# **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 6, 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))	

#### Item 7.01 – Regulation FD Disclosure.

On May 6, 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 March 31, 2008, described certain business developments and provided an update on financial guidance for the second quarter and full year 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

Exhibit

Number 99

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

#### 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, 2008 By:  $\frac{\mbox{/s/ Jack E. Jerrett}}{\mbox{}}$ 

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

# **Index to Exhibits**

Description
Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2008 Analyst/Investor Conference Call Held May 6, 2008. Exhibit No.

## OraSure Technologies, Inc.

#### 2008 First Quarter

## **Analyst/Investor Conference Call**

May 6, 2008

# 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 Judy,

Good afternoon everyone. Welcome to our first quarter 2008 earnings conference call.

Ron Spair will begin with a review of our first quarter results followed by a discussion of our Q2 and full year 2008 financial guidance. Earlier today we issued a press release detailing our Q1 results. As you can see from this release, our first quarter financial performance was in line with guidance. However, since our last call, there have been a number of unexpected developments in our business and the markets that we serve which necessitate an adjustment in our guidance for the rest of the year. Following Ron's remarks, we will open the floor for your questions on these developments.

After that, I will provide an update on several aspects of our business, including our principal strategic initiatives and efforts to grow our business. We will conclude by again opening the floor for your questions.

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

# Financial Overview - Ron Spair

Thanks, Doug, and good afternoon everyone.

#### 2008 First Quarter Financial Results - Ron Spair

First, I will start with a brief review of the first quarter results.

#### Revenues - Ron Spair

Total revenues for Q1 were in line with guidance at \$18.1 million. Increased sales of OraQuick *ADVANCE*®, our insurance risk assessment products and professional cryosurgical product were offset by expected decreases in revenue from our over-the-counter ("OTC") cryosurgical wart removal products and substance abuse testing products.

A 6% growth in our infectious disease revenues was the result of continued strong sales of our OraQuick *ADVANCE*® rapid HIV test. Sales to public health during the quarter increased 45% over 2007 as result of continued growth in our base business and increased sales related to the Centers for Disease Control and Prevention's ("CDC") efforts to increase HIV testing among populations disproportionately affected by HIV. These increases were partially offset by the absence of bulk purchases by CDC and the Substance Abuse and Mental Health Services Administration ("SAMHSA") that were recorded in the year-ago period. Our sales to Abbott decreased 11% as a result of their ordering patterns for the U.S. hospital market. International sales of OraQuick® decreased 14% compared to the same period in 2007, largely as a result of a 25% decrease in revenues from Africa.

Our cryosurgical revenues during Q1 experienced an overall decrease of 41% compared to 2007. This was expected and forecasted as this decrease was primarily due to the absence of U.S. OTC sales resulting from the termination of

our distribution relationship with Prestige Brands at the end of 2007. First quarter 2007 sales to Prestige were \$2.1 million. Our international OTC sales for the first quarter 2008 were \$1.6 million, a 22% decrease from 2007 that largely resulted from reduced sales in Europe due to the variability of distributor purchasing patterns. First quarter cryosurgical sales to the professional markets increased 17% to \$1.8 million compared to \$1.5 million in the same period of 2007.

In substance abuse testing, sales were \$3.3 million for the first quarter, a 17% decrease compared to 2007. Sales of our Intercept® drug testing system totaled \$2.4 million, a 19% decrease from 2007. Our total workplace testing business was down 34%, our international sales were down 13% and our criminal justice sales decreased 4% compared to 2007. Our direct sales grew 34% for the quarter. The Company's workplace testing business continues to be directly impacted by the decline in employment rates in some of the market segments which buy our Intercept® product. The international market has also experienced a decrease in public sector funding which has slowed the implementation of drug testing by criminal justice customers.

Finally, insurance risk assessment sales in the first quarter were \$1.5 million, up 73% compared to \$900,000 in the comparable period of 2007. While we are adding new accounts for this product line, the increase was largely caused by lower sales during the first quarter of 2007 due to the timing of our lab partners' purchases of devices and reagents in the latter part of 2006 and early 2007.

First quarter 2008 licensing and product development revenue included royalties of \$458,000 from Schering-Plough pursuant to our settlement arrangement. First quarter 2007 revenues included \$625,000 of funded research and development under our 2006 HCV collaboration agreement with Schering-Plough.

