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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): August 5, 2008

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**OraSure Technologies, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-16537**  
(Commission File Number)

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

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

**18015-1360**  
(Zip Code)

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

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

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

On August 5, 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 June 30, 2008, described certain business developments and provided an update on financial guidance for the third quarter 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**

<u>Exhibit Number</u>	<u>Description</u>
99	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2008 Analyst/Investor Conference Call Held August 5, 2008.

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**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: August 5, 2008

By: /s/ Jack E. Jerrett

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Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

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**Index to Exhibits**

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99	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2008 Analyst/Investor Conference Call Held August 5, 2008.

OraSure Technologies, Inc.

2008 Second Quarter

Analyst/Investor Conference Call

August 5, 2008

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

**Please see "Important Information" at the conclusion of the following prepared remarks.**

**Introduction – Doug Michels**

Thanks Judy,

Good afternoon everyone, and welcome to our second quarter 2008 earnings conference call.

In a press release issued earlier today, we announced our Q2 results and provided an update of our Q3 financial guidance. Ron Spair will review both in a few minutes. Our second quarter revenues were in line with our guidance and we did a bit better than our guidance on the bottom line. As Ron will explain further, we are changing our policy for updating forward-looking guidance beginning with this call to provide a forecast for only the next quarter, in this case Q3.

Following Ron's remarks, I will address the recently reported performance issues involving our OraQuick® test and then describe additional business developments, including the progress we are making in our major clinical and development projects. We will then conclude the call by opening the floor for your questions.

Before turning the call over to Ron, I would like to address two other announcements made earlier today.

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## **Stock Repurchase Plan**

Before today's call, we issued a second press release announcing a share repurchase program. Under this program, we may purchase up to \$25 million of our common stock, based on market conditions, at times and prices to be determined in our discretion.

Our Board of Directors has authorized this repurchase program primarily because we think the price of our common stock does not reflect the earnings potential of the Company. While we are working through near-term challenges in certain segments of our business, we are confident that achievement of the Company's long-term goals is still on track. Specifically, the replacement of lost revenue from the cryosurgical channel has been a significant challenge. Not surprisingly, when guidance was adjusted lower earlier this year, the stock sold-off, putting downward pressure on the stock price. Moreover, the news regarding discordant results with the use of OraQuick® for oral fluid tests in the New York City STD clinics put further pressure on the stock.

We are actively taking steps to address the issues that have pressured the stock. Starting in Q1 2009, we plan to return to the US market with an OTC cryo product and begin to rebuild that channel. We are also nearing the point in time when we will be able to extend the shelf life of our OraQuick® domestic product, and we are on track with our HIV-OTC and HCV clinical programs. Finally, our infectious disease business continues to grow and we believe we are well positioned to compete in that market.

After considering the above factors, we believe now is an appropriate time to initiate a share buyback program. Our strong balance sheet will allow us to repurchase shares based on current market conditions.

## **Organizational Changes**

Earlier today, we also announced some organizational changes in a Form 8-K filed shortly before the call.

In reviewing our recent business performance, we have decided to take several steps to improve certain areas of our business, which in turn should improve our operating results. These actions will enable us to sharpen our focus on the key drivers of our business and accelerate achievement of the high potential value of our strategic programs. Specifically, these actions will initially involve some reassignments of executive responsibilities and a significant organizational change.

First, Joe Zack, OraSure's Executive Vice President, Marketing and Sales, will be leaving the Company as of August 29. Joe has been an important part of senior management at OraSure for the past 6 years. Joe has agreed to consult with us as he moves out of the Company and will provide transitional support and assistance with our sales and marketing programs.

Effective immediately, I will personally assume responsibility for the day-to-day operation of our Sales and Marketing Department. As you know, before joining OraSure, I spent 20 years at Johnson & Johnson with many of those years in senior sales and marketing positions, both in the U.S. and internationally. I intend to use this experience to drive our sales and marketing efforts in our infectious disease and substance abuse testing businesses. My direct, day-to-day involvement has already begun and is critical not only to improving our existing business performance but also to maximizing our future opportunities once we obtain FDA approval of our OraQuick® HCV test and OraQuick® HIV test for sale over the counter.

A second change within Sales and Marketing is in the international arena. Our current Vice President, International Sales will be leaving the Company at the end of August. International markets continue to be an important component of our overall business, and our plan is to bring in additional depth and experience in this area. Once a new head of international sales is appointed, that individual, along with the heads of our domestic sales organization and our marketing organization, will report directly to me.

