
**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): February 11, 2009

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other
Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

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

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

18015-1360
(Zip Code)

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

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

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

On February 11, 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 and full year ended December 31, 2008, described certain business developments and provided an update on financial guidance for the first quarter of 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.

The information in this Current Report and attached Exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

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. Fourth Quarter and Full Year 2008 Analyst/Investor Conference Call Held February 11, 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: February 11, 2009

By: */s/ Jack E. Jerrett*

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

Index to Exhibits

Exhibit No.

Description

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Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2008 Analyst/Investor Conference Call Held February 11, 2009.

OraSure Technologies, Inc.
2008 Fourth Quarter and Full Year
Analyst/Investor Conference Call
February 11, 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 February 11, 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 fourth quarter and full year 2008 earnings conference call.

For today's call, Ron Spair will begin with a review of the fourth quarter and full year 2008 financial performance. You will note our adjusted full year financial results exceeded the guidance provided on the third quarter earnings conference call. Ron will also provide our financial guidance for the first quarter 2009.

After that, we will discuss some additional updates, including progress we are making on the Company's major clinical development projects. We will conclude by opening the floor for your questions.

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

2008 Full Year Financial Results – Ron Spair

Thanks Doug and good afternoon everyone. I will start with a brief review of our full-year 2008 financial results.

Revenues – Ron Spair

2008 revenues were \$71.1 million, representing a 14% decrease from the \$82.7 million reported in 2007. Increased sales in infectious disease and insurance risk assessment testing, together with an increase in licensing revenues, were offset by an expected decline in sales of our cryosurgical wart removal and substance abuse testing products.

The overall 6% growth in our infectious disease revenues in 2008 was a result of strong sales of our OraQuick® Rapid HIV-1/2 Antibody test. Sales to public health increased 28% over 2007 and benefited from the growth in our base business and from the incremental sales driven by the Centers for Disease Control and Prevention's ("CDC") efforts to increase HIV testing. Our sales to Abbott decreased 18%. This was driven by our decision to go to a direct sales model in 2009 for U.S. hospitals, which resulted in a reduction of Abbott's purchases late in 2008.

Our overall cryosurgical revenues decreased 55% compared to 2007. The absence of U.S and Mexican over-the-counter ("OTC") sales coupled with reduced OTC sales in Europe were large contributors to this decrease.

As we explained in prior calls, our Latin American OTC distributor, Genomma, reduced its purchasing levels in 2008 in response to an increase in returned product from retailers due to overstocking during the winter months. The absence of U.S. OTC sales resulted from the termination of our domestic distribution relationship with Prestige Brands at the end of 2007, and European OTC sales declined due to lower revenues experience by our distributor, SSL, in key markets outside of the United Kingdom.

Our combined cryosurgical sales in the professional market decreased by 15% as the business was affected by the diversion of some lower priced Histofreezer®

product from international sources into the U.S. professional market. We have addressed this diversion by increasing our international pricing, changing product labeling and packaging, and enforcing contractual rights against certain international distributors. We believe we stopped most of the diversion in 2008 and expect no material impact from it in 2009.

Our substance abuse business decreased 11% in 2008 as sales of our Intercept® drug testing system were directly impacted by the continuing adverse economic conditions, resulting in a decline in pre-employment testing in some of the markets that buy our Intercept® product. Pre-employment drug screening represents approximately 50% of our workplace drug testing business, and the decrease in hiring has had a direct impact in this segment of our business.

Our insurance risk assessment sales increased 11% from \$5.5 million in 2007 to \$6.1 million in 2008 and licensing revenues increased 7% compared to 2007.

Gross Margin – Ron Spair

Our margin for the full year 2008 was 58%, a decrease from 61% in 2007. The decrease was largely due to a less favorable product mix, driven by significant declines in cryosurgical product revenue and increases in manufacturing scrap and spoilage expense. Although scrap and spoilage exceeded 2007 levels, OraQuick® scrap and spoilage was down sequentially in each quarter of 2008 as we identified the root-cause and made the appropriate adjustments. We expect overall OraQuick® 2009 scrap and spoilage to be significantly lower compared to 2008, primarily due to the product and process enhancements recently approved by the FDA.

