# 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 3, 2011**

# 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**<br>**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 August 3, 2011, 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, 2011, described certain business developments and provided financial guidance for the third quarter of 2011. 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 contained in this Item 7.01 (including Exhibit 99) is being furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

**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 2011 Analyst/Investor Conference Call Held August 3, 2011. |

**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 3, 2011

By: */s/ Jack E. Jerrett*
Jack E. Jerrett
Senior Vice President, General Counsel and Secretary

## Index to Exhibits

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|---|---|
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**Exhibit 99**

**OraSure Technologies, Inc.**

**2011 Second Quarter**

**Analyst/Investor Conference Call**

**August 3, 2011**

**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, and good afternoon everyone.

As indicated in our press release, we continued our solid performance in 2011 with a strong second quarter. Both our revenues and bottom line exceeded our guidance.

In addition, we made good progress on the strategic front. The most recent development is our announced plan to acquire DNA Genotek Inc., the leading provider of oral fluid collection devices for molecular diagnostic applications. This represents a significant step for our Company, and we look forward to completing this acquisition in the third quarter. As I will discuss more in a few minutes, we have also continued to make good progress in our major clinical programs.

I will start the call today with some additional commentary on the DNA Genotek acquisition. Ron will follow with financial highlights from the quarter, and then I will close by providing an update on our clinical programs and certain other business developments. We will then take your questions.

***Acquisition of DNA Genotek – Doug Michels***

We are very excited about the acquisition of DNA Genotek and believe this transaction is compelling for a number of reasons.

- First, the Company has built a strong financial track record and is extremely well run. The management team is seasoned and has extensive experience in the molecular field. The Company has generated revenues with a compound annual growth rate of 40% over the last 4 years. It has also consistently reported gross margins above 80% along with positive cash flows and EBITDA. These results are driven by their best-in-class products which are supported by an exceptional sales and customer service team. Not surprisingly, the company has enjoyed high levels of customer satisfaction and customer loyalty over the past several years.
- Second, the DNA Genotek business fits nicely with our oral fluid franchise. Like OraSure, DNA Genotek is a leader in oral fluid collection systems, but with a specific focus on molecular testing applications. Because oral fluid collection is simple and non-invasive, it offers a significant advantage over competing collection methods, particularly blood. In addition, the products have a standardized format that can be used with high throughput processing and they reliably collect sufficient quantities of high quality genetic material with little risk of contamination.
- Perhaps the most attractive feature of DNA Genotek's products is the ability to store collected samples for long periods of time without refrigeration — up to five years for DNA samples and at least several months for RNA. This key feature alone gives DNA Genotek a distinct competitive advantage over other DNA and RNA collection methods.
- The acquisition of DNA Genotek will also help diversify our business and provide us entry into the fast-growing molecular diagnostic market, which is currently valued at almost $4 billion. We believe molecular testing represents the future of diagnostics and it is a field in which we are eager to participate with DNA Genotek's industry-leading products. The molecular testing market is expected to grow at more than 10% per year and thus represents a significant growth opportunity for OraSure.

- Finally, I should point out that DNA Genotek's products incorporate a proprietary technology that is protected by a robust patent estate.

Once closing occurs, we will be working closely with DNA Genotek management to build upon our core competencies and plan our future goals and objectives. I look forward to updating you as we finalize our strategy for the combined companies. For now, I can share a few thoughts about how DNA Genotek may contribute to our future growth.

- Based on DNA Genotek's historical financial performance and our assessment of its prospects, we expect this business to provide a significant and growing contribution to both revenues and EBITDA. As previously discussed, this transaction should be accretive to revenue growth in 2011 and accretive to both revenues and EBITDA for 2012 and future years.
- The DNA Genotek acquisition also provides a great opportunity for growth in the form of new product offerings. These could include products developed internally by DNA Genotek or in collaboration with other companies in the molecular diagnostics market. Potential opportunities being considered include:
    - Expansion of DNA Genotek's products for use with diagnostic applications, particularly infectious diseases, and for use with sample types other than oral fluid; and
    - Development of molecular diagnostic products that would be complimentary to, and used downstream from, the sample collection, stabilization and preparation products. These latter products would include molecular assays that could be used with oral fluid or other sample types and possibly a near-patient or laboratory-based reader platform to perform molecular testing.

