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OSUR - Q2 2012 OraSure Technologies, Inc. Earnings Conference Call

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

Good day everyone, and welcome to OraSure Technologies 2012 second quarter financial results conference call and simultaneous webcast. As a reminder, today's conference call is being recorded. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer period.

(Operator Instructions)

To allow time for as many questions as possible, questioners are asked to limit themselves to only a single question with no more than one follow-up question related to the same topic. Once the follow-up is completed, a questioner can rejoin the queue for further questions. I would like to begin by telling you that OraSure Technologies issued a press release at approximately 4.00 PM Eastern time today regarding our 2012 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 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 14, 2012, by calling 855-859-2056 for domestic, or 404-537-3406 for international. The access code is 11264311. 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, you should know that this call may contain certain forward-looking statements, including statements with respect to revenues, expenses, profitability, earnings or loss per share, and other financial performance, product development, performance, shipments and markets, and regulatory filings and approval.

Actual results could be significantly different. Factors that could affect results are discussed more fully in the Company's SEC filings, including its registration statements, its annual report on Form 10-K for the year ended December 31, 2011, 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 the 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 and CEO*

Thank you Judy, and good afternoon everyone. Thank you all for joining us on our call this afternoon. I'm pleased to report that results for the second quarter exceeded our guidance range on both the top and bottom lines. Consolidated revenues were up almost 20% compared to the second quarter of 2011, primarily as a result of DNA Genotek. As many of you know, the most significant development in the second quarter was the receipt of FDA approval of our OraQuick HIV test, which was covered extensively in the media. I'll provide an update on our commercialization efforts for this exciting new product, as well as certain other developments in our business, but before I do that, let me turn the call over to Ron for an overview of our financial results.

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

Okay. Thanks Doug, and good afternoon everyone. Our second quarter 2012 revenues were $22.6 million, compared to $19.1 million reported in 2011. Revenues for the current quarter included $3.3 million from our molecular diagnostic collection subsidiary, DNA Genotek, acquired in August 2011. Our product revenues increased 19% as a result of the molecular collection system sales and higher sales of our cryo surgical systems products. These increases were partially offset by lower sales of our infectious disease, substance abuse, and insurance risk assessment products.

Our infectious disease testing revenues were $10.4 million in the second quarter of 2012, compared to $11.3 million in the second quarter of 2011. The overall 8% decrease was primarily a result of lower domestic OraQuick HIV sales, partially offset by higher sales into the international market and by higher OraQuick HCV sales. Domestic HIV revenues were down $1.6 million year-over-year, or 16%, due to various factors, including changes in public health testing programs, reductions in government funding, some lost business due to price competition, and timing of certain orders. Our HCV revenues were $954,000 for the quarter, a $712,000 increase over the second quarter of 2011. HCV revenues were also sequentially up from Q1 of 2012.

In our substance abuse testing areas, revenues decreased to $2.9 million in the second quarter of 2012 from $3.2 million in the second quarter of 2011, primarily as a result of lower intercept sales. This decrease was the result of a reduction in purchases by our largest domestic laboratory distributor, who began selling its own competitive oral fluid drug testing system at the end of 2011, and lower international sales due to a reduction in our UK distributors' target inventory levels. Second quarter 2012 cryo revenues increased 61% compared to the second quarter of 2011, primarily as a result of higher over-the-counter sales. OTC cryo sales during the quarter increased $1.3 million, or 160% when compared to 2011, largely as a result of higher sales to both our Latin America distributor, Genomma, and our European distributor Reckitt Benckiser.

As discussed in previous calls, early in 2011 the Mexican government imposed restraints on the advertising Genomma could use for our product. At the same time, the Brazilian government required us to make changes to our package insert. Both of these issues negatively impacted our sales to Genomma during 2011, but were resolved by the end of that year. Resolution of those issues, coupled with sales growth in Argentina, and customer order patterns in Brazil, all contributed to the increase in Latin American OTC revenues during the current quarter. The higher sells to Reckitt Benckiser were the result of increased advertising and promotional activities initiated by them, as well as expansion into additional European countries.

Professional cryo sales in the US increased 13%, and international professional sales increased 50% from the second quarter 2011. The increase in domestic sales was due to the ordering patterns of one of our large distributors, and the increased success of sales and promotional efforts by our distributors and manufacturers representative organizations. On the international side, professional sales were due primarily to higher sales in Europe, Australia, and Asia. As mentioned earlier, our molecular collection systems revenues were $3.3 million for Q2, and primarily represent sales of the Oragene product line.

Turning to our gross margin, our overall margin for Q2 of 2012 was 65%, compared to 64% reported for the second quarter of 2011. A 67% margin at DNA Genotek contributed to the higher margin for the quarter. Turning to operating expenses. Our total operating expenses for the second quarter increased $3.6 million, or 25%, compared to the second quarter of 2011. The second quarter of 2012 expenses included $3.2 million from our molecular collection systems subsidiary. Research and development expenses decreased from $5.1 million to $3.1 million for the quarter, due to lower clinical trial costs associated with our OraQuick In-Home HIV Test. Sales and marketing expenses were $9 million for the second quarter, an increase of $3.7 million over 2011, due to the inclusion of $1.8 million of DNA Genotek expenses and higher spending of $1.8 million associated with our preparation for the commercialization of our OraQuick In-Home HIV Test.

