FINAL TRANSCRIPT

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PRESENTATION

Operator

Good day everyone and welcome to OraSure Technologies 2011 second quarter financial results conference call and simultaneous web cast. As a reminder today's conference is being recorded. All lines have been placed on mute to prevent any background noise. After the speaker's remarks there will be a question and answer period. (Operator Instructions).

For opening remarks and introductions I would now like to turn the 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 4PM Eastern Time today regarding our 2011 second 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 in real time on our website and will be archived there for seven days. Alternatively, you can listen to an archive of this call until midnight August 10, 2011 by calling 855-859-2056 for domestic or 404-537-3406 for international. The access code is 84284990. 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 sessions. 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*

Thank you, 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, 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 the 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. We are very excited about the acquisition of DNA Genotek and we 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 the 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 the 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 these 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 here 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 diagnostic applications for infectious diseases.

We think there will be opportunities to share our respective technical skill sets in such 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. So 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. With that let me turn the call over to Ron for his financial update.

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

Thanks, Doug, and good afternoon, everyone. Let's start with revenues. 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 cryo 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 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 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 US 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 cryo surgical 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 over-the-counter sales. Over-the-counter sales decreased $433,000 when compared to 2010 largely as a result of the lower sales to our European, over-the-counter distributor, Reckitt Benckiser. This is partially offset by higher sales to our Latin American over-the-counter 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 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 as a result of both order timing and the continued general softness of the life insurance market.

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 of 2010 benefited from the $1 million 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.

Turning to operating expenses, our total operating expenses for the second quarter increased $1.9 million or 15% compared to the second quarter of 2010. R&D expenses increased by approximately $2.1 million due to higher clinical trial costs associated with our OraQuick HIV over-the-counter program. Sales and marketing expenses decreased by approximately $258,000 as a result of lower consulting costs, which were partially offset by higher staffing costs. G&A expenses were essentially flat for the quarter.

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 of 2010. Turning briefly to our balance sheet and cash flow, our cash balance remained strong at $75.4 million at June 30. We generated $1.7 million in cash flow from operations compared to $1.9 million generated in the second quarter of 2010.

Turning to guidance for the third quarter of 2011, since the DNA Genotek acquisition has yet to be closed, we will only provide guidance for the third quarter exclusive of that business. Once the closing occurs and we have had an opportunity to complete our purchase price allocation, we would then expect to be in a position to update our guidance. With that caveat, we are projecting revenues of approximately $19 million 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 with that I will turn it back to Doug.

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

Thanks, Ron. Let's turn to our clinical programs and start out with OraQuick HCV. 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 some 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 early fourth 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, HHS, 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 19 as "National 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 as soon as the CLIA waver 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 details 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. And 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.

Turning to our OraQuick HIV over-the-counter 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 to 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 module submissions. 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 the customer care call center. And 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 over-the-counter 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 they will continue through the end of this year and into 2012.

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 over-the-counter product as the retail market typically requires a shelf life of 24 months or more. 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 amphetamines. The launch of these new assays for use with our Intercept collection device, is expected in the fourth quarter. As for the THC assay, or marijuana, good progress has also 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. 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. And 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 a lot 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 so with that, I will now open the floor to your questions. Operator please proceed.

QUESTIONS AND ANSWERS

Operator

Yes, sir. (Operator Instructions). Our first question in queue is Sameer Harish with ThinkEquity.

Sameer Harish - *ThinkEquity LLC - Analyst*

Hi, thank you guys. Good afternoon.

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

Hi Sameer.

Sameer Harish - *ThinkEquity LLC - Analyst*

To start off maybe we could start off with the hepatitis C program. Can you talk a little bit about the nature of the study that you are looking to complete? And can you also just address the turn around time from the end of the trial completion to when you think you could submit the full package to CLIA?

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

Absolutely. As I indicated in the prepared remarks, we have been in active dialogue with the FDA. And as a result of discussion, the review that we had a week ago Thursday they requested we conduct an additional study, it's a small study, it's a reproducibility study actually. It's going to be conducted in approximately four sites. It is going to take us a week to actually conduct the study. It is very small, very contained. We have already drafted the protocol. That's down at the FDA. It is under review. We have to hear back from them. We have to get the approval.