Net Income (Loss) – Ron Spair

For the full year 2008, we delivered an adjusted loss per share of \$0.11, compared to 2007 where we ended with earnings per share of \$0.05. Our financial

performance was impacted principally by lower revenues and increased R&D expenditures. R&D expenses for 2008 increased \$6.1 million and in turn decreased our EPS by approximately \$0.08 as we continued our efforts to obtain FDA approval to sell our OraQuick® HIV test over the counter, develop our Rapid Hepatitis C (“HCV”) test, and develop homogeneous fully-automated drugs of abuse assays for use with our Intercept® oral fluid collection device in collaboration with Roche Diagnostics. The status of these projects will be discussed by Doug in greater detail later in the call.

It should be noted that on an unadjusted or GAAP basis, and as explained further in our press release issued earlier today, we recorded a \$26.0 million non-cash charge related to the establishment of a valuation allowance on our net deferred tax asset. This is reflected in our results reported under GAAP for both the fourth quarter and full year.

Now, I will turn to our quarterly results.

2008 Q4 Financial Results – Ron Spair

Our fourth quarter performance, on an as adjusted basis, exceeded our prior guidance, on both the top and bottom lines.

Revenues – Ron Spair

Total revenues for Q4 were \$17.2 million, a 13% decrease from the same period in 2007. Sales of our Intercept® drug testing system increased 10% and our insurance risk assessment sales increased 5% in the fourth quarter. These increases were offset by lower sales of our infectious disease and cryosurgical products.

In the infectious disease testing market, we booked sales of \$8.8 million, a 6% decrease from the fourth quarter of 2007. Public health sales for the quarter

increased 13%. This was offset by a 44% decline in sales to Abbott as they decreased their purchases to reduce inventory levels in preparation for the conclusion of our distribution agreement at year end. Also contributing to the overall decrease was a 21% reduction in international OraQuick® revenues largely due to lower sales into Africa.

In substance abuse testing, sales were flat compared to 2007 at \$3.4 million for the fourth quarters of 2008 and 2007. Included in these sales were \$2.9 million from our Intercept® drug testing system, which represents a 10% increase from 2007. This increase was principally driven by the Criminal Justice and International sectors.

Cryosurgical systems sales were \$2.9 million for the fourth quarter, a 45% decrease compared to the same period in 2007. This decrease was expected and is consistent with the explanations provided earlier in the call for the year to date results.

Finally, insurance risk assessment sales in the fourth quarter increased 5% to \$1.7 million.

Gross Margin – Ron Spair

Turning to Gross Margin, our margin for Q4 of 2008 was 56%, a decrease from 58% for Q4 of 2007. The decrease was largely due to a less favorable product mix, driven primarily by significant declines in cryosurgical product revenues, and increases in manufacturing scrap and spoilage expense. The majority of scrap and spoilage charges in Q4 were related to events affecting products other than OraQuick® and are not expected to recur. We expect OraQuick® scrap and spoilage to continue to drop in 2009.

Operating Expenses – Ron Spair

Research and Development expenses for Q4 were up 27% or approximately \$1.2 million over 2007, primarily due to a \$1.0 million charge associated with a patent license milestone payment required as a result of the filing of our OraQuick® HCV pre-market approval application with the FDA.

Sales and Marketing expenses increased 7% or approximately \$348,000, mostly due to increased staffing and related charges as a result of the recruitment of our direct sales force for the U.S. hospital market and recent organizational changes. We don't expect overall spend in Sales and Marketing to be materially higher in 2009 even though we have switched to a direct sales model in the hospital market. The majority of the increase in the fourth quarter of 2008 was caused by recruiting expenses.

General and Administrative expenses increased approximately \$1.3 million primarily due to costs associated with the ending of our OraQuick® distribution agreement with Abbott Laboratories. These costs, which were accrued in Q4 of 2008 and will be paid in the first quarter of 2009, represent the last of our obligations to Abbott under our agreement. During the quarter, we also incurred legal fees associated with the patent infringement lawsuit filed against us by Inverness Medical and Church & Dwight. In comparison, fourth quarter 2007 legal expenses reflect the reimbursement of certain legal fees awarded in connection with our arbitration with a former distribution partner.

