# 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): August 8, 2006

# **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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-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 August 8, 2006, 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, discussed the Company's financial results for the quarter and six months ended June 30, 2006 and provided an update on financial guidance for the third quarter and full year 2006. A copy of the prepared remarks of Messrs. Michels and Spair is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

### Item 9.01 - Financial Statements and Exhibits.

#### (d) Exhibits

Exhibit

Number Description

99 Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2006 Analyst/Investor Conference Call Held August 8, 2006.

# 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.

Date: August 9, 2006

ORASURE TECHNOLOGIES, INC.

By: /s/ Jack E. Jerrett

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

# Index to Exhibits

<u>Exhibit No.</u> 99

Description
Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2006 Analyst/Investor Conference
Call Held August 8, 2006.

#### **OraSure Technologies, Inc.**

#### 2006 Second Quarter Analyst/Investor Conference Call

#### August 8, 2006

# 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 Shannon,

Good afternoon everyone and welcome to our second quarter 2006 earnings conference call. We're very glad you have joined us.

For this afternoon's call, I will first review our financial performance for the quarter and various developments involving our product lines. Our Chief Financial Officer, Ron Spair, will then provide a more detailed review of our financial results for Q2 and our expectations for the rest of the year. Throughout my prepared remarks, I will, where appropriate, also provide an update on the progress we are making against our strategic initiatives. We will conclude by opening the floor for questions.

# Financial Overview- Doug Michels

Second quarter revenues were higher than we last projected, coming in at \$17.6 million. This compares to revenues of \$17.4 million in Q2 2005. Increased revenues from the substance abuse testing and cryosurgical systems markets were partially offset by lower revenues in insurance risk assessment testing. We also received a strong contribution from our infectious disease business.

Net income for Q2 was also somewhat higher than expected at \$1.2 million, which represents \$0.03 per share on a fully-diluted basis. This compares to net income of \$1.4 million, or \$0.03 per share during Q2 of 2005. The current quarter includes the impact of stock option expensing and is fully taxed while the results for the second quarter of 2005 do not reflect these items. As Ron will explain, eliminating these items illustrates the substantially improved bottom line results we delivered for the current quarter.

Our cash and liquidity position remained strong at the end of the quarter. We had \$84.6 million in cash and short-term investments and about \$96.8 million in working capital at the end of Q2.

Now let me turn to some highlights for each of our product lines. Starting first with our infectious disease business - -

#### **Business Review – Doug Michels**

#### **OraQuick**<sup>®</sup>

Although revenues for infectious disease testing during the second quarter were flat compared to the same period in 2005, we are very pleased with the sales performance of our OraQuick *ADVANCE* test. We saw continued strong demand, as illustrated by an 82% increase in sales of OraQuick to the public health market and a 123% increase in the hospital market. These increases completely offset the substantially lower sales of OraQuick under bulk government orders and some reduction in sales of our OraSure oral fluid collection device.

As I have previously explained, one of our top priorities has been to secure additional large bulk orders for OraQuick *ADVANCE* from the CDC and other government agencies. In the second quarter, we were successful in obtaining another such order from the CDC, which has committed to purchase an additional \$2.3 million of our OraQuick tests. We expect this order to be entirely deployed this year. Earlier in the year, we also received an additional \$500,000 order from the Substance and Mental Health Services Administration, or SAMHSA, in connection with SAMHSA's continuing testing initiative.

While we are certainly pleased with these additional orders, we have not yet shipped product under the SAMHSA order because of delays in completing contract negotiations with a third party logistics firm used by SAMHSA. We also shipped less than 15% of the CDC order during Q2. As a result, we expect to realize the benefit of these orders during the second half of this year.

We continue to believe that demand for additional bulk orders remains strong. Our customers have confirmed that the demand for our OraQuick test exceeds the orders we have received to date. Consequently, discussions with the CDC and other agencies regarding additional bulk orders are continuing.

Support for additional orders and a significant expansion in rapid HIV testing is also seen in statements from President Bush and developments in the budget process for 2007. In several recent speeches, the President has reiterated his support for expanded use of rapid HIV testing. More importantly, we believe there is a strong likelihood, in light of the \$90 million proposed by President Bush for the purchase and distribution of rapid HIV test kits, that a significant amount of funding for rapid testing will eventually be approved by Congress. We are watching the budget process carefully and will continue efforts to access new funding for rapid HIV testing that is ultimately approved.

