American OTC distributor, Genomma. This compares to no sales volume during the first quarter of 2009. We believe Genomma has largely worked through their excess inventory, which we previously reported, and we expect sales to Genomma to begin again during the second quarter of 2009. Also during the quarter, we launched our

own nationally branded cryosurgical wart removal product in the U.S. OTC market. We have shipped product to one major retailer, Rite Aid, and we will look to expand distribution to other retailers in the future.

On the professional side, our combined cryosurgical sales decreased by 11% compared to the first quarter of 2008. As you may recall, we were experiencing diversion of this product domestically from sources outside the U.S. We believe we have substantially corrected the issue, although we did see some impact during the first quarter.

Moving to substance abuse testing, revenues decreased 18% in the first quarter of 2009 compared to the first quarter of 2008. Sales of our Intercept® drug testing system continue to be directly impacted by the current challenging economic and employment environment.

Our insurance risk assessment sales increased 6% from \$1.5 million in 2008 to \$1.6 million in 2009, while licensing revenues decreased from \$453,000 to \$335,000.

**Gross Margin – Ron Spair**

Turning to Gross Margin, our overall margin for Q1 of 2009 was 64%, an increase from 59% for Q1 of 2008. This is the highest gross margin the Company has achieved in over 2 years. The improvement resulted from a decrease in scrap and spoilage charges when compared to the prior year quarter as well as the incremental gross margin associated with the switch to a direct sales model in the U.S. hospital market. We are very pleased with the hard work of our Operations and R&D groups in lowering our scrap and spoilage levels over the prior year. We expect there will be some volatility in this number from quarter to quarter.

**Operating Expenses – Ron Spair**

Our total operating expenses for the first quarter were down \$823,000 or 6%.

Research and Development expenses for Q1 were down 27% or approximately \$1.2 million from the first quarter of 2008, 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. We do expect that our clinical spend will increase above first quarter levels later this year.

Sales and Marketing expenses decreased 4% or approximately \$193,000, despite an increase in staffing and related charges as a result of the recruitment of our direct sales force for the U.S. hospital market. The increase in staffing was offset by decreases in many expense categories across the board as we focused on cost control and limiting our discretionary spending. For the remainder of 2009, we expect Sales and Marketing expenses will increase above first quarter levels.

General and Administrative expenses increased approximately 16% or by \$616,000, primarily due to increased legal fees associated with the continuing patent infringement lawsuit filed by Inverness Medical and Church & Dwight.

**Net Income (Loss) – Ron Spair**

From a bottom line perspective, we reported a pre-tax loss of \$1.6 million, or \$0.04 per share, which exceeded our guidance. This is an improvement compared to an adjusted non-GAAP pre-tax loss of \$2.1 million for the same period of 2008, as our bottom line benefitted from the improvement in gross margin and decrease in operating expenses.

**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 \$78.6 million at the end of the first quarter. Our working capital of \$90.1 million at March 31, 2009 is comparable to the working capital balance at December 31, 2008 of \$90.9 million, and our current ratio improved from 6.95 at December 31, 2008 to 8.97 at March 31, 2009.

During the first quarter of 2009, we used \$2.7 million in cash flow from operations compared to \$3.7 used during the first quarter of 2008. The decrease in cash used in operating activities is largely the result of improved accounts receivable collections as we collected a large outstanding balance due from one of our international customers. Day



sales outstanding improved from 69 days at March 31, 2008 to 59 days at March 31, 2009. Accounts receivable at March 31, 2008 were inflated by large balances due from two of our largest distributors, Quest Diagnostics and SSL. Decreases in accounts payable and accrued expense balances offset by non-cash charges for stock compensation and depreciation and amortization contributed to the cash used in operations. It should also be noted that our use of cash during the first quarter included a contract termination fee paid to Abbott and accrued at year end.

In addition, during the quarter we purchased 108,293 shares of common stock under our stock repurchase program for an aggregate consideration of \$308,605. Cumulative purchases under the Company's Board approved repurchase program now total \$5,429,713 and cover 1,256,023 shares of the Company's common stock. The initial authorization was for a maximum purchase of up to \$25 million.