We have also decided to make a significant organizational change involving our cryosurgical systems business. We believe this business can achieve a significantly higher return than shown by our results over the past few years. In addition, as previously disclosed, we plan to be back in the U.S. OTC cryosurgical market beginning in 2009. It is therefore critical that we focus additional management attention on this business. To do so, we are establishing a global cryosurgical systems business unit which will be headed by Mike Formica, who is currently the Company's Executive Vice President, Operations. Mike will assume the new position of Executive Vice President and General Manager for Cryosurgery and will focus exclusively on our cryosurgery franchise worldwide.

Mike joined the Company in 2000 and has made substantial contributions to our operations, particularly on the manufacturing side. However, Mike has much broader management experience. Prior to joining OraSure, he was Division Manager, Mobile Measurement Technologies for an affiliate of Dräger Safety AG in Lubeck, Germany. Mike held this position for eight years and had worldwide responsibility for all facets of the business unit, including marketing and sales, and operations. We believe this experience can be more fully utilized by giving Mike direct and complete responsibility for the cryosurgical business and provide more focus on this important business.

Mike's responsibilities will include both the professional and over-the-counter cryosurgical product lines, along with ancillary support functions for these products. Mike will also continue to oversee operations under the direction of Ron Spair until a new head of operations is recruited and hired.



The foregoing changes are an important part of our efforts to reinvigorate and refocus our current operations and plan for new product offerings as we achieve our strategic development goals. We are working hard to accelerate this process and will continue to evaluate whether additional changes are needed.

And with that, let's move to Ron's financial overview.

### **2008 Second Quarter Financial Results – Ron Spair**

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

#### **Revenues – Ron Spair**

Total revenues for Q2 were in line with guidance at \$18.9 million. Increased sales of our OraQuick *ADVANCE*<sup>®</sup> and insurance risk assessment products and higher product development revenues, were offset by expected decreases in revenue from our cryosurgical products and lower substance abuse testing sales.

A 9% growth in our infectious disease revenues was the result of continued strong performance by our OraQuick *ADVANCE*<sup>®</sup> HIV test in an increasingly competitive environment. Sales to public health during the quarter increased 25% over 2007, as a result of continued growth in our base business and incremental sales driven by the Centers for Disease Control and Prevention's ("CDC") efforts to increase HIV testing among populations disproportionately affected by HIV. International sales of OraQuick<sup>®</sup> increased 36% compared to the same period in 2007, largely as a result of a 48% increase in revenues from Africa. Our sales to Abbott decreased 4% as a result of their ordering patterns for the U.S. hospital market.

Our cryosurgical revenues during Q2 experienced an overall decrease of 53% compared to 2007. This was expected because of the absence of U.S. OTC sales in the current quarter resulting from the termination of our distribution relationship with Prestige Brands at the end of 2007. Second quarter 2007 sales to Prestige were \$983,000. Our international OTC sales for the second quarter 2008 were \$1.1 million, a 64% decrease from 2007 that resulted from reduced sales in Europe as well as the absence of sales in Mexico. As we explained during our first quarter conference call, our Latin American distributor, Genomma, reduced its purchasing levels this year in response to an increase in returned product from retailers due to overstocking during the winter months. Second quarter cryosurgical sales to the international professional markets increased 30% to \$665,000, offset by a decrease in US professional sales of 26%. This decrease has been traced to diversion of some lower priced Histofreezer<sup>®</sup> product from several International distributors into the U.S. professional market. We intend to address this diversion by increasing our international pricing and enforcing contractual rights against certain international distributors.

In substance abuse testing, sales were \$3.7 million for the second quarter, a 16% decrease compared to 2007. Sales of our Intercept<sup>®</sup> drug testing system totaled \$2.9 million, a 19% decrease from 2007. Our total workplace testing business was down 36% and our international sales were down 11%. Our criminal justice and direct sales grew 7% and 25%, respectively, 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 that buy our Intercept<sup>®</sup> product. The international market has also experienced a decrease in public sector funding which has slowed the implementation of drug testing in those markets.

Finally, insurance risk assessment sales in the second quarter were \$1.7 million, up 25% compared to \$1.4 million in the comparable period of 2007. While we are adding new accounts for this product line, the increase in the current period was largely caused by lower sales during the early months of 2007.