Apart from the federal government, we have also had some recent significant success working with several

major cities who intend to substantially increase their HIV testing efforts. On June 27, which was National HIV Testing Day, the District of Columbia announced a major new initiative to offer increased HIV testing services with OraQuick *ADVANCE*. The program, which we created is called "Coming Together to Stop HIV in DC", and has established the goal of ensuring that all of the approximately 500,000 District residents know their HIV status by 2007. The program was driven by the fact that DC has the highest rate of new HIV infections among major U.S. cities, with approximately 1 in 50 DC residents now living with HIV/AIDS. It is estimated that 25% of those infected do not know their status, and they account for about 55% of new HIV infections. The District has given us an initial purchase order for 75,000 units, and we expect an additional order later this year. We are excited to be working with the District and are committed to the success of this important initiative. We are now using the D.C. Initiative as a model program in discussions with other cities around the country.

In late June, we were also pleased to announce the signing of a new \$6 million, multi-year purchase contract with the City of New York to expand its use of our OraQuick *ADVANCE* test. This contract, which commenced on July 1, 2006, will extend the City's aggressive program of HIV prevention, including wide-spread access to OraQuick testing and prevention services throughout the City. The availability of oral fluid testing has had a significant and beneficial effect in New York, particularly at the City's STD clinics where blood has been the traditional testing matrix of choice. By switching to rapid oral fluid testing with OraQuick, it appears testing has increased by more than 30% at these clinics.

Turning now to other highlights in our infectious disease business:

- A major bright spot continues to be sales of OraQuick *ADVANCE* to Abbott for hospital distribution, which increased 123% over Q2 of 2005. The strong cooperation between our companies and focus on our hospital customers continues to pay dividends.
  - During the second quarter, 50 new hospital customers were added, and there was significant exposure outside the hospital laboratory in our existing customer base as we added 60 new labor and delivery departments, 18 new emergency departments and 10 new infectious disease clinics as customers.
  - 34 of the 50 new hospital customers added in Q2 were part of the Novation system of healthcare facilities. The 3-year single source agreement Abbott signed with Novation became active on April 1. We believe this important contract will provide an opportunity to sell OraQuick *ADVANCE* into many more hospitals throughout the country.
  - We continue to track the revised guidelines under development by the CDC for routine HIV testing in healthcare settings and specifically in emergency departments and labor and delivery units in hospitals as well as various other points of care like physicians' offices, clinics and the like. These guidelines are expected to issue in the next couple of months. The CDC has shared with us their intent to widely promote the guidelines after

their issuance. We understand their promotional programs will target hospitals, OBGYN's, and general practitioners. We believe this type of promotion will help support and encourage widespread adoption of the guidelines.

- During the second quarter, our direct sales of OraQuick in the public health market grew 82% over 2005. This increase was due to the expansion of
  public health testing programs, including an initial shipment of tests ordered under the District of Columbia initiative. Of particular importance is that
  this increase was achieved despite the absence of significant deployment of tests under bulk orders from both the CDC and SAMHSA during the
  quarter.
- Although the public health sector and hospitals currently represent the largest markets for OraQuick, we are successfully expanding use of this product in other markets. As HIV testing becomes more mainstream and routine, several new markets are now being successfully penetrated, including corrections facilities, student health centers and family planning clinics. We believe these markets and possibly others will contribute to the future growth of our infectious disease testing business. For example, last year we signed an agreement with Planned Parenthood. Of the approximately 120 Planned Parenthood affiliates that conduct HIV testing around the country, 35% are now using OraQuick *ADVANCE*. Each affiliate represents 7 to 10 additional testing sites.
- In observance of National HIV Testing Day, we once again partnered with the National Association of People with AIDS, or NAPWA, to sponsor the second annual Mayors Campaign Against HIV. This is a national campaign designed to encourage testing for HIV and promote the benefits of individuals knowing their status. Under this campaign, we worked with public health departments and community-based organizations across the country to solicit mayoral support to urge HIV testing and prevention among their constituencies. This was a great success as we had 18 mayors offices in major metropolitan cities participating, including San Francisco, Chicago, Los Angeles, Houston, New Orleans, Seattle and Phoenix.
- On the international front, there have also been several developments of note:
  - We continue our efforts to obtain registration and regulatory approval for OraQuick *ADVANCE* in Africa and several other foreign countries and territories. A top priority has been to obtain a CE mark for OraQuick *ADVANCE*, which is required to sell this product in the EU. We continue to work closely with the notifying body to obtain final approval as soon as possible. We have also continued to meet with potential marketing and distribution partners.
  - We have also prioritized identifying and signing new distributors for our products in foreign territories. We have signed new distribution agreements for OraQuick in the Middle East and Central America and are close to signing an agreement for Brazil. We are also in discussions for agreements in Russia, China and Thailand. With respect to other products, we have made progress on distribution agreements for Histofreezer in Mexico and Japan and for Intercept in Europe and other countries.

