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): July 5, 2012

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

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

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

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

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 – Other Events.

On July 5, 2012, 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, discussed the receipt of FDA approval of the OraQuick® In-Home HIV Test and the Company's plans to commercialize this product. A copy of the prepared remarks of Mr. Michels is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Prepared Remarks of Douglas A. Michels for OraSure Technologies, Inc. Analyst/Investor Conference Call Held July 5, 2012.

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: July 5, 2012

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

Index to Exhibits

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Exhibit 99.1

OraSure Technologies, Inc.

Analyst/Investor Conference Call

July 5, 2012

Prepared Remarks of Douglas A. Michels

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

Thanks Judy and good morning everyone.

The purpose of today's call is to provide additional information regarding the FDA's recent approval of our OraQuick® In-Home HIV Test, which we announced earlier this week. OraSure is now permitted to sell the first and only over-the-counter ("OTC") rapid test that can detect antibodies to both HIV-1 and HIV-2 with an oral swab. This is a significant achievement for our Company and is the result of great work by many of our employees. We are very excited about this opportunity and believe that this product represents an important and critical tool in the fight against HIV/AIDS.

As you know, about a month and a half ago we submitted our clinical data for this product to the Blood Products Committee ("BPAC"), an advisory committee to the FDA. Based on its review of our submission and input from the FDA and CDC, the BPAC voted unanimously, 17-0, in support of the OraQuick® In-Home HIV Test. We appreciate the thorough and careful review by BPAC and the broad support shown for our product, particularly by the numerous members of the HIV/AIDS community who participated in the public comment portion of the BPAC meeting.

As you might expect, since the BPAC meeting we have been engaged in extensive discussions with the FDA regarding our product. Much of those discussions

revolved around finalizing the product labeling and packaging. The FDA also completed a pre-approval inspection of our Bethlehem manufacturing facilities and is finishing up the bioresearch monitoring, or BIMO, audits it had been conducting on the 20 clinical sites we used to generate our clinical data. Based on its consideration of the BPAC recommendation, the results of its inspection and audits, and its own thorough review of our clinical data, the FDA issued the approval this past Tuesday, July 3.

As I have indicated on prior earnings calls, this project was a monumental effort by virtually all functional areas within our Company. The receipt of FDA approval of our OraQuick® In-Home HIV Test as the first and only rapid HIV OTC test is clearly the most significant achievement in our Company's history. I would like to take this opportunity to thank all of our employees and the members of our senior management team, and in particular the Regulatory, R&D and Operations departments, for their hard work, dedication and perseverance in making the approval of this product a reality.

For some time now, we have been planning for this approval and the subsequent steps we must take to commercialize this exciting new product. As an initial matter, we must be able to produce sufficient quantities of product to meet demand. As they say, "you can't sell from an empty wagon." Since we could not begin production of a significant part of our product packaging until approval of final labeling by FDA, we followed a two-pronged approach to production planning. First, we have already been producing "at risk" those portions of our packaging which we believed would not be affected by the FDA's label review process. Secondly, we have developed a plan to complete the remaining packaging and produce test devices to enable a commercial launch as quickly as possible now that the approval has been received. At this point, all product components for the launch have been purchased and are scheduled for our manufacturing process. We expect to begin shipping completed product to all major retailers by mid-September, with a goal of having product on retail shelves by the beginning of October of this year.

As you know, we have been developing a distribution and sales strategy which is designed to ensure that product will be available in the right stores and in the right markets to maximize this opportunity. We expect to have product in more than 30,000 retail outlets at launch, with an 85% All Commodity Volume for this initial placement. The term “All Commodity Volume,” or ACV, represents the dollar value share we expect to achieve in the stores projected to constitute the market for our product. In short, we anticipate having broad distribution of our OraQuick® In-Home Test in the highest value retail outlets representing our primary market for this test. The product will also be available for purchase on-line through retailers and our website, **www.oraquick.com**.

In order to meet these distribution goals, we have established vendor relationships with key retailers, such as Wal-Mart, Walgreens, CVS, Rite Aid and Kroger. We will also be distributing product through several large drug wholesalers and additional food retailers.

We have developed plans for pharmacist education, trade ads, shelf signage and the use of pharmacy counter displays. Our Company website will also provide links to the various retailers in order to further drive retail sales. We expect most retailers to place the product in the family planning and sexual health sections of their stores, with a small number of retailers considering placement with other diagnostics products.

In addition to driving awareness and recognition at the retail outlet level, we intend to launch a robust, targeted consumer education and advertising program. Although designed to reach all consumers, this program would have a particular

focus on certain at-risk populations who we believe, based on our market research, are most likely to use our product. These include African Americans, men who have sex with men, Hispanics and adults 18 and over who engage in high-risk sexual activities. Two primary ad campaigns have been developed and are currently in quantitative testing with consumers. Our messaging will be reviewed with the FDA and will be delivered through a variety of media including, TV, print, digital and social media.