Net Income (Loss) – Ron Spair

From a net loss perspective, and excluding the deferred tax asset charge, we reported a loss of \$3.3 million on an as adjusted basis, or \$0.07 per share which exceeded our guidance. This compares to net income of \$27,000 or break-even earnings per share for the same period of 2007.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, our cash balance remained strong with cash and short-term investments of \$82.5 million and working capital of \$91.0 million at December 31, 2008. During 2008, we used \$2.7 million in cash flow from operations. The decrease in cash provided by operating activities as compared to the prior year is largely the result of our net loss coupled with increases in inventory and decreases in accounts payables and accrued expenses. Day sales outstanding increased to 60 days from 50 days in 2007 as one of our international customers held a large outstanding balance at year end which was secured by a letter of credit and collected in early 2009. This represented the equivalent of 9 days sales outstanding. In addition, under the terms of our \$25 million share repurchase program we purchased \$5.1 million of our common stock during 2008, \$2.1 million of which was purchased in the fourth quarter.

First Quarter Financial Guidance – Ron Spair

Turning to guidance for 2009, for the first quarter we are projecting revenues of approximately \$16.5 to \$17.0 million and a loss per share of approximately \$0.07. As a result of fully reserving our deferred tax asset, we will not record Federal income tax expense or benefit in 2009.

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

Business Update – Doug Michels

Thanks, Ron. I will now provide an update on several important initiatives and programs.

Direct Sales to Hospitals – Doug Michels

As you know, we terminated our distribution agreement with Abbott Laboratories at the end of 2008, and on January 1, 2009 we began selling our OraQuick ADVANCE[®] HIV 1/2 test directly to U.S. hospitals and reference laboratories. These customers were previously served on an exclusive basis by Abbott.

I am pleased to report that the transition to a direct sales and service model has been well executed. We have secured contracts, either through assignment or a new agreement, with all major hospital group purchasing organizations previously buying OraQuick® from Abbott. These GPOs represented approximately 80% of Abbott's OraQuick® business in 2008 with the balance being conducted with hospitals without GPO affiliation. We now have agreements in place to serve over 1,500 hospitals and we have already received, in January alone, orders from customers that represent nearly 35% of Abbott's 2008 customer base. In short, our direct sales effort is off to a great start, and we have the necessary resources in place to capitalize fully on opportunities in the hospital market in 2009 and beyond.

Now, turning to some of our strategic priorities—

OraQuick® HCV – Doug Michels

As you know, during the fourth quarter we filed a premarket approval application (“PMA”) with the FDA for our OraQuick® HCV test. Since the filing, we have been in frequent communication with the FDA and responded to questions and provided additional information to the agency as they have progressed through the review process. We expect this process to continue over the next several months.

As part of its review, the FDA came to our Bethlehem facilities to conduct the first audit related to our filing, called a Bioresearch Monitoring, or BIMO, audit. This is a normal part of the PMA review process. This audit was fairly narrow in its scope, focusing solely on the conduct of the Company's clinical studies, our management of the CRO and clinical sites, data integrity and generally whether we followed Good Clinical Practices. The FDA has also audited one of the clinical sites that we used. I am happy to report that the FDA reported no observations or findings as a result of either of these audits.

As the FDA completes its review of our submission, we look forward to addressing any further requests they may have. We also expect that the FDA will conduct a full facility audit, which would typically occur prior to product approval.

We intend to submit for a CLIA waiver as soon as our PMA submission is approved by the FDA. The studies required for a CLIA waiver are timed for completion so that a submission can be filed as soon as approval is received.

Finally, as previously discussed, CE mark approval will be required in order to sell our OraQuick® HCV test in Europe. The additional clinical work required to file a submission for a CE mark is continuing. We expect the studies to conclude in the next couple of months and hope to make our submission shortly thereafter.

OraQuick® Stability – Doug Michels

As previously announced, we recently received FDA approval for a 12-month shelf life for our OraQuick ADVANCE® HIV-1/2 antibody test.