#### Gross Margin - Ron Spair

Turning to Gross Margin, our margin for Q1 of 2008 was 59%, a decrease from 62% for Q1 of 2007 but up sequentially from 58% in Q4 of 2007. This decline compared to Q1 of 2007 was due to several factors, including an unfavorable product mix versus the year ago period, increased scrap and spoilage expense, and higher unabsorbed overhead.

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

Research and Development expenses for Q1 were up 58%, or approximately \$1.7 million 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 9%, or approximately \$445,000, mostly due to increased staffing and related charges and general marketing expenses, partially offset by a decrease in advertising reimbursement costs related to our international OTC cryosurgical product.

General and Administrative expenses decreased approximately \$397,000, largely as result of a decrease in legal costs, outside consulting fees and corporate taxes, partially offset by increased staffing related expenses.

## Net Income – Ron Spair

From a bottom line perspective, we reported net income of \$2.0 million, or \$0.04 per share, which is in line with our guidance. This compares to \$1.5 million or \$0.03 per share for the same period of 2007. Included in first quarter 2008 Other Income is a payment of \$4.9 million received from Schering-Plough under the terms of our settlement agreement executed earlier this year. First quarter 2007 other income included a \$1.4 million gain on the sale of our investment in a privately-held nonaffiliated company.

#### 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 \$90.4 million and working capital of \$106.0 million at March 31, 2008. During the first quarter of 2008, we used \$3.7 million in cash flow from operations compared to \$1.0 million used during the first quarter of 2007. The increase in the use of cash was largely due to payments of royalty obligations and legal expenses that were accrued at the end of 2007, as well as an increase in accounts receivable balances. Days sales outstanding was at 69 days compared to 66 a year ago.

Now turning to our financial guidance update - -

## Second Quarter and Full Year 2008 Financial Guidance - Ron Spair

As you know, a patent infringement lawsuit was recently filed by Inverness Medical and Church & Dwight and this will result in an increase in our legal costs for 2008. In addition, there was an unexpected inventory buildup at our OTC cryosurgical distributor in Mexico and a recent change in funding sources for the purchase of OraQuick® HIV in Africa. Both events have affected our business. In the U.S., there has been lower than expected growth in the sales of OraQuick® to the hospital market and the continued economic slowdown has impacted hiring and workplace drug testing. As a result of these developments, we have decided to lower our previously released guidance for both revenues and EPS for 2008.

First, the revenue guidance.

In the Mexican OTC cryosurgery market, our distributor recently informed us of their reduced need for our product resulting from an unexpected return of product to them by a number of retail outlets in the latter part of the first quarter of 2008. As we have discussed previously, the treatment of common and plantar warts is a seasonal business and a number of retailers had accumulated an inventory level based on in-season demand that was not required over the winter months.

Rather than retain this stock at the retail level, these retailers exercised their right to return product to our distributor, Genomma, who subsequently reduced their forecasts for new purchases once the extent of the returns were known and revised supply requirements were recalculated. The product returned by the retailers will be retained for future sale by Genomma. We are working closely with Genomma to drive greater uptake of our product in the retail channel in Mexico and are exploring ways to draw down this inventory and generate new orders through sales in other Latin and South American countries upon successful registration of our product. We continue to believe that these markets have great potential, but the full realization will be delayed.

When we announced our full year 2007 results back in February, we highlighted a significant increase in our international revenues from OraQuick® that occurred in Africa and Asia. We have been working on both existing and developing collaborations for many years in these regions and believed several of these business prospects to be reasonably assured for 2008. As we moved through the first quarter of 2008 and beyond, however, significant developments occurred with our African business. In the case of one significant existing governmental customer in Africa, the primary funding source changed and with it the willingness to spend more on a per test basis for an oral fluid OraQuick® test versus a less costly blood-based alternative.

With respect to new business, we had great expectations for significant initiatives that we were pursuing in East Africa, a region experiencing political unrest and ethnic conflict emanating from Kenya. Although we continue to remain optimistic regarding the ultimate testing volumes that will accrue under new initiatives in this region, the timing of initiation is now less certain and consequently we are moving

these potential revenues to upside.

Domestically, our OraQuick® revenues continue to grow, particularly in the public health market. In the U.S. hospital market, Abbotts' outsales have not grown as expected. As you may recall from our February call, sales to Abbott and their outsales for 2007 increased nicely, compared to 2006. We expected this trend to continue in 2008, largely as a result of the CDC's recent funding initiatives and revised testing guidelines. However, this did not occur in Q1.