- We are also working through the registration process in Israel, Korea and Mexico.
- Finally, during the second quarter, we made significant progress in our efforts to ultimately obtain FDA approval of an OraQuick *ADVANCE* HIV over-the-counter test. On May 9, we met with the FDA to review our clinical development plan and obtained input and concurrence from the FDA on our approach. Some of the studies are expected to begin as early as September, while others will require IDE approval by the FDA and are not expected to commence until later in the year or in 2007. We are developing the trial protocol for two types of studies. The first type, which we refer to as "flex" studies, will test for the impact of conditions that might affect test performance and use by consumers. The second type of studies will test label comprehension and will validate that consumers can properly use and interpret the test. Late last week we completed and filed our initial IDE submission with the FDA. We expect to hear back from the agency within 30 working days and hope to launch our initial studies shortly thereafter.

Now, moving on to substance abuse -

# Intercept<sup>®</sup>

Our Intercept lab-based oral fluid drug test continued its upward trend in Q2:

- Total Intercept revenues in Q2 were up 8% over 2005, as a result of increases in Workplace testing, Criminal Justice and International. This growth rate is a bit lower than we have been reporting for the past few quarters primarily because Q2 of 2005 was a bit higher than normal. Sales last year were positively impacted by the initial stocking and rollout of testing at Lowes, which as you know is a very large account.
- During the quarter, we signed 38 new Intercept accounts, 18 in Workplace and 20 in Criminal Justice.
- Workplace specimens processed exceeded 100,000 per month in April, May and June up 46% from the first half of 2005. Criminal Justice specimens processed exceeded 60,000 per month throughout the quarter up 64% from the first half of 2005. The Intercept business hit a record high of over 200,000 specimens per month in the second quarter.
- In the second quarter the governor of Oklahoma signed a bill approving the use of oral fluids for workplace testing which will go into effect November 1. This will allow several of our current customers to rollout Intercept testing to their locations in this state. We are now poised to capitalize on other companies located in Oklahoma which have been awaiting this approval.
- In addition to working closely with our laboratory partners in the workplace market, OraSure has established relationships with key third party administrators who play an important role as HR service and product providers. OraSure believes these relationships will play a significant role in growing our workplace business.

Finally, in past calls we have talked about the draft oral fluid testing guidelines under consideration by SAMHSA. In a surprising turn of events, these
draft guidelines were recently withdrawn for further consideration by the Office of Management and Budget. At this moment there is no visibility as to
why the regulations were withdrawn or what SAMHSA's next steps might be. We will provide an update as soon as an official explanation for the
withdrawal becomes available. In the meantime, we are continuing to sell to non-federal markets.

# **Cryosurgical Systems**

During Q2, our cryosurgical systems business increased 7% over 2005.

