FINAL TRANSCRIPT

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OSUR - Q1 2011 Orasure Technologies Inc Earnings Conference Call

Event Date/Time: May. 04. 2011 / 9:00PM GMT

THOMSON REUTERS

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PRESENTATION

Operator

Good day, everyone, and welcome to OraSure Technologies' 2011 first-quarter financial results conference call and simultaneous webcast. As a reminder, today's conference is being recorded. (Operator Instructions). For opening remarks and introductions I would now turn this call over to Judy Clarke at OraSure Technologies. Please go ahead.

Judy Clarke - *OraSure Technologies, Inc. - IR*

Thank you. Good afternoon, everyone, and thank you for joining us today. I would like to begin by telling you that OraSure Technologies issued a press release at approximately 4 p.m. Eastern time today regarding our 2011 first-quarter financial results and certain other matters. The press release is available to you on our website at www.orasure.com, or by calling 610-882-1820. If you go to our website, the press release can be found by opening the Investor Relations page and clicking on the link for news releases. This call is also available realtime on our website and will be archived there for 7 days. Alternatively you can listen to an archive of this call until midnight June 11, 2011, by calling 800-642-1687 for domestic, or 706-645-9291 for international. The access code is 61775799. With us today are Doug Michels, President and Chief Executive Officer, and Ron Spair, Chief Operating Officer and Chief Financial Officer. Doug and Ron will begin with opening statements which will be followed with question-and-answer session.

Before I turn the call over to Doug, I must also remind you that this call may contain certain forward-looking statements, including statements with respect to revenues, expenses, profitability, earnings per share, and other financial performance, product development, performance, shipments and markets and regulatory filings and approvals. Actual results could be significantly different. Factors that could affect results are discussed more fully in the SEC filings of OraSure Technologies, including its registration statement, its annual report on Form 10-K for the year ended December 31, 2010, its quarterly reports on Form 10-Q, and its other SEC filings. Although forward-looking statements help to provide complete information about future prospects, listeners should keep in mind that forward-looking statements may not be reliable. The Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call. With that, I would like to turn the call over to Doug Michels.

Doug Michels - *Orasure Technologies Inc - President, CEO*

Thanks, Judy, and good afternoon, everyone, and thank you for joining us for this evening's -- this afternoon's teleconference. Let me start off by indicating that 2011 has gotten off to a solid start, as our results for the first quarter were better than expected. We exceeded our guidance for both revenues and the bottom line, and we also continue to make good progress on our major clinical programs. Our manufacturing improvements are yielding results and our balance sheet remains strong.

As you will hear in the next 20 minutes, the OraSure team is executing effectively against our goals and objectives. And although the economy remains a challenge with funding and employment trends still under pressure, I'm pleased with response by our management team during these challenging times. For the call today, Ron will start with some financial highlights and then I will address some factors affecting our business and provide an update on our major clinical programs. We will then open the floor for your questions. And with that I'll turn things over to Ron.

Ron Spair - *Orasure Technologies Inc - COO, CFO*

Thanks, Doug, and good afternoon, everyone. So starting with our revenues, first-quarter 2011 revenues were $17.4 million compared to $17.9 million reported in 2010. Our product revenues increased 3% as increased sales of our infectious disease and substance abuse testing products were partially offset by lower sales of our cryo systems products and lower insurance risk assessment revenues. The increase in product revenues was offset by lower licensing and product development revenues caused by the absence of $1 million milestone payment received in the first quarter of 2010 under our HCV collaboration with Merck.

Infectious disease testing revenues were $10 million in the first quarter of 2011, compared to $9.5 million in the first quarter of 2010. The overall 5% increase was primarily a result of higher OraQuick HIV sales in international markets. Domestic OraQuick sales rose 2%. International OraQuick revenues increased 115%, largely because certain private and government customers were able to make purchases for HIV testing.

In substance abuse testing, revenues increased from $2.7 million in the first quarter of 2010 to $3.1 million in the first quarter of 2011 as a result of a 17% increase in sales of our Intercept drug testing system. This increase was a result of an improvement in pre-employment testing rates when compared to the first quarter of 2010, and the return by our primary drug testing laboratory customer to a more normal ordering pattern. In 2010, this customer changed its inventory management model and this change negatively impacted Intercept sales during the year-ago period.

