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 10, 2010

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street Bethlehem, Pennsylvania	**18015-1360**
(Address of Principal Executive Offices)	**(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 February 10, 2010, 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, 2009, described certain business developments and provided financial guidance for the first quarter of 2010. 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

Exhibit Number	Description
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 10, 2010.

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 10, 2010

By: /S/ JACK E. JERRETT

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

Index to Exhibits

Exhibit No.	Description
99	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2009 Analyst/Investor Conference Call Held February 10, 2010.

Exhibit 99

OraSure Technologies, Inc.

2009 Fourth Quarter and Full Year

Analyst/Investor Conference Call

February 10, 2010

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 10, 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 and welcome to the call.

I am pleased to report that our financial performance during the fourth quarter of 2009 was strong. We exceeded our guidance on both the top and bottom lines and ended the year with positive momentum. For the full year, when compared to 2008, our revenues grew, we improved our gross margin, and reduced our use of cash flow from operations. We also continued to make progress on our major clinical programs. We accomplished all of this despite a very difficult economic environment and the unexpected challenge we experienced in manufacturing our OraQuick® HIV test.

Later in the call, I will highlight some of the more important accomplishments during 2009 and provide some expectations for 2010. However, before I do that, Ron is going to discuss our 2009 financial performance and provide financial guidance for the first quarter of 2010.

We will conclude the call by opening the floor for any questions you may have.

And with that, I will turn things over to Ron.

2009 Full Year Financial Results – Ron Spair

Thanks Doug and good afternoon everyone. I will start with a brief review of our full-year 2009 financial results and will follow that with more detail on the fourth quarter.

Revenues – Ron Spair

2009 revenues were $77.0 million, representing an 8.3% increase from the $71.1 million reported in 2008. Increased sales in the infectious disease, cryosurgical systems, and insurance risk assessment markets were partially offset by declines in sales of our substance abuse testing products and a reduction in license and product development revenues.

The overall 21% growth in our infectious disease revenues in 2009 was primarily a result of the higher average selling price for our OraQuick *ADVANCE*® HIV test realized under the direct sales model into the U.S. Hospital Market which we implemented last year along with continued volume growth in public health.

Our cryosurgical revenues increased 2% in 2009 compared to 2008. The increase is a result of higher sales into the international OTC market primarily to Genomma, our Latin American OTC distributor. Genomma successfully worked through its excess inventory levels from 2008, resumed purchasing from us for the Mexican market during the second quarter of 2009 and prepared for the Brazilian launch in December 2009. This increase was offset by lower sales into the international professional market of 24% as we ceased doing business with several international distributors that we believe were diverting product to the U.S. market.

Our substance abuse business decreased 14% in 2009 primarily as a result of lower sales of our Intercept® devices and assays. Intercept® continued to be negatively impacted in 2009 by the current recession and high unemployment levels in the domestic economy. However, we have seen this business stabilize during Q3 and Q4. Our primary drug testing lab partners have also indicated that they have seen stabilization in the downward trend of workplace testing.

Licensing and product development revenues decreased to $1.9 million in 2009 from $2.3 million in 2008 as a result of lower royalty-bearing sales by our licensee.

Gross Margin – Ron Spair

Our margin for the full year 2009 was 61%, an increase from 58% in 2008. Gross margin was favorably impacted primarily by our switch to the direct sales model for hospitals in 2009 and its related higher average selling price. Also benefiting margin during the year was an improvement in manufacturing efficiencies.

Operating Expenses – Ron Spair

Operating expenses for the year were $55.9 million compared to $52.6 million in 2008. 2008 operating expenses included a $4.9 million pre-tax gain related to a lump sum payment received under a favorable litigation settlement entered into during that year. 2009 operating expenses included a $3.0 million pre-tax impairment charge recorded in the second quarter related to the net book value of previously capitalized payments under a HCV patent license agreement and a $1.5 million pre-tax litigation settlement related to our patent infringement litigation with Inverness which was settled in the fourth quarter of 2009. Increased spending in sales and marketing and general and administrative expenses of $307,000 and $561,000, respectively, also contributed to the overall increase in operating expenses during 2009. Partially offsetting these increases was a decline in research and development costs of $6.9 million as a result of reduced clinical trial spending on our OraQuick® HIV OTC and OraQuick® HCV tests.