As I previously mentioned, we also plan to sell the OraQuick® At-Home HIV Test through a company-managed website. We currently have a pre-launch website in place, which is a temporary site intended to serve consumers until a more complete website has been finalized and approved by the FDA. This temporary site is pretty basic and will contain core product information, information as to when product will be available in retail outlets or over the website, call center information and the timing for activation of our full website.

The final comprehensive website is expected to contain more complete product information, a video demonstrating how to operate the test, a link to the CDC's medical provider and counseling referral database, general HIV and AIDS education materials and resources, links to various relevant PR and community events and, of course, access to an e-commerce site through which consumers can purchase the product. We have already submitted some initial information about this website to the FDA and we would expect it to go live in October when product is expected to be on retailers' shelves.

Another piece of our communications program will focus on pharmacists, doctors and other healthcare professionals. During the course of our research, we learned that healthcare professionals are generally not as focused on the need for HIV testing as you might expect, given the CDC's existing recommendations for broad-based HIV screening. Consequently, we will be rolling out an initiative to help

change this, through increased awareness and focus on HIV testing by professionals. Under this initiative, we will inform the professional market about the launch of our at-home test, provide additional information about HIV and AIDS, and encourage healthcare professionals to promote increased HIV testing among their patients.

In conjunction with our advertising, we will implement media outreach in support of our product. The purpose of this PR program also will be to help drive awareness and brand recognition through the media in support of our advertising initiatives. As you may have noticed, our OraQuick® In-Home HIV Test has generated quite a bit of news coverage lately. For example, the results of the BPAC meeting resulted in more than 121 million media impressions. We hope to continue to drive a high level of coverage and interest through both national and regional media outreach programs. In addition, we are planning a number of launch events during the next few months, which we expect to be covered by many traditional and social media outlets.

Finally, we will support individuals who purchase and use our test through a live toll-free customer support center to be operated on a 24/7, 365-day per year basis. Through the center, consumers will have access to highly-trained, bi-lingual representatives to obtain answers to questions about HIV/AIDS, taking the test and interpreting their test results. In addition, our support center representatives will be able to refer consumers to appropriate resources for follow-up confirmatory testing, counseling and medical treatment. The support center will also be equipped to properly capture and report any customer or product complaints and accept and process on-line product purchase orders from consumers. As you can see, a lot has gone into the development of our support center and our intent is to provide exceptional service to all of our retail customers who need it.

One final topic I'd like to briefly address is the financial impact of this product. Our revenue recognition practices will initially be different than those customarily used in the consumer package goods industry. Seasoned companies that operate in this space have experience with returned goods rates and are generally able to predict with a high level of precision the final amount of revenue generated by a product that is sold into the retail distribution channel. Because we are a new participant in this space and have a new product for which we do not have a track record of returns, we will only recognize revenue upon the consummation of a sale to the retail customer either in a store or over the internet. We are working with our retail distribution partners to gain access to this out sales data which will provide our team and investors transparency into the effectiveness of our launch and the actual uptake of our product in the hands of the consumer.

We have also been receiving a number of questions surrounding our anticipated launch costs. Currently, our plans are to leverage our public relations and digital media efforts to build broad awareness across all of our targeted consumer base. This will run from today forward, through the launch, and continuing thereafter. As you may know, this is a lower cost strategy than a full advertising campaign. We will look to test market our advertising content during the latter part of the year before investing in a targeted direct-to-consumer advertising campaign. From a spending perspective and for the balance of the year, we anticipate spending at, or above, our projected quarterly rate of approximately $1.7 million that we announced for Q2. When we have completed the test marketing of our focused advertising campaigns, we will have a better understanding of the spend levels required to build awareness and purchase demand amongst the consumer groups.

* * * *

Conclusion

So in summary, we are extremely pleased to have obtained FDA approval of our OraQuick® In-Home HIV Test. Our focus now is on executing our plans to bring this product to the market. There is still much to be done, but I believe we have a good plan and the right team in place. Over the next several months, we will be

producing product and building inventory, raising awareness and driving brand recognition through coordinated sales, marketing and PR initiatives, and closely monitoring consumer reaction and the operations of our call center to ensure that these activities are completed in a successful and compliant manner. This is an exciting time for OraSure Technologies, and we look forward to updating you on the launch of this new product offering during future calls.

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 product availability and related commercial matters. 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 market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; 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 integrate and realize the full benefits of the Company's acquisition of DNA Genotek; ability to identify, complete, integrate and realize the full benefits of future acquisitions; 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; adverse movements in foreign currency exchange rates; 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, 2011, 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.