First-quarter 2011 cryo revenues decreased 9% compared to the first quarter of 2010. Over-the-counter sales decreased $485,000 when compared to 2010, largely as a result of the absence of sales to our Latin American over-the-counter distributor, Genomma. One reason for the reduction was the absence of an initial pipeline fill by Genomma required for their commercial launch of our product in Brazil during the first quarter of 2010. Genomma's purchases during the first quarter of 2011 were also negatively impacted by regulatory issues in Mexico and in Brazil. The decrease in sales to Genomma was partially offset by higher European over-the-counter sales to our distributor, Reckitt Benckiser during the first quarter. On the professional side, combined domestic and international sales increased 14% as a result of improved distributor focus on our products, the continued impact of our manufacturer sales representative organizations, increased pricing, and some economic recovery. Our insurance risk assessment sales decreased from $1.4 million in 2010 to $1.3 million in 2011 due to the issuance of fewer new insurance policies.

Turning to gross margin, our overall gross margin for Q1 of 2011 was 65%, compared to the 64% reported for the first quarter of 2010. Margins in the first quarter of 2011 benefited from increased manufacturing efficiencies and a more favorable product mix. Product gross margins increased 340 basis points when compared to last year, primarily as a result of the manufacturing efficiencies. These benefits were partially offset by the decrease in licensing and product development revenues that I mentioned previously. The $1 million HCV milestone we received during the first quarter of 2010 accounted for approximately 210 basis points of margin for that period.

Our total operating expenses for the first quarter increased $240,000, or 2%, compared to the first quarter of 2010. R&D expenses increased by approximately $1.3 million due to higher clinical trial costs associated with our OraQuick HIV over-the-counter program, partially offset by a decrease in clinical trial costs associated with our OraQuick HCV test. Sales and marketing expenses decreased by approximately $762,000 as a result of lower staffing, recruiting and market research cost. G&A expenses decreased by approximately $311,000 as a result of lower consulting and staffing costs, partially offset by higher legal expenses. From a bottom line perspective, we reported a net loss of $2.6 million, or $0.06 per share, which exceeded our guidance. This compares to a net loss of $2.2 million, or $0.05 per share for the same period of 2010.

Turning briefly to our balance sheet and cash flow our cash balance remains strong with cash and short-term investments of $72.4 million at March 31. Cash used in operating activities in the first quarter of 2011 was $2 million. A $3 million improvement when compared to the $5 million used during the first quarter of 2010. Turning to guidance for the second quarter of 2011, we are projecting revenues of approximately $17.75 million to $18.25 million, and a loss per share of approximately $0.07 to $0.08. And with that, I'll turn things back over to Doug.

Doug Michels - *Orasure Technologies Inc - President, CEO*

Okay, thanks, Ron. In looking at our business, several points should be kept in mind. We were certainly pleased to see higher sales of our OraQuick HIV product during the first quarter, especially given the difficult economic environment. However, ongoing economic and funding challenges are likely to continue to affect our business, particularly in the domestic public health market. Although some improvements seem to be occurring in certain areas of the United States and in some international markets, it's difficult to predict with certainty whether and to what extent these conditions will continue over the long-term.

With respect to our OraQuick HCV test, we believe a number of factors will affect the commercial success of the product. Of most significance for the US is the receipt of a waiver under the Clinical Laboratory Improvement Amendments of 1988, or CLIA. This is approval is critical to our ability to penetrate both the physician office and the public health markets. As you know, we've submitted an application for a CLIA waiver, and I will provide an update on our HCV clinical program in a few minutes.

On the international front, we are still working to raise awareness, particularly in the European market. As we've discussed in the past, the adoption of point-of-care diagnostics remains challenging in Europe, where laboratory testing is entrenched and healthcare delivery systems are structured around centralized testing models. As you may know, there was a meeting of the FDAs Antiviral Drugs Advisory Committee in late April, at which the committee recommended that the FDA approve Merck's new pharmaceutical for HCV, a protease inhibitor called boceprevir. The committee also recommended FDA approval of a second protease inhibitor manufactured by Vertex called telaprevir. As a result of the Committee's recommendation, there is an expectation that both of these drugs will be approved by the FDA in the near future, and the expected approval in these drugs represents a major landmark in hepatitis C therapy.

By adding these new class of drugs to the existing regimen, physicians will likely achieve cure rates in two-thirds to three-quarters of their patients. And also many patients will likely be able to achieve a cure after a substantially shorter treatment duration than currently required. We believe this will help drive awareness and demand for increased HCV testing, including our OraQuick HCV product.

We are encouraged by the improved performance of our substance abuse business. As Ron indicated, this appears to be the result in part of improving employment conditions here in the United States. However, these conditions may not continue on a sustained basis. Overall, employment has not returned to robust levels, and in addition, the substance abuse area is likely to experience increased competition in the future. For example there at least two firms that are selling high throughput fully-automated oral fluid drug testing products in non-regulated markets. We believe that one of these competitors has also received FDA clearance for a 9-to-5 panel. These products will obviously compete with our Intercept business and with the high throughput assays we intend to commercialize jointly with Roche.