Net Income (Loss) – Ron Spair

Excluding the impairment charge in 2009 and the litigation settlements in 2009 and 2008, our adjusted pre-tax loss was $4.0 million in 2009 compared to an adjusted pre-tax loss of $13.6 million in 2008.

Now, I will turn to our quarterly results.

2009 Q4 Financial Results – Ron Spair

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

Revenues – Ron Spair

Total revenues for Q4 were $20.9 million, a 21% increase from the same period in 2008.

Overall infectious disease revenues increased 44% in the fourth quarter of 2009. Public health sales were up 19% over the comparable period of 2008. Hospital sales increased over 100% compared to the fourth quarter of 2008 due to the higher average selling price realized under the direct sales model implemented at the beginning of 2009 and higher volumes.

We are observing that an increasing number of our public health customers are also supplying hospitals with OraQuick® HIV tests purchased from us. This is a positive development as it indicates increased support of hospital testing initiatives by public health agencies. However, this overlap is making it more difficult to separately track OraQuick® sales to these markets. Since this trend is likely to continue, we intend to begin reporting public health and hospital sales as a combined market beginning in 2010.

International OraQuick® revenues were $2.1 million compared to $930,000 as a result of a 90% increase in sales to Africa. This increase was due to intra-year customer ordering patterns. Higher sales in Asia and Europe also contributed to the increase.

Fourth quarter 2009 cryosurgical revenues increased 8% compared to the fourth quarter of 2008 with revenue increases in the OTC market offset by decreases in the professional market.

International OTC cryosurgical sales were $1.8 million in the fourth quarter as a result of increased purchases by our Latin American OTC distributor, Genomma. As previously explained, Genomma resumed purchasing product from us in the second quarter 2009 after working through its excess inventory levels from 2008. In addition, Genomma launched our OTC cryosurgical wart removal product in Brazil during the fourth quarter. Sales to our European OTC distributor, SSL, declined $539,000 in the fourth quarter as compared to the fourth quarter of 2008. This decline was the result of an inventory build in the fourth quarter of 2008, which was not repeated in the fourth quarter of 2009, and a decrease in SSL’s transfer price in 2009.

Gross Margin – Ron Spair

Turning to Gross Margin, our margin for Q4 of 2009 was 59%, an increase from 56% for Q4 of 2008. The increase was largely due to the higher average selling price from our direct sales model as well as improvements in manufacturing efficiencies and a decrease in scrap and spoilage expense.

Operating Expenses – Ron Spair

Research and Development expenses for Q4 were down 14% or approximately $731,000 from 2008, primarily due to a $1.0 million patent license milestone payment made in the fourth quarter of 2008 which was required as a result of the filing of our OraQuick® HCV pre-market approval application with the FDA. This $1.0 million favorable variance was offset by an increase in clinical trial costs associated with our OraQuick® HCV test during the current quarter.

Sales and Marketing expenses increased 5% or approximately $273,000, mostly due to an increase in market research costs as we prepare to launch our OraQuick® HCV test in the European market in 2010.

General and Administrative expenses decreased approximately $1.0 million primarily due to higher costs accrued in 2008 in connection with the ending of our OraQuick® distribution agreement with Abbott Laboratories as well as a decrease in legal fees in 2009 resulting from the settlement of the patent infringement lawsuit filed against us by Inverness Medical and Church & Dwight.

During the quarter, we entered into several agreements with Inverness to settle the lawsuit. Pursuant to the terms of these agreements, we paid Inverness $3.0 million and Inverness granted us non-exclusive, worldwide licenses to certain lateral flow patents. We expensed $1.5 million of our payment directly through our statement of operations with the remaining balance recorded as a prepaid expense.

Net Income (Loss) – Ron Spair

From a net loss perspective, and excluding the settlement expense for the Inverness litigation, our adjusted pre-tax loss would have been $2.0 million, or $0.04 per share. This compares to a pre-tax loss of $5.7 million or $0.12 per share for the same period in 2008.