This has been a long-term project, involving excellent work by our R&D, Operations and Regulatory groups. This effort started over three years ago when we began to look for product enhancements that would improve the stability of our OraQuick® product and allow us to extend its usable shelf life. After several enhancements to both the product and our manufacturing processes were identified and production lots incorporating these changes manufactured, we conducted real time stability studies to demonstrate the improved product stability. The data for these studies, along with descriptions of the modifications to our production

processes and validation of these changes, were submitted to the FDA for review. We finally received approval for 12 months shelf life at the end of 2008 and announced the approval of extended shelf life product several weeks ago. Our inventory of 6-month dated product has been depleted, and we are now shipping only the enhanced product with 12-month dating.

The approval of these product enhancements is an important development, particularly because it makes what we believe is the best rapid HIV test on the market even more competitive and attractive to our customers.

HIV OTC – Doug Michels

Turning now to our efforts to obtain FDA approval for an OraQuick® Rapid HIV OTC test, we have continued to make good progress. As discussed in our prior call, we stopped our observed user study after testing was completed on the first 1,000 subjects because we met the 95 percent confidence intervals for specificity and sensitivity established by the FDA. We then submitted our results to the agency. 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.

In December 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 continues to review our data and has indicated that they will get back to us with any comments or questions on our observed user study and with guidance for the unobserved study soon. After we receive this input, our plan is to submit a protocol for the unobserved study and request an investigational device exemption, or IDE, for this study. We intend to begin the trial as soon as the FDA approves our IDE submission.

We remain excited about this opportunity because of its enormous potential. As this project moves forward, we will certainly provide you with appropriate updates.

Development of High Throughput Oral Fluid Drugs of Abuse Assays– Doug Michels

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

As discussed in prior calls, our development efforts have initially focused on a NIDA-5 panel of assays for marijuana, cocaine, opiates, PCP, amphetamines and methamphetamines. Assay development is now complete and individual assays are being transferred from R&D to manufacturing at Roche. It is our expectation that all NIDA-5 assays will be submitted to the FDA for 510(k) clearance by the end of the year, with the possible exception of the THC assay, which should occur early next year.

OTC Cryosurgical Product Update – Doug Michels

As discussed in prior calls, we launched our own nationally branded cryosurgical wart removal product in the U.S. OTC market beginning in this quarter. We have shipped product to one major retailer, and we will look to expand distribution to other major retailers in the future. We expect to issue a more specific announcement on this launch in the next few weeks.

Litigation Update – Doug Michels

Turning to litigation – the lawsuit filed against OraSure by Inverness and Church & Dwight for patent infringement continues to move forward. As you may know, last year Inverness filed a motion for summary judgment on the issue of infringement. Briefing on this motion is now complete, and we are waiting for the Court to issue a ruling. In the meantime, the discovery process is continuing and will continue through much of this year.

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

The current economic crisis has certainly created challenges for many businesses and their customers. Companies have cut back on hiring and many are reducing their workforce. Virtually every business is looking to reduce costs and this in turn puts pressure on pricing. Budgets are being cut and funding, in both the private and public sectors, is being reduced. While we certainly understand the environment in which we operate, we still believe OraSure is well positioned to succeed and that the future holds a lot of promise for our Company. We hold this belief for several reasons:

- HIV testing and treatment appears to be a high priority for the new Administration and Congress. You only need to look at the recently proposed stimulus bills to see that is the case. For example, the bill originally passed by the House of Representatives in January included \$335 million for the CDC's HIV/HCV/TB programs. Similar funding was included in the original Senate version of the bill. Regardless of whether this funding is ultimately retained as part of an economic stimulus, we believe it is likely to appear in legislation ultimately enacted this year and will remain a priority of the current Administration.
- Despite some well publicized funding challenges at the State and local levels, we have seen evidence that HIV testing and treatment programs will also continue to be a priority for these government agencies. Thus, although there will undoubtedly be budget cuts, we are optimistic that public health testing programs funded by State and local governments will continue to maintain or possibly increase their levels of testing.