- Lastly, since we are retaining the DNA Genotek management team and plan to operate the company as a stand-alone subsidiary, we also expect to achieve some cross-functional benefits for both companies. For example:
  - A particular strength of DNA Genotek is its customer management system, which captures extensive information about customer contacts and is fully integrated with the sales, marketing and customer service functions. DNA Genotek also has a robust process for both identifying commercial opportunities in the academic and research areas and converting those opportunities into actual product sales. We intend to see if DNA Genotek's success in this area can be used to improve the sales process at OraSure.
  - DNA Genotek has significant technical expertise in the area of DNA and RNA collection for molecular testing and our R&D capabilities are focused more on diagnostics applications for infectious diseases. We think there will be opportunities to share our respective technical skill sets in a way that benefits both companies.
  - We also believe each company can share best practices in other areas, including regulatory, quality assurance and quality control.

In short, we believe the DNA Genotek acquisition will provide substantial strategic, commercial and operational benefits to OraSure and help set the stage for our future growth.

And with that, I will turn the call over to Ron for his financial update.

***Second Quarter 2011 Financial Results – Ron Spair***

Thanks Doug, and good afternoon everyone.

***Revenues – Ron Spair***

Second quarter 2011 revenues were $19.1 million compared to $19.2 million reported in 2010. Our product revenues increased 6% as higher sales of our infectious disease and substance abuse testing products were partially offset by lower sales of our cryosurgical systems products and lower insurance risk assessment revenues. The overall increase in product revenues was offset by lower licensing and product development revenues caused by the absence of a $1.0 million milestone payment received in the second quarter of 2010 under our HCV collaboration with Merck.

Infectious disease testing revenues were $11.3 million in the second quarter of 2011 compared to $10.0 million in the second quarter of 2010. The overall 13% increase was driven by a 10% increase in domestic OraQuick® sales and a 171% increase in international OraQuick® sales. The higher domestic sales resulted primarily from new or expanded HIV-testing programs implemented in the U.S., as well as variability in customer ordering patterns. International sales increased largely because certain private and government customers were able to make purchases for HIV testing during the quarter.

In substance abuse testing, revenues increased from $3.1 million in the second quarter of 2010 to $3.2 million in the second quarter of 2011, primarily as a result of a 9% increase in sales of our Intercept® drug testing system. This increase was largely due to improvements in the workplace market as hiring conditions have slowly begun to improve and we are seeing the results of our focused sales and marketing efforts.

Second quarter 2011 cryosurgical revenues decreased 10% compared to the second quarter of 2010. Higher professional diagnostic sales in the U.S. were offset by lower international professional sales and reduced OTC sales.

OTC sales decreased $433,000 when compared to 2010 largely as a result of the lower sales to our European OTC distributor, Reckitt Benckiser, partially offset by higher sales to our Latin American OTC distributor, Genomma.

On the professional side, domestic sales increased 9% while international sales decreased 9%. The higher domestic sales reflect the continued efforts of our manufacturers' sales representatives and improved focus by our distributors. Furthermore, we are beginning to see orders from those customers that had previously worked through their inventory of less expensive international product that was diverted into the domestic professional market in 2009 and part of 2010. The lower international sales were caused by decreased sales in Asia and Australia, partially offset by higher sales in the European market.

Our insurance risk assessment sales decreased from $1.6 million in 2010 to $1.4 million in 2011. This is a result of both order timing and the continued general softness of the life insurance market.

***Gross Margin – Ron Spair***

Turning to Gross Margin, our overall margin for Q2 of 2011 was 64% compared to 63% reported for the second quarter of 2010. Gross margin in the second quarter 2010 benefited from the $1.0 HCV milestone payment received from Merck during that period. Gross margin for 2011 benefited from lower direct labor costs and improved absorption of overhead costs as a result of staffing optimization and a change to automated manufacturing during 2011. These changes accounted for 3.2% of margin improvement for the second quarter of 2011. This gain more then offset the negative margin impact associated with the absence of the HCV milestone revenues in 2011.