Turning to clinical programs, let me start with HCV . During the first quarter there were two significant developments related to our OraQuick HCV product, first in February, we received FDA approval for use of the test on fingerstick whole blood samples. This was the second application approved by the FDA, the first being venous whole blood which was approved in June of 2010. The second development was our submission in March of an application for a CLIA waiver for the OraQuick HCV product for use with both venous whole blood and fingerstick whole blood samples. Under its current approvals, the OraQuick HCV test can be used by laboratories certified or accredited under CLIA as being able to perform moderately complex tests. However with a CLIA waiver, we will be able to sell our tests to substantially more sites nationwide that currently hold a waiver, including outreach clinics, community-based organizations, and physician offices. As previously mentioned, the receipt of a CLIA waiver is critical to fully realizing the market potential for this product.

With respect to oral fluid claim, we have initiated additional testing which we hope will provide further support for our oral fluid submission and we intend to meet with the FDA to discuss and finalize the structure of that submission in the coming months. Assuming a timely CLIA waiver, we expect domestic revenues for this product to increase later this year. We have been working with Merck under our collaboration agreement so that we are prepared to begin detailing the product in physician offices after the CLIA waiver is received.

Turning to our OraQuick HIV over-the-counter product. The final phase of clinical testing was started at the end of 2010. You will recall that this phase involves the use of our test in an unobserved setting. One of the study objectives specified by the FDA is to identify at least 100 HIV-infected but undiagnosed individuals. In order to meet this requirement, we expect that we will need to enroll and test approximately 4000 to 5000 participants in this study.

I am pleased to report that we have made substantial progress on the study, and it remains on time and on budget. All clinical sites have initiated testing and, in fact, we are now starting to close several of our initial sites to ensure that we achieve the appropriate geographic diversity required by our protocol. We've rolled over 2500 patients and we have identified over half of the required number of newly diagnosed HIV individuals. Assuming enrollment continues as expected, and we meet our anticipated prevalence rates among those enrolled, we still expect to complete the study during the third quarter of this year.

Turning to OraQuick HIV shelf-life, as discussed during our last call, we previously extended the shelf-life for our OraQuick HIV test to 24 months. We continued our real-time stability studies and now have stability data for this product that should support an extension to 30 months. We expect to file a formal request for this extension with the FDA in the next several weeks.

In the area of substance abuse testing, during the quarter we announced several 510(k) clearances for the use of high throughput oral fluid assays with our Intercept device. Specifically, clearances were received for phencyclidine or PCP, cocaine, opiates and methamphetamine. An application for amphetamines has also been filed but remains pending with the FDA. We expect this essay to receive 510(k) clearance in near future.

As previously discussed the clinical work for the THC assay, or marijuana, has followed a somewhat extended schedule. This work is continuing, and although the goal is to resolve all open issues and make an FDA submission as soon as possible, this will likely not occur until near the end of the year at the earliest. In the meantime we expect to launch this product line with Roche with a panel consisting of PCP, cocaine, opiates, methamphetamine, and amphetamine beginning sometime near October. We are working with Roche to accelerate the availability of product in order to meet the competition expected in this market. Earlier this year, we announced the addition of a new infectious disease testing product to our portfolio, the OraSure QuickFlu Rapid Flu A+B Test. Our focus with this product is primarily on the US hospital markets. During the first quarter, we trained our sales team and prepared marketing materials for a formal launch. A number of our customers are currently evaluating this product in anticipation of the 2011/2012 flu season, and we expect sales of this test to begin to materialize during the second half of the year.

So as you've just heard, we've been busy on multiple fronts and measurable progress has been made. Our team has been effectively managing many demands and I thank them for all of their hard work. We are executing on our goals and objectives on time and on budget. and the Company is well-funded to accomplish the tasks at hand, and we've never been more optimistic

about the future of the Company. Although there is still much work that lies ahead, we believe 2011 is off to a good start and we look forward to updating you on our progress as the year progresses.

And finally, before we open this afternoon's call to Q&A, I'd like to mention one final item regarding the recent change in our Board of Directors. In April, we announced the addition of Dr. Stephen Tang as a member of the Company's Board. Steve has enjoyed a successful career in both the medical diagnostic and pharmaceutical industries, and is currently the President and CEO of the University City Science Center located in Philadelphia. We believe Steve will be a strong contributor and we are very pleased that he has joined our Board. Steve's appointment follows the retirement of Dr. Jack Goldstein as a Director. As you may recall Jack, is the Former President and Chief Operating Officer of Chiron Corporation, and Jack joined the Board in 2006. Jack made significant contributions to our Company and we are very grateful for his service. We thank Jack and we wish him every success in his future endeavors. And so with that, i'll now open the floor to your questions. Operator, please

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Our first question comes from Samir Harish, Thinkequity.