**Second Quarter 2009 Financial Guidance – Ron Spair**

Turning to guidance for the second quarter of 2009, we are projecting revenues of approximately \$18.5 to \$19.0 million and a loss per share of approximately \$0.06 to \$0.07.

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

**Program Update – Doug Michels**

Thanks, Ron. I will now provide an update on our major clinical programs.

**OraQuick® HCV – Doug Michels**

Since our last earnings call, we have continued to communicate with the FDA regarding our premarket approval ("PMA") application for our OraQuick® HCV test. We provided additional information and responded to questions as the FDA's review has progressed.

We were recently contacted by the FDA to schedule a full facility audit, which is a normal part of the PMA review process. It appears that this audit will be scheduled during

mid-summer, which is generally in line with our expectations for this project.

Other matters that we continue to work on with respect to the OraQuick® HCV test include studies required for a CLIA waiver and CE mark approval. These activities are continuing in line with our internal schedules. As you may recall, the studies required for a CLIA waiver are being timed for completion so that a submission can be filed as soon as FDA approval is received. Completion of additional data analysis and clinical reports required for CE mark approval should occur in the next couple of months, with our submission expected to be made shortly thereafter.

Finally, there are two investigational studies being initiated by independent third parties. The first will examine the utility of a prototype OraQuick® HCV test to identify HCV infection in at-risk individuals and the second will be used to test the product against current laboratory methods when used to test HCV positive and HCV negative individuals.

**OraQuick® Stability – Doug Michels**

As discussed on prior calls, we had been working for some time to extend the shelf life for our OraQuick® HIV test to at least twelve months. We were able to do that initially in certain international markets outside Europe and at the end of last year we received FDA approval to extend the shelf life here in the U.S.

More recently, we received an email from our notifying body that an extension to twelve months was approved for the European Union. We expect to receive their final report confirming this approval in the near future. This final approval enables us to sell OraQuick® product with twelve-month dating worldwide.

**HIV OTC – Doug Michels**

Turning now to our efforts to obtain FDA approval for an OraQuick® rapid HIV over-the-counter test, we had previously submitted the results of our observed user study to the FDA. This study was designed to assess 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 observed those activities. At the end of last year, we met with

the FDA to review the data from this study and to discuss our draft protocol for testing the device with consumers in an unobserved setting.

The FDA contacted us several weeks ago and indicated that our observed study results, along with our proposal for the final unobserved study, were going to be presented to upper management within the FDA. It is our understanding that this meeting recently occurred and we expect to receive guidance from the FDA shortly.

We obviously remain very excited about this opportunity because of the enormous potential for both our Company and the public in general. As we gain greater clarity from the FDA, we will provide you with updates as appropriate.

**Litigation Update – Doug Michels**

Turning to litigation — we are very pleased with the Court’s decision to deny the motion for summary judgment filed by Inverness and Church & Dwight on the issue of infringement. The motion was denied without prejudice, which means the plaintiffs can reinstate the motion after the Court’s Markman hearing is completed. The Markman process is a normal part of a patent lawsuit in which the Court will define the meanings of various patent claims relevant to an infringement determination. Depending on the Court’s Markman ruling, we may also decide to file our own motion for summary judgment seeking a determination of non-infringement. We remain very confident in our position in this litigation.

**Business Update – Doug Michels**

Finally, I would like to provide some perspective on major parts of our business as we begin a new year.

**OraQuick® HIV**

As Ron explained, our infectious disease testing business and in particular sales of our OraQuick® rapid HIV test were strong during the first quarter, and we remain bullish on this part of the business. Despite the challenging economy, there remains a high level of focus on HIV prevention and specifically on the expansion of HIV testing and we believe increased funding will be made available

through various legislative efforts. These legislative activities reinforce the priority being placed on HIV/AIDS including the need for more testing. We believe this will continue to create an environment for increased HIV testing in the years to come.