Once we have the approved protocol we have to recruit the sites and then we have to execute the study. Our hope is that we can get through that and our expectation is that we would be able to collect that data and get that additional data into the FDA sometime in the early part of the fourth quarter. We have also been discussing with the FDA other aspects of our submission, and right now this is the only thing that we have been asked to do at this time. Once we get that additional information into the FDA, then obviously the ball will be back in their court to wrap up their review, and hopefully quickly, grant us the CLIA waver that we have been waiting for.

Sameer Harish - *ThinkEquity LLC - Analyst*

Okay. And are they user observed or unobserved?

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

We are not recruiting subjects into the sites for this study. This is more of an analytical study that is not using clinical samples per say.

Sameer Harish - *ThinkEquity LLC - Analyst*

Okay. Got it. And switching gears, on the acquisition side, can you give us any clarity, I know are you not giving guidance, but just in terms of their operating structure or degree of profitability, also maybe for Ron, any particular CapEx expectations post transaction? Thanks.

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

Sure. So they have been profitable for the last four years while they have continued to grow their business. So the expectation is we will continue to enjoy revenue growth as well as profitability from the entity. And we will update our expectations as far as the contribution for that remaining part of the third quarter subsequent to the purchase price allocations being done and evaluations completed. As far as CapEx is concerned I would not anticipate there would be any significant amount of CapEx post the closing of the company.

Sameer Harish - *ThinkEquity LLC - Analyst*

Thanks, I will get back in queue.

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

Thanks, Sameer.

Operator

Thank you sir. Our next questioner in queue is Scott Gleason with Stephens. Please go ahead.

Scott Gleason - *Stephens Inc - Analyst*

Hi, Ron. Hi, Doug. Thanks for taking my questions. I guess, Doug, to start off with when we look at the total abuse testing program, I think THC is the last assay you guys are waiting for clearance on the Roche platform? Can you give us a time line when you guys are expecting that last piece of the puzzle there?

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

Like I mentioned, our expectation is that Roche is going to ramp up their clinical studies during the fourth quarter. Our hope is that they get that into the FDA before the end of the fourth quarter, latest in the first quarter of 2012. We still intend to launch the testing system absent THC during the fourth quarter. We will be providing our customers with evaluation material upon which they can do crossover studies. We have been in discussion with most of our customers about their plans to execute those crossover studies and begin to adopt a test.

Most of those customers will adopt the system without THC, but several want to wait for all six assays to be available. It is a 5-10-K process. The approval process has been pretty efficient with the first five assays that Roche has submitted. So hopefully we will see the same kind of turn around with THC. But, once it's submitted, obviously, how quickly approval comes is in the hands of the FDA.

Scott Gleason - *Stephens Inc - Analyst*

Great, and Doug is there any update in terms of the drug testing advisory board on the possible, I guess, inclusion of oral fluid based drug abuse testing and the actual guidelines for government workers?

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

They have actually put out some documents for comment and we can direct you to that, how you can access that on the website.

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

It was actually published in the federal register last month soliciting comments and in a proposal for the inclusion of oral fluid and regulated market place.

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

Certainly moving along.

Scott Gleason - *Stephens Inc - Analyst*

Great. And I guess Doug, just last question, while we are thinking about Mercks detailing effort in terms of the HCV test, I think their requirement was basically to begin detailing the product six months after it cleared submission. Are they still going to wait that amount of time frame? Can you talk about what you are seeing from them in terms of distribution partner.

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

No, as I mentioned in the prepared remarks we are already in the process of training. Our expectation is that they are going to begin detailing immediately after the clear waiver is received. We were targeting that they would begin their detailing efforts in the fourth quarter of this year. So hopefully we can still see that come to bear. Obviously, they are actively out there encouraging testing as evidenced by the promotional programs that I described in the prepared remarks. In addition to the baseball program that they announced and will begin to execute on actually this month. We expect there will be additional promotional opportunities with Merck and we are quite excited about that.

Scott Gleason - *Stephens Inc - Analyst*

Great. Thanks for taking my questions, guys.

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

Thank you.

Operator

Thank you sir. Our next questioner in queue is Caroline Corner with MLB. Please go ahead.

Caroline Corner - *McNicoll, Lewis & Vlak - Analyst*

Hi, guys, congratulations on the quarter. Just a quick follow-up regarding the hepatitis C. Doug, you mentioned you will be submitting for a clear waiver in the fourth quarter, and you said you would expect that clear waiver to come quickly. In your conversations with the FDA, have they said that, have they given you any expectation of a time line for how long that process will take once it is submitted?