***Operating Expenses – Ron Spair***

Our total operating expenses for the second quarter increased $1.9 million or 15%, compared to the second quarter of 2010. Research and development expenses increased by approximately $2.1 million due to higher clinical trial costs associated with our OraQuick® HIV OTC program. Sales and marketing expenses decreased by approximately $258,000 as a result of lower consulting costs, partially offset by higher staffing costs. General and administrative expenses were essentially flat for the quarter.

***Net Loss – Ron Spair***

From a bottom line perspective, we reported a GAAP net loss of $2.4 million, or $0.05 per share, which beat our guidance. This compares to a net loss of $553,000, or $0.01 per share, for the same period of 2010. EBITDA in Q2 2011 was a loss of $1.5 million, or $0.03 per share, versus a gain of $174,000, or $0.00 per share, in Q2 2010.

***Cash Flow from Operations and Liquidity – Ron Spair***

Turning briefly to our balance sheet and cash flow, our cash balance remained strong at $75.4 million at June 30th.

We generated $1.7 million in cash flow from operations compared to $1.9 million generated in the second quarter of 2010.

***Third Quarter 2011 Financial Guidance – Ron Spair***

Turning to guidance for the third quarter of 2011, since the DNA Genotek acquisition has not yet closed, we will only provide guidance for the third quarter exclusive of this business. Once the closing occurs and we have had an opportunity to complete a purchase price allocation, we would then expect to be in position to update our guidance.

With that caveat, we are projecting revenues of approximately $19.0 to $19.5 million and a loss per share of approximately $0.07 for the third quarter of 2011. The projected loss includes charges associated with additional spending for our HIV-OTC trial and certain deal related expenses associated with our acquisition of DNA Genotek.

And now back to Doug.

***Clinical Programs Update – Doug Michels***

Thanks, Ron. Turning to our clinical programs…

***OraQuick® HCV – Doug Michels***

Our CLIA waiver submission for the OraQuick® HCV test remains pending before the FDA, and we have been in active dialogue with the agency. We have received a request for additional data from the FDA, which will require us to design and perform a relatively small study. We expect the study itself to last only about a week, but with set-up and close-out activities this work will take us into the 4th quarter to complete. We hope to get this information to the FDA as quickly as possible upon completion of the study in order to facilitate the prompt completion of the agency's review of our application. We remain confident that our submission is approvable.

During the second quarter, we continued to pursue commercialization of the OraQuick® HCV test. We have been active on many fronts as we plan to maximize this opportunity.

- As you may know, the Department of Health and Human Services recently adopted a Viral Hepatitis Action Plan, which lays out a strategy for expanding awareness, prevention, care and treatment of viral hepatitis, including HCV. This is a multi-year plan that includes revising CDC guidelines for HCV testing and linkage to care and developing a cross-agency process for increased HCV testing. We believe this Plan evidences a strong commitment by the Federal government that will positively impact our HCV testing business.

- One tactical step that you may have seen in the implementation of this Action Plan, was the designation of July 28 as World Hepatitis Day in collaboration with the World Health Organization. This was announced last week in a proclamation issued by President Obama. The Plan also indicates that the Administration will continue to promote May as “Hepatitis Awareness Month” and in 2012 will designate May 19th as “Hepatitis Testing Day” in the United States. These steps are very similar to the successful approach followed by the government to substantially increase awareness, testing and treatment for HIV.
- In connection with World Hepatitis Day, there were also several events sponsored by industry. In particular, our HCV collaboration partner, Merck, sponsored a benefit concert in New York City as part of its “Tune In To Hep C” program to raise money and awareness in connection with Hepatitis C. In addition, Merck announced the launch of its “Step Up to the Plate Against Hepatitis C” initiative under which free hepatitis C testing using the OraQuick® HCV test will be offered at various professional baseball games later this summer.
- Under our collaboration with Merck, we continue to make progress. Domestically, in addition to the “Step Up to the Plate” initiative in which we are conducting testing events, plans are underway and training materials are being finalized for the physicians office market. We plan to begin detailing in the U.S. physicians office market as soon as the CLIA waiver is received. Internationally, our product is now registered in 23 foreign countries, training of the sales reps is underway, call decks have been assembled and detailing has begun with over 1,700 physician calls made through June.