In the U.S. substance abuse testing market, the economy and resulting slowdown in hiring continue to adversely affect pre-employment drug testing. This is evidenced by the fact that 8 of our top 10 clients experienced a 19% decrease in specimen testing volumes during Q1 of 2008 compared to Q1 of 2007. Although we are projecting second quarter substance abuse testing revenues to increase from the levels attained in the first quarter of 2008, we are not as optimistic about the prospects for an upturn during the balance of the year, absent a significant turnaround in the economy and hiring trends.

After reflecting on the impact these developments will have on our business in 2008, we are now projecting revenues to approximate \$83.0 million for the year and from \$18.5 to \$19.0 for the second quarter. The intra-year distribution of revenues also continues to be skewed towards the back end of the year as a result of the slower than expected ramp up of the CDC's incremental testing initiative and forecasted purchasing patterns of our international OTC cryosurgery distributors. As Doug will highlight, we are active with many of the jurisdictions funded by the CDC to conduct incremental testing and we expect a number of new testing programs to come online in the second and third quarters contributing to revenue growth.

The reduction in projected full-year revenues will have a

significant impact on our 2008 earnings per share. Additionally, legal expenses for the Inverness and Church & Dwight patent infringement lawsuit could have a significant impact on both quarterly and full year earnings per share. Given the uncertainties surrounding the magnitude and timing of such spending and some of our revenue projections, we have decided to take a prudent approach and project a loss per share of between \$0.06 and \$0.07 for the second quarter and a loss per share of between \$0.10 and \$0.11 for the full year.

As the year progresses, we expect to reassess our revenue forecast and the amount and timing for litigation spend and will be updating our expectations accordingly.

And with that, I would like to open the floor for questions.

# [Q&A Session – 2008 Q1 Financial Results and Updated Financial Guidance]

#### Business Update - Doug Michels

Thank you for the questions. We will now discuss various strategic and other business and updates.

# <u>OraQuick®</u> <u>HCV – Doug Michels</u>

Starting with our clinical development of an OraQuick® HCV test - -

Our clinical trials to support both our PMA submission to the FDA and our request for CE mark approval in Europe are progressing well. Both patient enrollment and testing at the several clinical sites we have initiated are proceeding on schedule. As previously discussed, we expect these trials to continue through the second quarter of this year. Once completed, we will analyze the results and prepare our submissions. We still expect to file a PMA application with the FDA this summer and intend to submit for European approval shortly thereafter.

In addition to the clinical trials, field development studies are being planned and will be executed both domestically and outside the U.S. in various settings where we expect significant levels of utilization. We continue to work closely with Schering Plough in our pre-market development efforts and building our marketing launch plans.

#### OraQuick® Stability - Doug Michels

We also continue to make good progress on extending the shelf life of our OraQuick® HIV test. Our real time stability studies continue to progress and support an extension beyond six months.

Product lots manufactured with certain process improvements have now completed testing after twelve months of storage and have met the performance criteria established at the start of this program. We have submitted documents to the FDA for approval of these process changes, along with our stability protocol and acceptance criteria. These documents are currently under review by FDA and we are in discussions with the agency.

We will continue with real-time stability testing over the next few months, before formally submitting to the FDA for an extension of product shelf life this summer. For markets outside the U.S. and Europe, we have already begun the process to increase the shelf-life and product dating of OraQuick®. In the next month or so, we will begin to manufacture product with extended dating at our Thailand supplier and expect to begin supplying that product later this quarter to Africa and other countries that already receive product made in Thailand.

Successfully extending the shelf life of our OraQuick® HIV test continues to be an important priority for our infectious disease business and our customers.

#### **HIV-OTC - Doug Michels**

Another major initiative is the ongoing clinical work to obtain FDA approval to

sell our OraQuick® rapid HIV test over the counter.

As discussed during our last call, in January we submitted a revised IDE amendment to the FDA for the observed user clinical study. As you may recall, this is a study where we assess an individual's ability to interact with our packaging and comprehend the instructions for use, take the test and interpret their results while a trained professional observes those activities. The FDA provided a few additional comments, a further revised IDE amendment was submitted and we received IDE approval. We initiated the observed user clinical trial in April.