- The CDC is continuing its support for routine testing and recently expanded funding of its heightened response initiative from 23 to 25 jurisdictions in 2009. We expect the CDC to continue funding this important program in the future.
- Although the CDC's guidelines recommending expanded routine HIV screening in healthcare settings have been in place since 2006, there is still substantial room for adoption of these guidelines which will drive more testing. The January 2009 issue of the *Journal of the American Medical Association*, or JAMA, highlighted the recommendations of prominent HIV/AIDS experts attending a recent national summit which encouraged healthcare providers to follow the CDC's guidelines and expand routine screening. Significantly, this report highlighted the availability of oral fluid testing as a way to implement the CDC's guidelines and noted that routine screening could increase awareness and help thousands of people access antiretroviral treatment while preventing new HIV infections from occurring.
- Expanded routine HIV testing is also being advocated by other groups. These include the American College of Physicians, American College of Obstetrics and Gynecology and the American College of Emergency Physicians.
- The CDC is now also expanding its recommendation for routine HIV screening beyond traditional healthcare settings. In January the CDC issued new guidance for the implementation of routine screening in correctional settings. We have always believed that prisons, jails and other correctional facilities represent a significant potential opportunity for our OraQuick *ADVANCE*[®] test. The issuance of this guidance document is significant in that it will provide a roadmap for the expansion of routine testing in these facilities.

- As discussed in prior calls, the economic slowdown and reduction in hiring has impacted sales of our Intercept® product line primarily in the workplace testing segment. However, we believe the biggest impact on this business occurred in 2008 since hiring is usually a leading indicator for our economy. We believe this part of our business will stabilize somewhat in 2009.
- In response to the negative economic outlook, we have taken many steps to reduce our own costs. The most visible of these actions was a reduction in our own workforce at the end of 2008. At the same time, we have refocused our resources on those parts of our business having the greatest strategic importance. A prime example was the expansion of our sales force and related support activities in order to sell our OraQuick ADVANCE® HIV test directly into the U.S. hospital market. This investment also lays the groundwork for marketing new products to hospitals, such as our OraQuick® HCV test once FDA approval is obtained.

Finally, in addition to the many positive factors affecting the near term operation of our business, it is important to keep in mind where we stand in advancing our major strategic objectives. As you know, we have made substantial progress during this past year, and we are in the late stages with respect to our main projects.

- We have spent significant time and resources developing an OraQuick® HCV test, which culminated in the filing of our PMA application last year, and we are now working hard to give the FDA everything it needs to issue its approval. We believe we are in the final stretch of this project and approval is now within our sights. In addition, we expect to submit for our CE mark this year so that we can focus on commercializing this important product in the near future.

- Similarly, our efforts to obtain FDA approval of an OraQuick® HIV test for the OTC market continues to advance. Our observed user study is complete and the data is now before the FDA, which was no small feat. We believe that we are now getting closer to the final required study for approval of this important product. We are eager to begin the unobserved study as soon as we get the nod from the FDA.
- Finally, the collaboration with Roche Diagnostics to develop fully automated high throughput oral fluid assays for use with our Intercept® device has gone extremely well, and we expect to begin submitting these assays for 510(k) clearance by the FDA later this year. Once approval is obtained, we will be ready to begin commercializing these assays both here in the U.S. and around the world. Based on our assessment of the drug testing market, we believe we will be the first to market with fully automated oral fluid assays, which will give us a significant competitive advantage in the drug testing marketplace.

Conclusion

So, in summary, despite past challenges and the current economic climate, we remain convinced that new opportunities will continue to emerge for our business, especially as we deliver against our strategic objectives. We are positioned for success and are committed to delivering a very successful 2009.

And with that, we will now open the floor to questions.

[Q&A session]

Conclusion – Doug Michels

I want to thank you all for participating in today's call.

Have a good afternoon and evening, everyone.

Important Information

This document contains certain forward-looking statements, including with respect to revenues, net income, earnings/loss per share and products. Actual results could be significantly different. Factors that could affect results include the ability to market and sell products, whether through internal, direct sales forces or third parties; 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 the services 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 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, 2007, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. Although forward-looking statements help to provide complete information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this document and OraSure Technologies undertakes no duty to update these statements.