- The primary reason for this increase was higher sales of our Histofreezer professional product.
- For the remainder of 2006 we are foreseeing a decline in OTC cryosurgical revenues. Prestige Brands recently advised us that they are substantially reducing their forecasted purchases for the year. The primary reasons for this are increased competition from the other OTC cryosurgical products sold in the U.S. by Wartner and Schering-Plough, ongoing efforts to reduce inventory levels beyond what we had expected, and Prestige's decision to substantially reduce advertising expenditures. The decision by Prestige to reduce advertising substantially below historic levels is very disappointing, especially since these reductions occurred during the peak wart season. Unfortunately, we do not have absolute control over a distributor like Prestige, and a significant reduction in advertising, especially for an OTC product, will have a significant negative impact on consumer purchases. The latest forecast from Prestige, which we only recently received, shows a \$5.5 million shortfall in sales for the year. Later Ron will explain the impact of this development on our full year guidance.
- SSL, our OTC distributor in Europe, Australia and New Zealand, has also delivered some disappointing news. Earlier this year we received assurances
  that SSL would meet its minimum purchase commitments, and we fully expected them to do so as indicated in our public guidance. We were
  comfortable with this because SSL had been extremely successful in the UK and seemed to be moving forward with commercial launches in France,
  Germany and other countries. However, we recently learned that orders for the second half of the year may be lower than expected, primarily due to
  the delayed or slower launch of the product in countries outside the UK. We have also reflected this development in our updated guidance.
- Finally, there have been no new developments in our patent infringement litigation against Schering-Plough. As you may recall, the parties filed motions for summary judgment in November, and we are currently waiting for the Court to rule on those motions, with a trial date expected to be scheduled shortly thereafter. We are hoping to hear something from the Court later this summer or in the early fall time frame.

#### Insurance Risk Assessment

Lastly, sales in Q2 to the insurance risk assessment market declined by \$700,000 from 2005. We believe this is attributable to an overall decrease in the number of applications for life insurance and an increase in the average policy amount. In an effort to stabilize sales, we continue to focus our marketing efforts on increasing the number and types of life insurance policies where oral fluid testing is used by life insurance companies. These efforts are starting to bear fruit as we recently signed 3 new large accounts, from which we expect 50,000 or more specimens processed per year. While this will not turn this part of the business around, it is clearly movement in the right direction

#### Manufacturing and Operations

As discussed previously, we have installed an automated assembly system in Bethlehem for our OraQuick product line. Regulatory and Operations Teams have been working through the many studies and validation requirements for submission to the FDA. We expect the submission to be completed and filed this fall.

As previously announced, earlier this year we decided to purchase our two leased facilities located on the Southside of Bethlehem, Pennsylvania. One of these facilities is our corporate headquarters and manufacturing facility for several of our products. The other houses our R&D and sales and marketing departments. These purchases closed on June 30. The primary benefit of owning rather than leasing these buildings will be an estimated reduction in operating expenses of approximately \$400-500,000 on an annualized basis. Owning these facilities will also give us greater flexibility to expand as needed in the future.

Finally, the work of a cross functional team to implement an enterprise resource software system for the Company is continuing, and making good progress. We still expect to implement this system during the last half of 2006 with a "go live" date scheduled for January 1, 2007.

Before turning the call over to Ron Spair, I would also like to mention two recent additions to our management team.

First, we hired Mr. Mark Kirtland as Senior Vice President, Business Development. Mark has more than 14 years of experience in the healthcare and medical diagnostics field and will lead our efforts to evaluate, license and acquire new technologies and products. Mark most recently worked for Valeo Medical, and prior to that for Cytyc Corporation, Wyeth and McKinsey & Company. I believe he will be a strong contributor to our management team.

Secondly, we also hired Mr. Tony Hill to head up our international sales efforts. Tony comes to OraSure from Sigma-Aldrich with more than 15 years experience in international sales, primarily in Europe. He will be based in the UK and will help drive the growth of our business in Europe, the Middle East, Africa and Asia.

With that, I will turn the call over to Ron Spair.

### <u> Revenues – Ron Spair</u>

Thanks, Doug, and good afternoon everyone.

Total revenues for Q2 were \$17.6 million, which is slightly more than revenues for the same period in 2005. Increased sales of the Company's Intercept oral fluid drug test and cryosurgical systems products were offset by a decline in insurance risk assessment testing revenues.

In the infectious disease market, sales of \$7.6 million were essentially flat compared to 2005. Strong growth in hospital sales and our direct sales to the public health market were offset by the absence during the quarter of any significant deployment under bulk government purchase orders. During Q2, we sold \$6.6 million of OraQuick, which included \$4.1 million in direct sales to the public health marketplace, \$2.1 million in sales to Abbott for distribution to hospitals, \$261,000 in sales to the CDC, and \$230,000 into the international marketplace. During the second quarter of 2005, we had more than \$2.6 million in sales to the CDC and SAMHSA. Sales of the OraSure device in the Infectious Disease market decreased to \$919,000 in the quarter, as compared to \$1.2 million in Q2 of 2005. This reduction is reflective of continued customer transition from oral fluid lab-based testing to our rapid testing platform. We expect our infectious disease revenues in the third quarter of 2006 to increase slightly from Q2, reflecting continued growth in the public health and hospital markets and deployment under the latest bulk orders from both the CDC and SAMHSA.