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 $79.7 million and working capital of $89.4 million at December 31, 2009. During 2009, we used $293,000 in cash flow from operations compared to $2.5 million used during 2008. Day sales outstanding increased to 65 days from 60 days in 2008. This was caused by an increase in our hospital receivables as well as an increase in hospital shipments in the fourth quarter of 2009 compared to the fourth quarter of 2008.

Q1 Financial Guidance – Ron Spair

Turning to guidance — For the first quarter of 2010, we are projecting revenues of approximately $19.0 to $19.5 million and a net loss per share of approximately $0.06 to $0.07.

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

Clinical Programs Update – Doug Michels

Thanks Ron. We made progress in all of our major clinical programs during 2009. This progress will help fuel our growth in 2010 and beyond.

OraQuick® HCV – Doug Michels

A major milestone last year was the receipt of CE mark approval for our OraQuick® HCV test. As you know, CE mark approval is required to sell the product in the 27 member countries of the European Union.

Although some European countries have individual registration requirements, many simply require notification that CE mark approval has been obtained. We have notified virtually all member countries of the EU and we are pursuing several country-specific registrations where needed.

Our launch plans for OraQuick® HCV in Europe are under development. We are identifying distributors and we are discussing the promotional support to be provided under our collaboration with Schering/Merck. We intend to announce the commercial launch of our test at a meeting of the Association for the Study of the Liver, or EASL, scheduled for April of this year. While we believe there is a public health need for rapid HCV testing in Europe, the actual commercialization and uptake of the test will likely be a gradual process as we attempt to create awareness and product acceptance.

On the domestic front, we continued to advance our clinical development program. As previously announced, we recently filed a pre-market approval ("PMA") application amendment which contains the additional clinical data requested by the FDA for use of the OraQuick® HCV test on venous whole blood samples. This additional data was very strong and is under active review by the agency.

Last year we initiated an additional study requested by the FDA for fingerstick whole blood and oral fluid claims. This study remains on schedule and is likely to take the rest of the first quarter to complete. We intend to file our results with the FDA as soon as possible after completing the study. At the same time, we are finalizing preparations for a pre-approval facility inspection by FDA and we are waiting to hear from the agency as to the specific timing.

We have also been developing a proposed protocol for our CLIA waiver study. Discussions with FDA have occurred and we expect these will continue through the end of this quarter. The actual study should start towards the middle of the year. We intend to submit the results of our CLIA study as soon as possible after we receive FDA approval for our fingerstick whole blood or oral fluid claim.

With respect to shelf life, our OraQuick® HCV test in Europe is being launched with product dating of 18 months. This was based on real time stability studies in which product met acceptance criteria for storage for 20 months at 30°C. Data from these ongoing stability studies will also be used to support approval of product dating in the U.S.

We continue to believe there is a need in the U.S. and around the world to increase hepatitis testing and that a rapid HCV test can be an important tool for healthcare providers. You may have seen a report recently issued by the Institute of Medicine, which is a branch of the U.S. National Academy of Sciences. This report confirms the need to increase health services related to both HCV and Hepatitis B, including testing, and urges federal and state agencies to increase funding for these programs.

HIV OTC – Doug Michels

Turning to our clinical program for an OraQuick® HIV OTC test, as previously discussed we participated in a meeting with the FDA's Blood Products Advisory Committee, or BPAC, in mid-November. The meeting was very productive. For those of you that attended or read the transcript from the meeting, you know that there was a tremendous showing of support at the meeting by representatives of the public health and HIV/AIDS communities.

During a portion of the session closed to the public, we reviewed with the Committee the results of our clinical studies and our view of the additional clinical work needed for approval. The BPAC indicated we could move forward with our clinical program and provided important guidance as to what will be required for final FDA approval of this product.

Since the BPAC meeting, we have engaged in regular dialogue with the FDA about the next phase of clinical testing. Recently, we prepared and are filing in the next several days an amendment to our Investigational Device Exemption, or IDE, which contains a proposed protocol for the final phase of clinical studies for review and comment by the FDA. Upon receiving feedback and comments from the FDA, we will make whatever revisions are warranted to the protocol and re-submit for official approval. We would expect the review and IDE approval process to occur over the next several months. Upon FDA approval, we are permitted to finalize setting up the clinical sites and begin actual subject enrollment for the final round of clinical testing. Assuming a timely IDE approval, we expect clinical testing to extend into 2011. Once the study is completed, we will submit our data and expect that another BPAC meeting will be needed before an approval can be issued by the FDA.