Second quarter 2008 licensing and product development revenue included \$804,000 in royalties from Schering-Plough related to sales of their OTC cryo product in the U.S. market. Second quarter 2007 revenues included \$649,000 of funded research and development under our domestic HCV collaboration agreement with Schering-Plough.

**Gross Margin – Ron Spair**

Turning to Gross Margin, our margin for Q2 of 2008 was 59%, a decrease from 63% for Q2 of 2007. The margin decline for the current quarter was primarily due to an unfavorable product mix versus the year ago period.

**Operating Expenses – Ron Spair**

Research and Development expenses for Q2 were up 85%, or approximately \$2.8 million or \$0.04 per share after taxes, over 2007, largely as a result of costs associated with our ongoing OraQuick® HIV OTC and HCV clinical development programs.

Sales and Marketing expenses decreased 5%, or approximately \$287,000, mostly due to a decrease in advertising reimbursement costs related to our international OTC cryosurgical products and decreased consulting costs in our marketing department. These lower costs were partially offset by increased staffing and related charges.

General and Administrative expenses decreased approximately \$435,000, largely as result of a decrease in legal costs compared to the second quarter of 2007.

**Net Loss – Ron Spair**

From a bottom line perspective, we reported a net loss of \$2.2 million, or \$0.05 per share, which is slightly above our guidance. This compares to net income of \$955,000 or \$0.02 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 \$91.0 million and working capital of \$104.4 million at June 30, 2008. During the first six months of the year, we used \$1.9 million in cash flow from operations compared to \$2.7 million provided from operations during the first six months of 2007. The use of cash in 2008 was largely due to decreased net income and payments of royalty obligations and legal expenses that were accrued at the end of 2007, as well as an increase in our inventory and accounts receivable balances. Days sales outstanding was at 61 days compared to 63 a year ago.

Now turning to our financial guidance update - -

**Third Quarter and Full Year 2008 Financial Guidance – Ron Spair**

As Doug discussed earlier in the call, there are many developments and factors that will make it difficult to provide the investment community with long-term forward looking guidance. After much consideration, we have decided to change our guidance policy. We have always strived to provide accurate and timely guidance but for the following reasons, we think it is prudent to limit our forecasts to the upcoming quarter at this time.

As you know, we are in the process of two major clinical initiatives and a patent infringement lawsuit with Inverness and Church & Dwight. Spending levels can vary substantially based on the pace of clinical trials and timing of litigation. On the revenue side, there is also the potential for variability given the timing of purchase orders. Rather than issue guidance with broad ranges, we prefer to provide short-term guidance that is more specific. Therefore, until we are able to provide longer-term guidance with more confidence, we will be issuing forward looking guidance only for the upcoming quarter at each quarterly call.

With respect to the third quarter, we now project that revenues will be in the range of \$16.0 - \$16.5 million, and our loss per share will approximate \$0.09. In the aggregate, this would bring our total revenues through September 30, 2008 to between \$53.5 and \$53.8 million. We would expect to provide updated guidance for the rest of 2008 during our Q3 conference call.

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

**Business Update – Doug Michels**

Thanks, Ron. We will now discuss various strategic and other business matters.

**OraQuick Discordant Results – Doug Michels**

As you know, there were recent reports by the CDC and in the media regarding a slightly elevated number of discordant results from use of our OraQuick ADVANCE<sup>®</sup> HIV test with oral fluid at several STD clinics operated by the New York City Department of Health and Mental Hygiene. While discordant results did occur at these clinics, we believe the public reporting of these events was not very balanced and did not present an accurate or complete picture of the performance of our test.

- All screening tests generate a certain percentage of false positive results. This happens with our test as well as the blood tests sold by our competitors. That is one of the reasons why specimens that screen positive for HIV must be confirmed by additional testing.
- Data from the STD clinics in New York for the period October 2007 to April 2008 showed an average specificity of 99.4%, or 0.2 percent below the lower end of the expected range of specificity of 99.6 % for our OraQuick ADVANCE<sup>®</sup> test. In terms of overall accuracy, the deviation from expected performance occurred during a limited period at a small number of testing sites.