- Finally, as you may know, we have been building on our capability to produce OraQuick® products using the fully automated manufacturing system. We have already received approval to manufacture our OraQuick *ADVANCE*® HIV product in this manner. I am pleased to tell you that we just received FDA approval to add the OraQuick® HCV test to our automated manufacturing line. This will allow us to generate significant cost savings as the volume of our OraQuick® HCV sales increases in the future.

***HIV OTC – Doug Michels***

Turning to our OraQuick® HIV OTC product, you will recall that the final phase of clinical testing, which was started at the end of last year, involves the use of our test in an unobserved setting. One of the study objectives specified by the FDA was to identify at least 100 HIV infected, but undiagnosed individuals. In order to meet this requirement, we expected to enroll and test approximately 4,000-5,000 participants in our study. This trial is progressing well, and we remain on track to complete this study here in the third quarter.

In planning for our FDA submission, we have decided to split our filing into three separate parts or modules, the timing of which will be spaced to allow the FDA sufficient review time between modules. This is an accepted technique used to start the formal review process as early as possible. The first module, which we expect to file later this month, will contain data from all studies performed prior to the final phase that is currently under way. The second module will contain information about our manufacturing and Customer Care Call Center. The final module will contain the results of the unobserved clinical trial and is anticipated to be filed around the end of this year.

As the clinical program has progressed, we have also been preparing for the commercial launch of the OTC product. Activities include updating our market research, identifying appropriate advertising and public relations firms, developing a robust retail sales strategy and determining who will be the commercial provider of our 24/7 customer care center. These activities have been ongoing for some time and will continue through the end of this year and into 2012.

***OraQuick® HIV Shelf Life – Doug Michels***

Turning to product stability — since our last call, we formally requested approval for a shelf life extension for our OraQuick® HIV test to 30 months. I am pleased to report that this extension was approved by both the FDA and by our notified body in Europe. This is important not only for our current professional business but also for our HIV OTC product as the retail market typically requires a shelf life of 24 months or more.

***Drugs-of-Abuse High Throughput Oral Fluid Assays – Doug Michels***

In substance abuse, we remain on track to launch the high throughput oral fluid drug assays developed with Roche Diagnostics later this year. During the second quarter, the FDA issued a 510(k) clearance for the amphetamines assay. With this latest approval, the initial launch panel will consist of assays for PCP, cocaine, opiates, methamphetamine and amphetamine. The launch of these new assays for use with our Intercept® collection device, is expected in the fourth quarter.

As for the THC assay (marijuana), good progress has been made. We believe the final technical issues have been resolved and final clinical studies are expected to be completed by the end of the year. Our goal is to have Roche submit this assay for 510(k) clearance later this year or sometime during the first quarter of 2012.

***OraSure QuickFlu™***

A final area I would like to address relates to the most recent addition to our infectious disease product line - the OraSure QuickFlu™ test. We have launched this product and are just beginning to enter this seasonal business. Recently, we signed an agreement with a leading group purchasing organization, or GPO, serving the hospital market. We are in active discussions with several other major GPO's and anticipate that additional agreements will be signed.

* * * *

So in summary, we have accomplished much on multiple fronts. We have achieved a significant business development milestone with the announced agreement to acquire DNA Genotek, we delivered a strong second quarter and we continue to make progress on all of our major clinical programs. We remain extremely optimistic and excited about our future.

And with that, I will now open the floor to your questions. Operator please proceed.

**[Q&A session]**

***Conclusion – Doug Michels***

Thank you for participating on today's call and 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 expected revenues, earnings/loss per share, and expected clinical development, regulatory filings and approvals. 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: 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; changes in relationships, including disputes or disagreements, with strategic partners or other parties 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; ability to identify, complete, integrate, and realize the full benefits of potential future acquisitions, including the Company's acquisition of DNA Genotek; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; 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, extended shelf life or other factors; 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; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to refinance outstanding debt under expiring credit facilities on acceptable terms or at all; ability to retain qualified personnel; exposure to 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; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2010, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.