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

No they haven't, but just for clarity we have already submitted for clear waiver and through the dialogue that we have had with them they asked us to do this very short, additional study. The submission that I spoke of is simply the data from that study which we might be able to get to them before the end of this quarter. It might bleed into the early part of Q4. How quickly they are able to turn that around and hopefully grant us a submission obviously is in their hands.

We have been in active dialogue with them. We know that they have reviewed other aspects of the CLIA submission. And the dialogue that we have had with them to date has been quite positive. As I mentioned, we remain extremely confident that we are going to receive the approval on the clear waiver. We just have to do this small additional study and get it in their hands.

Caroline Corner - *McNicoll, Lewis & Vlak - Analyst*

Very good. And then just real quickly, the R&D costs related to the new data, is that just something small and incremental? I am just noticing that the R&D costs for this current quarter came in a little bit ahead of where we thought they would be based on the OTC trial. I'm just trying to figure out how it's all going to shape up looking into the third and fourth quarter.

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

Yes. That's a great question. The actual costs associated with the CLIA study that Doug was speaking of for HCV is less than $100,000. But the costs associated with completion of the HIV-OTC is higher than we anticipated it would be when we put the trial projections together. What's happened, Caroline, is that the prevalence rate has been a little bit lower than what we had anticipated when we did our model. We are now looking at, likely, accruals coming in at 5500 to 5600 patients as apposed to the 4,000 to 5,000 that we had expected.

Additionally the compliance rate for those that are moving through the entire three visits that are required under the trial protocol, the compliance rate is up around, north of 95%. Whereas we thought it was going to be lower in the 80% range when we did the model itself. So those two factors really have contributed to an additional amount of R&D spend such that our expectations now are the Q3 R&D is going to be higher than Q2 R&D.

Caroline Corner - *McNicoll, Lewis & Vlak - Analyst*

Very good, thank you. And then just one quick one on the cryo side, you mentioned there has been a recovery with regard to the Latin American market. Should we assume from that now that Mexico and Brazil are both back up and running how they should be?

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

No, Brazil was back up and running as we had talked about previously, but Mexico is still challenged by their regulatory prohibition against advertising the product and the DTC space there in Mexico. That being said, Mexico is buying product for further distribution into other Latin and South American countries outside of Brazil in which they have approval and that they market the product.

Caroline Corner - *McNicoll, Lewis & Vlak - Analyst*

Okay. Very good. Thanks for taking my call.

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

Sure, thanks, Caroline.

Operator

Thank you. (Operator Instructions). Our next questioner in queue is Spencer Nam with Madison Williams. Please go ahead.

Spencer Nam - *Madison Williams - Analyst*

Hi. Thank you for actually taking my questions. I just have a couple of follow-up questions on the clinical development side. Number one, you guys have already commented on the small study, on this clear waiver on HCV. The FDA sometimes tries to drag things on but sometimes certain requests for them to really move the process forward. Some of the other requests are delaying tactics, if you will. How do you guys have the confidence level that this is more of a, hey let's close all of the loops kind of a request? How do you think about this whole process moving forward from the point when you will finish this small study how the FDA would respond to that, if you will.

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

Like I described, it is a very, very short contained study. It will take us five days to conduct in four sites. We are not recruiting additional subjects into the trial. We are very confident we will be able to execute this study very effectively and efficiently and get the data into the FDA. And they have been very responsive in the most recent dialogue that we have had with them. At least our sense of things is they are eager to move this along. And like I said we are confident they will.

Spencer Nam - *Madison Williams - Analyst*

Great. That's all. But the second question is just moving on to the HIV, the OTC process. Again, going back to this, the interactions with the FDA. The reason why you guys are splitting up the submission, could we look at it as maybe that you feel there would be some additional Q&A, if you will, that you may see more sort of back and forth between the two parties coming down the pike? Is that why you guys would like to send in all of the peripheral stuff first and then really contain the final data and submit it at the end when ever you have it ready and available?

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

Let me give you a little bit more context. We have been talking about and we have been planning for at least the last year that we were going to execute this phase three study and our target was to complete it during the third quarter of this year, and as I mentioned we are still on track for that. We have also said that our objective was to be able to submit our entire PMA submission to the FDA by the end of 2011, and we are still on track for that. In dialogue with the FDA when we talk to them about our intention we then began to dialogue about how we might be able to accelerate things.