#### **OraQuick® Hospital Sales**

As Ron mentioned, the transition to a direct sales approach in hospitals has gone extremely well. Sales for Q1 exceeded our expectations despite a slower start in January due to an acceleration of sales to hospital customers by Abbott at the end of last year.

Based on results in Q1, we have already established and received product orders from more than 1,000 individual hospital accounts. In addition, we saw the percentage of hospitals ordering increase by nearly 10% from the start to the conclusion of the first quarter. And we have secured agreements with 5 major hospital group purchasing organizations or GPO's, providing thousands of hospitals with immediate access to our OraQuick® product.

We believe we have secured most of the business previously managed by our distributor, Abbott Laboratories, and we are now focused on expanding sales to this critical marketplace.

#### **Cryosurgical Systems Business**

As Ron indicated, revenues from our cryosurgical business were down compared to the year ago quarter. However, we are working hard to improve the performance of this business.

- Our cryosurgical business is already benefitting substantially from increased management focus and attention. As you may recall, last year Mike Formica, who also heads our Operations, assumed responsibility for this business on a global basis. He is doing a fine job by providing our cryosurgical products with the additional attention they need.
- One of Mike's immediate objectives has been to stop the diversion of

Histofreezer<sup>®</sup> product into the U.S. from some of our foreign distributors. It has been a difficult and time consuming endeavor, but we believe this is largely resolved and should have little impact during the remainder of the year.

- Another area of focus has been to improve the performance of our OTC product line internationally. We have extended the contract with our European distributor, SSL, on favorable terms, and expect better performance in 2009 as they work through an inventory position built at the end of last year. We are in a similar position in Latin America. Although our distributor, Genomma, made no purchases in the first quarter, we expect that to change as orders have been placed for the remaining three quarters of the year.
- On the domestic OTC front, we have shipped a small quantity of product to Rite Aid and recently received both a second and third order from this retailer. Discussions with other chains and some retail internet sites are ongoing.

#### **Substance Abuse Testing**

The economic downturn and reduction in hiring has negatively impacted sales of our Intercept<sup>®</sup> product line, primarily in the workplace testing segment. The U.S. Department of Labor announced in March that the number of individuals unemployed reached 13.2 million and the unemployment rate rose to 8.5 percent nationally. Pre-employment drug screening accounts for the majority of drug testing conducted in the workplace. The declining trend we experienced is also consistent with the public pronouncements from the nation's largest laboratories. For example, Quest Diagnostics, which is our largest Intercept<sup>®</sup> customer, indicated that its first quarter drugs of abuse testing volume declined by 25% primarily due to the hiring trends. A similar experience was reported at the nation's second largest laboratory, LabCorp where they saw a 20.1% decline in drug testing year over year in the first quarter. A change in these trends is not expected until we see improved economic and employment conditions.

On the positive side, there has been added Federal support in drug court funding where we have seen some success with our Intercept<sup>®</sup> test. President Obama signed the 2009 Omnibus Appropriation Bill in March, which increased drug court funding to \$63.9 million in 2009, a 250% increase over the last year's mark.

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### **Launch of Newly Designed Website**

A final item I want to mention is that we recently launched a newly designed website. This project had been underway for a number of months and our focus was to improve both the content and function to make it easier to use by our customers, our investors and any others interested in OraSure. We are very proud of the new site and believe you will be impressed as well. If you have not done so already, I would encourage you to visit our website at [www.orasure.com](http://www.orasure.com).

### ***Conclusion***

So in summary, we accomplished a great deal in the first quarter. We successfully transitioned to a direct sales model for hospitals, continued to grow the infectious disease business in a difficult economic climate, continued to advance our major clinical initiatives, received 12-month dating on our OraQuick ADVANCE® test, substantially ended the diversion in the professional cryosurgical market, launched our OTC cryo product into the domestic market, improved yields on scrap and spoilage, and brought down our days-sales-outstanding substantially. 2009 is off to a great start and we intend to deliver a very successful rest of the year.

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.

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; 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.