- As we previously announced, we have collected national surveillance data for approximately 400 sites and over 250,000 individual tests during the same time period as the New York City data. This data indicates that our test performed at 99.8% specificity across the country, excluding the New York data. Moreover, specificity with oral fluid in the New York City STD clinics returned to 99.9% during the month of May with nearly 5,000 oral fluid tests performed. This performance is at the upper end of our FDA-approved label claims.
- Contrary to the suggestion in many media reports, New York City did not stop purchasing or using our test. OraQuick *ADVANCE*<sup>®</sup> continues to be used for HIV screening with blood samples in the STD clinics, and with oral fluid and blood at HIV and TB clinics throughout the City.
- Our FDA-approved labeling for the OraQuick *ADVANCE*<sup>®</sup> test indicates that the test is slightly less specific when used with oral fluid compared to when it is used with blood, i.e. 99.8% vs. 99.9%. However, our OraQuick oral fluid test is actually **more** specific than several of the competing rapid laboratory-based HIV blood tests.
- Because of its accuracy, ease of use and noninvasive nature, rapid oral fluid testing with OraQuick *ADVANCE*<sup>®</sup> has substantially increased the number of individuals who get tested in New York City. In fact, data at some sites indicates testing increased by as much as 30% due to the availability of oral fluid testing. It is not surprising that oral fluid is often the testing matrix strongly preferred by both patients and testing sites over blood.

The OraQuick<sup>®</sup> test has and continues to work exceptionally well despite New York's recent experience. Nevertheless, we are determined to figure out why New York experienced a slight deviation from expected performance earlier this year. We have met with both the City and the CDC to investigate the discordant results and are committed to determining the root cause of their experience, if possible. We are also currently undertaking our own experimental and clinical studies to determine if there are any potential site-specific or patient factors which could have caused the discordant results. These factors have not yet been ruled out.

Although finding the root cause for the New York City discordant results is a top priority, this is not an easy task. Our OraQuick *ADVANCE*<sup>®</sup> test continues to perform at a very high level and within its FDA approved claims throughout the country. The reports of false positives that we have seen in the past and more recently in New York City appear to be infrequent and not widespread. Moreover, as was the case with New York City, any deviation from our label claims is usually quantitatively very small. The bottom line is that we remain confident in the performance of the product and believe it will continue to be widely used and play an important role in the fight against HIV/AIDS.

On a related topic, there was an article published yesterday in the *Annals of Internal Medicine* regarding an early 2007 study by Brigham and Women's Hospital on the rate of false positive results with the use of the OraQuick *ADVANCE*<sup>®</sup> oral fluid test in a low prevalence hospital emergency department population. The authors of the study concluded that there is a higher rate of false positives when using the OraQuick<sup>®</sup> oral test with this population. However, these results are not consistent with other published studies and our own national surveillance data which have affirmed that the test performs as expected and according to product claims. For example, a study published in late 2007 where OraQuick<sup>®</sup> was used to screen almost 2,500 emergency department patients at George Washington University Medical Center demonstrated specificity of 99.8%, which is directly within our FDA-approved label claims.

#### ***HIV-OTC – Doug Michels***

Turning to our clinical development programs, the ongoing clinical work to obtain FDA approval for an OraQuick<sup>®</sup> rapid HIV OTC test continues to go extremely well.

As previously discussed, we started our observed user clinical study earlier this year, where we 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 observes those activities. This study was initiated in April, and I am happy to report that we recently completed testing for the first 1,000 subjects, and believe we have met the stopping criteria under our protocol. What this means is that at a predetermined point in the testing we were permitted to examine the data to see if we have met the 95% confidence intervals for specificity and sensitivity thresholds initially established by the FDA for this phase of the trials. We believe the data shows this and we have stopped the observed user study.

Another requirement of this study was to identify a minimum of 10 previously unidentified HIV positive individuals. We also successfully met this criteria. Twelve newly identified HIV positive individuals were found in our testing of healthy subjects and all 12 initially HIV positive persons have been confirmed positive by Western blot.

We are now compiling the data and intend to submit it to the FDA for its review. We have also requested a meeting with the FDA to review this information and discuss the next steps. This is all extremely promising, and we expect to meet with the FDA and move this project forward as quickly as possible so that a final submission can be made.