Samir Harish - *Thinkequity - Analyst*

I thought I would start off on the pending CLIA approval with hepatitis C and QuickFlu. Can you talk about just how active the dialogue there is, have you gotten back any questions? Just in terms of the hepatitis, in particular, is there any additional risks to the regulatory event that you would typically see? Are they more focused on the package label, the test performance or something else?

Doug Michels - *Orasure Technologies Inc - President, CEO*

No. I think as we've mentioned before, we got the application into the FDA towards the end of March. It's a real solid submission, we believe. We have had some back-and-forth dialogue, nothing extraordinary in the back and forth. And as we mentioned we continue to expect to receive CLIA waiver sometime within the next couple months.

Samir Harish - *Thinkequity - Analyst*

Okay, great. And, just to follow up on the international (inaudible), you mentioned that it was sequentially higher which is a little unusual. Was it additional orders that came through from existing customers or did you sign up some new customers, and what are the implications for that through the year?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Our international revenues have been pretty lumpy over the last several years. You recall that they generally have been back-end-loaded, we've seen higher international revenues usually in the third and fourth quarter. First quarter of 2010 was pretty light from an international revenue perspective.

We're pleased with what we saw in the first quarter. We generally saw increased revenues across Africa, Asia, and the EU. So we are enthused about that. We'll see how the rest of the year plays out. We are seeing some improvement, we believe, on the global economic front. But we'll try to keep a close eye on it and see how the second quarter comes in.

Samir Harish - *Thinkequity - Analyst*

Great. Thank you, guys. I will get back in queue.

Operator

Thank you. Our next question comes from Caroline Corner, McNicoll and Lewis.

Caroline Corner - *Montgomery & Co. - Analyst*

So quick question quickly about Genomma, you said there were some regulatory issues in Brazil. Have those ben resolved? Should we expect a rebound there or is it something that is ongoing?

Ron Spair - *Orasure Technologies Inc - COO, CFO*

So the issue in Brazil has been resolved. It was related to and ultimately settled by a modification to the package insert. So I think overall that business is back on track.

With respect to the Mexican situation, I think that's a little bit more complicated and ongoing, and has resulted in a suspension of advertising for the product, which, as you know, Genomma is all about advertising to the consumer. So that is one we are continuing to monitor. We don't have resolution to that -- they don't have resolution of that issue at the moment.

Caroline Corner - *Montgomery & Co. - Analyst*

Okay, and then the CLIA Waiver with regards to the QuickFlu, am I correct in that, we don't have that one yet?

Doug Michels - *Orasure Technologies Inc - President, CEO*

No. We do not. And you know, Princeton BioMeditech is actually responsible for that submission.

Caroline Corner - *Montgomery & Co. - Analyst*

Okay, fair enough. With regards to the new competitive pressures with regard to Intercept, your initial conversations with Roche around that, how are they going, what does Roche think of the competitive threats, given that Roche has 70% your analysis market. Are they concerned at all or is it something that they are still pretty confident that they will be able to do well once the panels are approved?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Well, we mentioned this, one of the competitors is a Company called LINV, they've actually had an oral fluid automated assay approved since 2006. They have four assays approved, they still don't have a couple of the key assays, THC obviously being one of them. Another is Microgenx, and to our understanding that they were just recently approved. So we will be working with Roche just make to sure that our competitive response is appropriate. We just wanted to call it out as a consideration for the businesses as we move forward.

Caroline Corner - *Montgomery & Co. - Analyst*

Thanks. Congratulations on the quarter and thank you for taking my call.

Operator

Our next question comes from Scott Gleason, Stephens Financial.

Scott Gleason - *Stephens Inc. - Analyst*

Just to start off you, will you talk a little about the detailing effort and what we should expect from Merck after you guys get the CLIA waiver status? What would be the next steps, and how fast they could be out and into the physician office market?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Yes. So they have e a contractual agreement to begin that within the first 6 months after we gain approval. We're right now planning for them to start that detailing effort assuming we have CLIA waiver sometime in the next 2 to 3 months. No later than the fourth quarter, the beginning of the fourth quarter. The teams are working on that right now. Obviously we've got someone of a head start in that based on the work that has been done in Europe, where we've seen continued progress.