The productive and positive meeting with BPAC and the significant progress made in our subsequent discussions with the FDA reflect the great work of our Regulatory, Clinical and R&D groups. Getting to this stage of development for what would be the first ever FDA approved rapid HIV OTC test, is a huge accomplishment. We have gained greater clarity on the path forward and remain confident that approval is within our reach. We are very pleased with our progress and excited about the opportunity this product represents.

High Throughput Assays and Substance Abuse Testing Business – Doug Michels

In the Substance Abuse Testing area, our collaboration with Roche Diagnostics for fully automated homogeneous drugs of abuse assays continues to go well.

As discussed in prior calls, this collaboration initially focused on the development of a NIDA-5 panel of assays for marijuana, cocaine, opiates, PCP, amphetamines and methamphetamines. Submissions for FDA 510(k) clearance were filed at the end of 2009 for four of these assays, and we expect the other two, cocaine and marijuana, to be filed this year. Our hope is that 510(k) clearance will be received for all but the marijuana assay later this year, at which time we expect to launch with Roche a partial NIDA-5 panel for use with our Intercept® collector in the workplace testing and other markets.

Shortly after the new year started, we announced the signing of a worldwide commercialization agreement with Roche for the newly developed assays and our Intercept® device. The agreement is structured to take advantage of each party's strengths. Our contribution is an established market presence with oral fluid drug testing, primarily in the United States. Roche has an established base of automated analyzers and extensive marketing capabilities, particularly in international markets.

We will exclusively serve the U.S. and Canadian criminal justice markets and have exclusive marketing rights to the UK. We will jointly serve the U.S. workplace market and Roche will exclusively serve other international markets. We believe the new automated drug testing system will be enthusiastically received by our lab customers.

OraQuick® HIV Performance and Shelf Life – Doug Michels

During 2009, we also made some important enhancements to our OraQuick® HIV Test.

As previously discussed, several enhancements were implemented during the first half of the year, which enabled us to extend our FDA-approved shelf life to 12 months. This increase in shelf life has improved our ability to manage inventory and has strengthened the competitive position of our OraQuick® HIV test. This is particularly true in international markets, where there was a greater need for a longer shelf life due to the more complicated distribution logistics.

We have continued our real time stability studies for this product and now have data for 17 months. Later this year, we expect to request FDA approval for a product dating extension to 18 months. We will continue our ongoing stability studies to support additional dating extensions for the product.

During 2009, we also enjoyed outstanding field performance by our OraQuick® HIV test. We have continued collecting data from our sentinel sites and this data, which reflects over 185,000 test results, indicates that our oral fluid test performed at a 99.94% specificity last year, which is at the very top of the range reflected in our FDA approved claims. We expect that these field performance results will soon be published.

Organization Changes – Doug Michels

In 2009, we continued to strengthen our organizational capabilities. As you know, we added a new Vice President, Marketing and Sales and a new Vice President, Regulatory Affairs and Quality Assurance during the year. We also filled a vacancy at Vice President, U.S. Sales with an internal promotion. These individuals have outstanding qualifications and are already making significant contributions in their respective positions.

More recently, Nancy McLane joined our company as the new Vice President, Operations. She will be taking over the manufacturing, facilities management and quality control functions previously handled by Mike Formica. As you may recall, last year we asked Mike to manage our worldwide professional and OTC cryosurgical products, and he is now devoting 100% of his time to this part of the business.

Nancy brings with her over 20 years of experience in medical device manufacturing at several leading healthcare companies. Most recently, she served as Senior Vice President at LifeSync Corporation where she was responsible for operations, QA, regulatory affairs, global supply chain management and customer service. Prior to that, she held senior operations positions at Cords Corporation and C.R. Bard. We are very happy that Nancy has joined our management team.

Business Update – Doug Michels

And now, I would like to provide some additional perspective on various aspects of our business.