Subject enrollment has gone well, and we continue to initiate new sites in the study each week. We are pleased to be fully engaged in consumer self-testing with our OraQuick® HIV test. As part of this study, we have also brought our medical resource and referral system for consumers on line. This call center is available for all clinical study participants to access by telephone during the trial. The center is fully functional, manned with trained and certified call agents who are able not only to respond to questions about the use and performance of OraQuick®, but also can provide information about HIV/AIDS and refer consumers to medical care within their geographic locations.

Finally, we are continuing to move forward with preliminary plans for the final unobserved user clinical study while the observed user study is underway. Our schedule has not changed since our last earnings call. We intend to submit a draft IDE amendment for the unobserved user study concurrently with our submission to the FDA of data from the observed user study once it is completed. We are still targeting the back half of 2008 for commencement of the unobserved study.

#### <u>High Throughput Assays - Doug Michels</u>

The final development program I want to discuss is our work with Roche to

develop fully-automated homogeneous drugs of abuse assays for use with our Intercept® oral fluid collection device. The development of these oral fluid assays continues to go extremely well.

Prototype assays for all of the initial launch menu, which is a NIDA-5 test panel, are now operational on automated instrumentation. As you may know, NIDA-5 includes tests for amphetamines, methamphetamines, cocaine, opiates, cannabinoids or THC, and phencyclidine or PCP. We expect to begin customer evaluations of these automated assays in the next month or so and expand the evaluations at multiple sites throughout the year. When the tests have been fully developed, optimized and transferred to manufacturing, 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.

Now I would like to provide additional details regarding the strategy for growing each of our businesses.

#### Efforts to Grow Business - Doug Michels

# <u>Infectious Disease – Doug Michels</u>

The growth in our infectious disease testing business for the first quarter was primarily attributable to a 45% increase in direct sales of our OraQuick® HIV test, primarily to public health. We will continue our efforts to expand in the public health market and have put in place strategies to improve our results in the U.S. hospital and international markets.

• In public health, sales have increased and should continue to increase as a result of the CDC's revised recommendations for routine HIV testing in healthcare settings and \$35 million in additional funding disbursed by the CDC last fall to increase testing opportunities among populations disproportionately affected by HIV. Of the 23 jurisdictions receiving

grants under this program, we have shipped product to 14, and we expect another 4 jurisdictions to purchase product during the second quarter and another 2 shortly thereafter. Thus, 20 of the 23 grantees are expected to purchase OraQuick® for a majority of their incremental HIV testing funded by the CDC. While jurisdiction implementation of increased testing has been slower than expected for this program, we have been working closely with each of the jurisdictions to ensure increased utilization as the year progresses.

- In addition to this specific CDC grant program, there are other government-funded initiatives, both federal and local, that are in place or expected to be announced in support of increased HIV testing.
  - For example, at the end of last year, the Substance Abuse and Mental Health Services Administration, or SAMHSA, awarded 67 grantees funding for year one of a 5-year program to offer, among other services, rapid testing on site or through referral to their clients. Of these sites, 29 are currently OraQuick® customers, and we have made shipments to 21 under this program. We will continue to work with these grantees to further expand this funded testing program.
  - Several other federally-funded grants are expected to be issued in support of HIV testing, and while there may be limits on the availability of this funding and there are no guarantees with programs of this type, we expect our public health sales to benefit from these initiatives.
  - Our support of city-wide HIV testing initiatives also continues to be a priority for the OraQuick® business. During the first quarter, there was significant activity in both the Philadelphia and Washington, D.C. initiatives. For example, testing in Philadelphia increased by about 33% over the first quarter of 2007 and the District of Columbia also purchased additional tests during the quarter. The

economy has impacted the budgets of several cities that we have been talking to and may impact the timing and amount of either new or existing initiatives. Nevertheless, we expect testing to continue to grow in Philadelphia and Washington, D.C. throughout 2008 primarily through expansion in various healthcare settings, and we continue to provide support to and work closely with major cities such as New York, Los Angeles and Baltimore in their stated efforts to expand HIV screening.