You might recall that during our last update, I think the numbers at that time, we had commenced detailing in the European Union, and 7 of 23 countries as of March 31 were now detailing in 14 of the 23 countries, obviously the product is registered and approved for sale of those 23 countries. We've trained 20 of the 23 Merck sales teams now in Europe. So things have progressed pretty well. Obviously, once we get the CLIA waiver, we are going to need to finalize the training materials, make sure that's all in place, then we're going to have to train the US sales organization. But the teams are working collaboratively to make sure the detailing starts no later than the beginning of the fourth quarter.

Scott Gleason - *Stephens Inc. - Analyst*

Great, and then, Doug, you had mentioned on last call that there were some developments that led you to believe that the government might potentially, in the next 12 to 24 months, advocate oral fluid drug abuse testing. Has there been any new developments on that front are anything else you can talk about?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Yes. There has, actually, there was a DTAB meeting earlier this week. As I understand it, there is discussion about a 10-step process that is going to lead up to the next DTAB meeting, which is September 12 and 13. During which it is expected that a decision will be made as to whether or not to move forward.

Assuming that the decision is made to move forward, then of course they would have to move on a federal register notice, proposing new guidelines and we would expect that that might come within several months after September. So I think the good news is that this is on the agenda, active discussion and it appears to be moving forward.

Scott Gleason - *Stephens Inc. - Analyst*

Doug, from a distribution standpoint, how would you target that market? Or was there a tender process, or how does that typically work?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Well, this is all part of our relationships with Roche, and we will be working those details out collaboratively as we anticipate any changes in the regulation.

Scott Gleason - *Stephens Inc. - Analyst*

Okay, great, and then just last question, you talked about the two competitors, LINV and Microgenx, I just wanted to make sure those are automatic systems on automated clinical chemistry analyzers?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Yes.

Scott Gleason - *Stephens Inc. - Analyst*

Okay, thanks for taking my questions.

Operator

Thank you again -- (Operator Instructions). Our next question comes from Jeff Frelick, Canaccord.

Jeff Frelick - *ThinkEquity LLC - Analyst*

Good evening, folks. I have kind of a follow-up on your comment on the economic impact for funding for the public health sector. Are you leaning more towards the federal funding or state and local?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Federal funding has been pretty robust throughout all of these economic challenges, and the federal government is operating under a continuing resolution, so we don't see too much of a change there over the next several months for sure.

Challenges at the local level continue, some areas worse than others. I don't think that we've seen a deterioration in funding at the local level. So we'll keep track of it as we move forward, but generally we expect generally a status quo, I would say, in terms of funding pressures, at least from where we are at right now.

Jeff Frelick - *ThinkEquity LLC - Analyst*

Doug, remind us what percent of public health funding is federal; what percent is state and local?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Yes, as we've described previously, on a national basis it is generally about 70% federal, and 30% generated locally.

Jeff Frelick - *ThinkEquity LLC - Analyst*

Okay, just last follow-up. With respect to your relationship with Merck, are they giving you any indication they are going to want to move quickly with the detailing of OraQuick HCV? Obviously there is somewhat of a limited window out there. What is your sense?

Doug Michels - *Orasure Technologies Inc - President, CEO*

Well, it's a pretty exciting time for Merck as well as for Vertex. They are on the verge of something pretty historic here with these new therapies. I think both of them understand that there's going to be a lot of excitement and a lot of demand for the product early on. I think they also know that, in order to continue to build demand for the product, we've got to increased testing and identify infected individuals, newly diagnosed. There is also competitors coming behind both Merck and Vertex.

It's believed that they are several years away, but obviously to the extent that we can identify more individuals that are chronically infected with hepatitis C, in the near-term, that is going to benefit both of the companies, and obviously benefit the public. So I know that both companies are enthusiastic about increasing testing. Both are working on promotional plans. To do that, we are obviously actively engaged with Merck and discussing some of our exciting promotional programs which we will be part of. And look forward to increasing demand for HCV testing overall, and obviously demand for rapid testing specifically.

Jeff Frelick - *ThinkEquity LLC - Analyst*

Okay, great. Thanks, Doug.

Operator

Thank you. The allotted time for this call is up. We do apologize to all of those who are still holding to ask questions. I will now turn the call back over to Mr. Doug Michels for closing remarks.

Doug Michels - *Orasure Technologies Inc - President, CEO*

Okay. No other questions? I just want to thank you again for participating on today's call and obviously for your continued interest in the Company. I look forward to talking to you next quarter and hope you have a good afternoon and evening, everyone. Thank you again. Bye-bye.