OraQuick® HIV

As Ron indicated, revenue growth in 2009 was primarily the result of higher sales of our OraQuick® HIV test. A number of factors contributed to this growth and will help set the stage for continued growth in 2010.

- A major achievement during 2009 was the deployment of a new direct sales force for the U.S. hospital market and the successful transitioning of business from our prior distributor, Abbott Labs.

- As part of the Abbott transition, we renewed or secured new purchase agreements with all major hospital Group Purchasing Organizations in the U.S., including most recently Premier and Health Trust Purchasing Group.
- We also began to secure new business with VA hospitals after the Department of Veterans' Affairs announced a policy change eliminating the need for written consent and mandated pre- and post-test counseling.
- In public health, we successfully renewed contracts with a number of key customers, including New York, Florida, Chicago and the District of Columbia.
- On the international front, we gained additional traction during 2009, with growth of almost 40%, primarily due to higher sales in Asia, Latin America and Europe.
- Finally, we settled the patent infringement lawsuit filed by Inverness and Church & Dwight that targeted our OraQuick *ADVANCE*® test. The settlement terms are very favorable and will provide opportunities to grow our business with new product offerings.

Our OraQuick® HIV test is the most versatile on the market, and we believe it continues to be well positioned competitively. Our sales and marketing efforts continue to focus on maximizing new opportunities – especially in the U.S. hospital marketplace. In public health, we expect to support the expansion of several major city testing initiatives in 2010 and to continue to grow this important segment. Lastly, we believe 2010 will be a strong year internationally, with sales growth comparable to 2009.

Cryosurgical Systems Business

Turning to cryosurgery, although revenues from this business were only up slightly last year, there have been a number of developments which should position this business for future growth.

- We are now seeing evidence that our efforts to reduce diversion by foreign distributors into the U.S. market are working. This should help return our Histofreezer® sales in the domestic professional market to a more normal pattern.

- Earlier this year, we signed agreements with two manufacturer's sales representative organizations. Under these arrangements over 40 additional sales reps will be working with our physicians' office distributors throughout the United States and should contribute to domestic Histofreezer® sales growth.
- At the end of 2009, our Latin American OTC distributor, Genomma, successfully launched our OTC product in Brazil. We believe Brazil represents a substantial opportunity. Based on initial product orders, this launch seems to be going very well.

As we move into 2010, we have a number of priorities for our cryosurgical products. We are considering a change to the distribution model currently in place for our European OTC product in order to better serve some of the European countries outside of the UK. We are also focused on improving our distribution network for Histofreezer® in international markets. Finally, we are working to expand the number of retail outlets here in the U.S. that carry our national OTC brand, Freeze 'n Clear Skin Clinic™.

Substance Abuse Testing

In the substance abuse testing area, the continued economic challenges, high unemployment and reduced funding negatively impacted our business during 2009. However, our revenues were a bit more consistent in the second half of 2009, and we believe this business is now stabilizing and that the biggest negative impact from the economy is behind us. We expect the launch of high throughput assays with Roche beginning later this year will be an important factor in helping to get this business growing again.

Operations

Finally, I want to highlight two items in Operations.

During 2009, our Operations group played a critical role in successfully resolving the manufacturing issue impacting our OraQuick® HIV test. This group was integral to resolving the issue, and resumed full scale production almost immediately after the issue was resolved. By replenishing our critical inventory levels, we were able to eliminate a large second quarter backlog with minimal negative customer impact. The hard work of our Operations group, along with our R&D personnel, was invaluable in overcoming a difficult challenge.

More recently, we submitted our OraQuick® automated manufacturing line for validation by the FDA. This is an important filing, as we believe the use of full automation will improve efficiency in our manufacturing and help us be prepared to meet the future demand for our OraQuick® HIV test.

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

[Q&A session]

Conclusion – Doug Michels

Thank you for participating on today's call. We believe the Company is extremely well positioned for continued growth and we look forward to updating you on our progress. Thank you for your continued interest in OraSure. Have a good afternoon and evening.

Important Information

This document contains certain forward-looking statements, including with respect to revenues, net income/loss, 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; impact of the economic downturn, high unemployment and credit crisis; 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 carry forwards 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.