In the substance abuse testing market, sales were \$4.0 million, up 14% over Q2 of 2005. Total Intercept sales were up 8% over the 2nd quarter of 2005, reflecting increases in workplace testing, criminal justice and international. Sales of Intercept devices, which are predictive of future demand, totaled \$1.7 million, up 1% in Q2 vs. 2005, with Workplace down 9%, Criminal Justice up 34%, International down 15%, and Direct Sales through our website up 56%. Sales of Intercept oral fluid drug assays are indicative of the number of oral fluid specimens being processed. Assay sales in Q2 grew by 13% over last year to \$1.5 million, with Workplace up 27%, Criminal Justice down 6% and International up 2%. We expect our substance abuse revenues to increase in Q3 and throughout the remainder of 2006 as additional new Intercept accounts begin implementation.

Sales to the cryosurgical systems market in Q2 were up 7% compared to last year. Sales of Histofreezer

into the U.S. professional market increased 19% to \$1.3 million, and Histofreezer sales to the international professional market increased 82% to \$550,000, as compared to 2005 due to abnormally low revenues in the year ago period. Domestic OTC sales were down 25% from Q2 of last year to \$2.1 million. Sales of our international OTC cryosurgical products totaled \$580,000 during Q2. We expect total cryosurgical revenues to approximate \$4 million in the third quarter of 2006.

Insurance risk assessment sales of \$1.3 million in the quarter were 34% lower than the comparable quarter in 2005. This decrease reflects a continued reduction in domestic life insurance application activity and a recent increase in the average policy amount. We expect that third quarter revenues will approximate \$1.6 million in this market.

## <u>Gross Margin – Ron Spair</u>

Gross margin for Q2 of 2006 was 63%, which is an improvement over the 54% gross margin for the same period in 2005. Gross margin for the second quarter of 2005 reflected a \$1.5 million charge associated with the UP*link* assets, which accounts for the bulk of the variance.

# **Operating Expenses – Ron Spair**

Our operating expenses for Q2 increased to \$9.7 million from \$8.5 million last year. This increase was primarily attributable to charges for stock option expensing and a \$600,000 charge for in-process research and development.

Our operating margin for the second quarter was 8%, up 38% over the comparable period last year.

#### <u>Net Income – Ron Spair</u>

Net income for Q2 was \$1.2 million or \$0.03 per share on a fully-diluted basis. This compares to net income of \$1.4 million, or \$0.03 per share on a fully-diluted basis for the second quarter of 2005. Q2 2006 includes a charge of \$953,000 related to stock option expensing and a \$991,000 provision for income taxes. If these items were excluded, our net income for Q2 would have been \$3.2 million or \$0.07 per share on a fully-diluted basis. Our effective tax rate for financial statement purposes was 45% and was heavily influenced by the inclusion of stock option expense in the calculation.

# Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, we continue to maintain a very strong liquidity position. The Company's cash and short-term investments were \$84.6 million and working capital was \$96.8 million at June 30, 2006. Cash flow from operations was positive at \$5.6 million for Q2, an improvement of \$1.3 million over the comparable period in 2005.

Capital expenditures in the second quarter amounted to \$10.2. We also received \$136,000 from the exercise of stock options. Depreciation and amortization amounted to \$449,000 for the quarter. Our accounts receivable days sales outstanding decreased from 58 days at March 31, 2006 to 52 days at June 30, 2006.

# Guidance Update

Turning to our guidance for the third quarter and the full year 2006, I believe we should first look at what the prior projections were. During our call last quarter, we indicated that we would be splitting our guidance between the base business and updating that with government orders when received. The base business had been projected to account for \$78 million in FY 2006 revenues and \$0.09 - \$0.11 in earnings per share. We increased this when we received the CDC order to target \$80 million in revenues and \$0.10 - \$0.12 in earning per share. As you know, our practice is to review trends and update our guidance in connection with each quarterly earnings call.