And knowing that there was a lot of data that would be coming into them in and around the end of the year, we began to talk about the possibility of submitting it in a modular fashion to give them more time to digest these things. I made comment that the submission that we are going to submit here in the next couple of weeks is going to largely be comprised of the data that has already been generated out of our non-clinical studies, the label comprehension studies, the phase two and the phase 2b and the label mitigation studies.

All of the data that the FDA has already seen and reviewed, and much of the data that we have already reviewed with advisory committees before. So we are trying to get this into the FDA so they can review it so that once we put in the final submission at the end of year we can move things along faster. So the first module is going to be as I described it. The second module is going to be information about our manufacturing as well as our call center operations.

So basically the only thing that will be left to submit at year-end is going to be the clinical data from the study that we are currently executing, along with our proposed labeling, along with our post marketing plan. The study we are conducting right now is a big study. As Ron talked about, we are going to end up somewhere north of 5500 subjects. That's basically going to be the new data that's going to be submitted to the FDA. All of the rest of the submissions or most of what has been submitted before that in modules one and two will have already been data that has been shared with the FDA in some fashion or form previously.

Spencer Nam - *Madison Williams - Analyst*

Great. And then a quick follow-up. When it comes to HCV, I know you guys are doing obviously a series of activities with Merck. Has there been any sort of discussion with Vertex on that front, or are you pretty much exclusive with Merck at this point?

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

No, our arrangement with Merck is pretty specific in terms of our obligations and in terms of theirs, obviously. We have had discussion with Vertex, who also is very keen on increasing awareness around testing and prevention. We don't have anything formal in the works right now with Vertex. And actually by agreement with Merck, we are prohibited in some respects in interacting with Vertex. But we know that Vertex is very committed to increasing diagnosees of new hepatitis C infections and obviously to the extent we can assist those in those efforts we will do that, provided it is compliant with our agreement with Merck.

Spencer Nam - *Madison Williams - Analyst*

Great. Thanks very much.

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

Thanks, Spencer.

Operator

Thank you, sir. Our next questioner in queue is Sameer Harish with ThinkEquity. Your line is now open. Please go ahead.

Sameer Harish - *ThinkEquity LLC - Analyst*

Hi, guys, thanks for taking a follow-up.

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

Sure.

Sameer Harish - *ThinkEquity LLC - Analyst*

I wanted to ask a little bit, in the news and certainly driving the markets these days has been kind of the national debt, and the debt deal that got put in place and some of that either speculates around that or over potential decreases in government spending. Can you talk about your dialogue with CDC and other entities where a significant amount of public health funding is coming in and any sense you have on their commitment to HIV testing longer term?

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

I don't think there is any question about their commitment to HIV testing. And it has been demonstrated time and again with increased requests for more funding from the federal government. We still continue to deal with some of the funding challenges at the state and local level. We don't anticipate that is going to ease up anytime soon. We are trying to work with the jurisdictions to manage their testing programs as efficiently and effectively as possible. You saw a nice increase in OraQuick sales both domestically and internationally in the second quarter.

We are pretty pleased with that, particularly on a domestic front where we saw a pretty nice increase quarter-on-quarter. We saw a number of programs expand testing through expansion into new sites, and we have actually seen a couple new sites come on. Pretty encouraged by that. We saw a nice increase in the physician office market actually on the OraQuick front here

domestically. Internationally we saw some nice growth where certain governments, and it was pretty consistent growth across each one of the different geographies where different governments seem to be spending a little bit more on rapid HIV testing.

Sameer Harish - *ThinkEquity LLC - Analyst*

Great, and if you could just maybe comment on what you are seeing in terms of marketplace from a competitive standpoint in your market share?

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

We haven't seen any significant shifts up or down on the market share perspective. I think we continue to hold our own. As you know we've got leading market shares in the public health sector as well as in hospitals. And competitive tactics don't appear to have changed too much generally leading with price given the fact that they don't have either the market presence nor the product features, flexibility that we have with the OraQuick advance product.

Operator

Sameer's line is no longer in the queue. I think he may have dropped off. And I am showing no more questioners in the queue. Thank you for your questions today participants. And I would now like to turn the call over to Doug Michels for any closing remarks.

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

I would like to thank you all for participating on today's call and for your continued interest and support of OraSure. I hope you all have a good afternoon and evening and we look forward to talking to you again in the weeks and months to come. Take care.

Operator

Thank you. Ladies and gentlemen this does conclude today's program. Thank you for your participation and have a wonderful day. Attendees, you may log off at this time.