One final item I want to mention is the performance of our resource and referral system for consumers during the observed user study. This call center was available throughout the trial and was manned by trained and certified call agents and performed very well. Specifically, approximately 5% of the subjects during the trial interacted with the call center. This level of interaction provided valuable information that will enable us to estimate the expected usage of the call center and the types of questions and requests we can expect to receive once the product is being sold to consumers. Moreover, the system was challenged by an unexpected power outage



resulting from a severe storm, during which our contingency operational plan was successfully implemented without disruption of service to our clinical trial subjects and demonstrating the robustness of the system as designed.

Overall, this project is progressing exceptionally well. Our schedule remains on track, and we look forward to updating you on additional developments as they occur.

**OraQuick® HCV – Doug Michels**

Additionally, we have made excellent progress in our clinical trials to support both our PMA submission to the FDA and our request for CE mark approval in Europe of an OraQuick® HCV test. We have completed enrollment of patients for the main clinical study to support product claims. We are currently engaged in data analysis and writing clinical reports, as well as preparing other required manufacturing and quality documentation to include in our FDA and CE submissions. We expect to file our initial PMA application with the FDA in September and to submit for European approval shortly thereafter.

In addition, we are engaged in collaborations with various scientific and medical groups, both in the U.S. and Europe who are interested in evaluating the performance of the OraQuick® HCV test. The purpose of these studies is to evaluate the utility of the product in typical use settings and in the hands of independent testing centers prior to launch. These studies will continue throughout the year, and we expect results to be published in the near future.

**OraQuick® Stability – Doug Michels**

Our efforts to extend the shelf life of our OraQuick® HIV test also continue to progress smoothly.

We now have completed stability testing for 14 months, and we have submitted this data to the FDA in support of a request for shelf life extension. This improvement in stability is based on process changes in the manufacture and packaging of the OraQuick® device that we submitted to the FDA previously. The FDA has requested a small additional study in support of the process changes, which we plan to perform in the next month and then submit to the FDA.

For markets outside the U.S. and Europe, we recently extended the shelf life and product dating of OraQuick® to twelve months, based on previously generated stability data. This applies to product manufactured by our Thailand supplier. In the next 30 days, we expect to request a shelf life extension to twelve-months from our notified body in the EU.

We are pleased with the progress made so far on extending the shelf life of our OraQuick® HIV test, and we continue to make this a top priority.

**High Throughput 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 extremely well.

The initial launch menu will be a NIDA-5 panel consisting of amphetamines, methamphetamines, cocaine, opiates, cannabinoids or THC, and phencyclidine or PCP. Performance data for several of these tests was recently presented at the American Association of Clinical Chemistry held in Washington, D.C. during a workshop on oral fluid drug testing that we co-sponsored with Roche Diagnostics. In addition, we recently conducted successful evaluations of several prototype automated assays at consumer sites, and we expect to expand these evaluations at other sites throughout the year.

**New HIV Immunoassay – Doug Michels**

A final development project that we have mentioned in prior calls is to obtain FDA approval of a new HIV lab-based enzyme immunoassay, or EIA, for use in testing oral specimens collected with our OraSure® collection device. The OraSure® device is used primarily in the insurance risk assessment testing and public health markets. As you may recall, last year bioMérieux indicated that it would cease manufacturing the only HIV-1 immunoassay approved for use with our OraSure® collection device.

We have identified another blood-based HIV-1 immunoassay which, with some optimization, we believe can be used with oral specimens collected with an OraSure® device to screen for HIV-1. The optimization is close to being finalized, and we are preparing to launch clinical trials to obtain FDA approval of this assay for use with the OraSure® device. These clinical trials will also incorporate the use of our oral fluid Western blot as the confirmatory test for oral specimens that initially screen positive with the new assay.

We expect these clinical trials to start shortly. Our submission to the FDA will be made as soon as possible after they are concluded.

**Litigation Update – Doug Michels**

As you know, a lawsuit was filed against OraSure by Inverness and Church & Dwight for patent infringement under one of their U.S. patents. We have filed a response to the complaint and a scheduling conference is planned for August 7. We would expect discovery to start later this year and extend through most of next year. Any trial would likely occur some time after that.

We continue to believe that our OraQuick® ADVANCE HIV test does not infringe

the patent asserted in this lawsuit and that the Inverness and Church & Dwight patent is invalid and unenforceable. Additional updates on material developments will be disclosed as they occur.

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

**[Q&A session]**

**Conclusion – Doug Michels**

I want to thank everyone 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; 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; 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 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.