We were recently informed by our OTC cryosurgery distributors that their business will be materially lower than expected and that they are lowering their forecasts for the year. This is particularly troublesome as their success in the second and third quarters generally sets the tone for the year as we are currently in the height of the "wart" season in the northern hemisphere. This season typically runs from May to September.

Prestige Brands, who markets our OTC cryosurgery product under the Freeze Off Compound W brand name, has recently informed us that they will not be purchasing any product during the third quarter and for the year their purchases are now expected to be less than 50% of their purchases for last year. We believe the increased strength of competing OTC cryosurgical products, Prestige's ongoing efforts to reduce inventory levels as well as their surprising decision to cut back on advertising during the peak wart season, are the main reasons for this change in their forecast.

SSL has also had mixed success with their campaign in Europe. They have established the Dr Scholl's brand as the number one brand in the U.K., but have been slower in rolling out their product offering to all countries of Europe. We are monitoring this situation very closely since it may result in their not achieving their contractual minimums for 2006 unless they purchase a large amount of product in the fourth quarter. At this point, based on recent statements by SSL, achieving their contractual minimums looks unlikely. Moreover, we are concerned that a large buy-in like that at the end of the year could negatively affect purchases and thus expected revenues in early 2007. We have been in frequent dialogue with SSL over the last several weeks after being made aware of this situation and are exploring our options in these markets should they not perform as originally expected.

In light of these events, we are currently forecasting revenues of \$17.0 million to \$17.5 million for the third quarter and revenues ranging from \$70 to \$73 million for FY-06, respectively. Our earnings per share are expected to amount to \$0.00 to \$0.01 per share in the third quarter and from \$0.04 to \$0.07 for the full year. Additionally, it is worth noting that subsequent to our discussions with the FDA related to the clinical trials

for our OTC OraQuick project, we have determined that the cost associated with the clinical trials will be substantial and could exceed \$10 million. Although we expect to begin this project shortly, this should not affect 2006 as most of these costs will be incurred in 2007.

I will now turn it back over to Doug.

# Strategy Update

Thanks, Ron.

One final strategic area I would like to address is our efforts to expand OraSure's infectious disease point-of-care testing business. We continue to make good progress in the development of a prototype rapid test for hepatitis C on our OraQuick platform. Most recently, we presented performance data on this prototype test at the American Association of Clinical Chemistry in Chicago in July. We are pleased with the progress to date, and our development efforts continue as expected.

We also continue to evaluate a number of other opportunities to acquire or otherwise gain access to tests in the infectious disease point of care market.

# Conclusion – Doug Michels

Before taking your questions, I would like to add a little context to what is happening in our business. Although we are disappointed by the performance of our OTC cryosurgical business, in the short run we continue to believe sales of the OTC product will continue to grow, especially in the international arena. We are working with both Prestige and SSL in order to help improve things in the U.S. and Canada and accelerate the launches throughout Europe.

However, the challenges we face in our OTC cryosurgical business should not overshadow the continued strength we are experiencing in other core areas. For example, the infectious disease and substance abuse testing businesses continue to do quite well and we expect that to continue. Demand for OraQuick remains strong and sales during the second quarter were sufficient to overcome the lack of shipments under government bulk purchase orders. With the signing of several new distributors, we continue to develop a strong foundation for future international sales of OraQuick. One of the biggest opportunities facing our company is the OTC distribution of OraQuick, and during the quarter we made significant progress towards obtaining FDA approval of this product and that work continues. On the new product development side, we are making great strides in developing a robust and state of the art rapid Hepatitis C test, which we expect to contribute significantly to our future growth. Similarly, our substance abuse testing business continues to grow nicely, as evidenced by the record number of oral fluid specimens processed during the quarter.

For these reasons, we remain extremely optimistic about OraSure and its future prospects.

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

#### **Important Information**

The foregoing "Remarks" contain certain forward-looking statements, including with respect to revenues, net income and products. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: the ability to market and sell products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other new products or technology; changes in market acceptance based on product performance; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; changes in relationships 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 our products; 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; ability to obtain, and timing and cost of obtaining, necessary regulatory approval for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability, patent infringement, and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2005, 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 the Remarks were made and OraSure Technologies undertakes no duty to update these statements.