- Turning to the U.S. hospital market, while sales were somewhat lower during the first quarter, compared to 2007 due to Abbotts' ordering patterns, Abbotts' outsales were flat. The hospital market is very important and we continue to add new hospitals and Emergency Departments to our list of OraQuick® customers. We believe the lower growth rate of Abbotts' outsales is primarily the result of increased competition in this market. In addition to focusing on signing new larger hospital systems, we are also now working closely with our existing customer base to expand OraQuick® usage within Emergency Departments. As part of this initiative, we are supporting several regional CDC urgent care workshops targeting hospital administrators, focused on establishing routine HIV screening in the Emergency Departments.
- Turning to the international front...
  - In Africa, despite the challenges we are facing, we are continuing to promote the advantages of OraQuick®'s oral fluid capabilities and to work within the changing funding and political landscape to ensure our product plays an important role in testing initiatives launched in this part of the world. We are also working to build the foundation for sales in Ghana and South Africa, and we are attempting to recover momentum in Madagascar, as well as with new and promising initiatives in Kenya and Rwanda. We think large testing

volumes in these markets are achievable, and we are pursuing these aggressively.

- In Europe, sales forces for our distributors in Spain and UK have been trained, and we are encouraged by customer interest and evaluation. We are close to completing an agreement in France, where there is recent high interest in rapid testing by the government. The registration process in Russia continues to move forward.
- In Brazil, our product is approved and launch plans are well underway, and there is high interest in the government for broader screening initiatives, as is the case in Mexico and Peru.

#### Substance Abuse - Doug Michels

Turning now to our Substance Abuse testing business, our revenues for the first quarter of 2008 were down compared to 2007, primarily as a result of the impact of economic conditions on workplace hiring practices. Despite this decline, the oral fluid drug testing value proposition continues to be very strong with our customer base and we have refined our sales and marketing strategy to address these conditions and position our substance abuse business for future growth.

• Examples include focusing on markets that experience employment growth or that are unlikely to be impacted by a decline in the employment rate; implementing new or expanded marketing initiatives with third-party administrators; securing new laboratories to adopt oral fluid drug testing in both the criminal justice and workplace testing markets; and increased direct marketing. We believe these new strategies and approaches, combined with new sales leadership for this team, will yield improved results.

# <u>Cryosurgical Systems - Doug Michels</u>

In our cryosurgical systems business, a 17% increase in our international and domestic professional sales during the first quarter was offset by the expected

absence of domestic sales of our OTC product here in the U.S. and lower international OTC sales. Each of the businesses have unique drivers and strategies are in place to foster future growth.

On the professional side of the business...

- In the U.S., we are continuing to strengthen our distribution network and we have successfully won business from our primary competitor in this market and increased our market share. New sales leadership at OraSure, together with a fully-staffed sales force, should drive results in Q2 and for the remainder of the year.
- In Europe, we have been experiencing slower than expected ramp-up of new distributors and there has been some pricing pressure from competing products on the market. We are working closely with our partners and are providing distributors appropriate incentives to gain better focus and traction against competition.

#### On the OTC side of the business...

- In Europe with SSL, our market share position in the UK consumer market is strong. Channel expansion has gone slower than expected because of aggressive pricing and promotion by Wartner, which sells a competing OTC product in France, Germany, and Italy. We are working on strategies to meet this competition and new launches are planned for Belgium, Spain, and parts of Eastern Europe.
- With Genomma, as Ron indicated, we are now working through an inventory build-up based on lower than expected outsales during the wart "off season". Our partner continues to aggressively promote POINTTS and we expect this inventory to move through the retail channels as the wart season progresses. We also continue to work through the registration process for Latin American expansion. We are targeting registration and launch in 12 additional Latin and South American countries by year end and we will work to accelerate this effort.

#### <u>Litigation Update - Doug Michels</u>

As you know, we were recently named in a lawsuit by Inverness and Church & Dwight for patent infringement under one of their U.S. patents. We believe our OraQuick *ADVANCE*® HIV test does not infringe the patent asserted in this lawsuit or any other patents. We also believe that the Inverness and Church & Dwight patent is invalid and unenforceable. We have selected an outside IP litigation firm to represent us and we intend to defend this matter vigorously. Although I am limited in what else I can say on this pending litigation, we will certainly provide you with updates on material developments as they occur.

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

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

# <u>Conclusion – Doug Michels</u>

I want to thank everyone for participating in today's call. There are several challenges facing our business at the moment and we are focused and will address them. At the same time, our OraQuick® business continues to grow nicely and we are making excellent progress in our clinical development efforts. The management team and I remain committed to a successful 2008 and to delivering significant value to our stockholders.

stockholders.

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; 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 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, 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 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, 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 press release and OraSure Technologies undertakes no duty to update these statements.