G&A expenses increased by approximately $1.9 million as a result of $788,000 of DNA Genotek expenses and higher consulting, legal, and staffing costs. So from a bottom line perspective, we reported a net loss of $3.6 million or $0.07 per share, compared to a net loss of $2.4 million or $0.05 per share for the same period of 2011. Turning briefly to our balance sheet and cash flow, our cash balance at June 30, 2012 was $23.3 million, compared to $23.9 million at December 31, 2011. Following the end of the second quarter, our cash balance increased by approximately $70 million, with the closing of our secondary stock offering. Cash used in operating activities in the second quarter of 2012 was $940,000, compared to $1.7 million generated during the second quarter of 2011. Turning to guidance for the third quarter of 2012, we're now projecting consolidated

revenues of approximately $22 million to $22.5 million, and a consolidated net loss per share of approximately $0.07 to $0.08 for the quarter. With that, I'd like to turn it back to Doug.

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

Okay. Thanks, Ron. Now that our OraQuick In-Home HIV Test has been approved, we're focussed on delivering a successful commercial launch. We continue to implement our distribution and sales strategy, and we expect that the in-home test will be available in more than 30,000 retail outlets beginning in October. As previously explained, we anticipate achieving a greater than 85% all-commodity volume for this initial placement. All-commodity volume, or ACV, represents the dollar value share that these stores represent out of the total market potential for our product. In addition to retailers such as Walmart, Walgreen's, CVS, Rite Aid, and Kroger, we have expanded our retail relationships to include Duane Reade, online retailers such as drugstore.com, large drug wholesalers such as McKesson, and AmerisourceBergen, and certain regional food retailers.

We are working closely with retailers to develop promotional plans for our product, including placement in advertising circulars, store and shelf signage, pharmacy displays, and internet ads. While the retailers will have the final say on pricing for our product once it is available in October, we anticipate the retail price for our OraQuick In-Home HIV Test to be approximately $39. We have activated a temporary website, currently available at www.OraQuick.com, to provide high level information about the product and its future availability. A more comprehensive website will be activated in late September, and provide additional information about HIV and AIDS and our product, and will offer consumers to purchase our product online.

We are now finalizing our advertising campaign, which will reach populations that have expressed high purchase intent, such as men who have sex without -- with men, or MSM, African-Americans, Latino Americans and sexually active adults ages 18 to 49. Additionally, our media plans will enable our ads to be broadly seen by consumers outside of these populations who may also be interested in taking advantage of a simple and private HIV testing option. Closely aligned with our advertising campaign will be an extensive PR campaign. As you know, our OraQuick In-Home HIV Test has already generated extensive media coverage, with FDA approval alone generating over 200 million media impressions.

We are planning a variety of PR events through the rest of this year as part of a coordinated national and regional media outreach effort. Because pharmacists and medical professionals play a key role in educating consumers and driving the usage of medical products, an important part of our communications program will focus on these individuals. We're finalizing several educational tools to be used by retail pharmacists and in clinics and doctors' offices. In order to successfully execute our distribution and sales strategy, we need to be able to provide a sufficient quantity of product. Our manufacturing process is well under way, and we are on schedule to begin shipping product to retailers by mid-September, as initially planned and previously communicated.

Finally, a very important component of our commercial plan is the consumer support center. This center has been operating since July 6, and provides consumers with toll-free support on a 24/7, 365-day-per-year basis. As previously discussed, each of our support center representatives are bilingual and highly trained, and are prepared to answer questions about our test and to provide consumers with resource referrals for follow-up confirmatory testing, counseling, and medical treatment. So in summary, the commercialization plans for our OraQuick In-Home HIV Test are well developed and are on schedule for an October launch, and I look forward to providing additional updates as these plans progress.

Turning now to our OraQuick HCV test, we're pleased to see continued market acceptance and sales growth for this product. HCV sales for Q2 increased over both second quarter of last year and the first quarter of this year. The primary drivers for this growth are the CLIA waiver we received in late 2011, the impact of our new distribution relationships with McKesson, Henry Schein, and PSS, and other testing and awareness initiatives. Our direct sales efforts in the public health market are bearing fruit, as we saw numerous repeat customers and 34 new customers during the second quarter. Our new HCV distributors have been trained, and their sales teams are now actively calling on physician offices, community health organizations, and other potential customers.

A big focus for these distributors is the education of medical professionals about the proposed new CDC guidelines on HCV testing. As previously discussed, the CDC has issued draft guidelines recommending that all persons born between 1945 and 1965, or approximately 81 million people according to the 2010 census, receive a one-time test for hepatitis C. Our distributors are implementing extensive education and awareness campaigns to alert medical professionals that these guidelines are likely coming, and once adopted can be met through the use of our OraQuick

HCV test. We are also supporting our distributor sales efforts with the same manufacturer sales representative organizations that have helped to enhance sales of our Histofreezer product line.

To further assist our distributors, we are collaborating with the Chronic Liver Disease Foundation by supporting an initiative to educate and certify physicians as HCV testing centers in anticipation of the adoption of the proposed CDC guidelines. Through education, training, and promotional activities, this program will target approximately 6000 physicians in 2000 practices, and this is expected to launch later this month. We are also working with the National Medical Association to implement an educational awareness and testing campaign. The NMA is the largest and oldest national organization representing African-American physicians in the United States. Current NMA membership is estimated at 50,000 physicians.

With assistance from OraSure, the goal of this campaign is to have NMA member physicians test thousands of individuals for HCV in 10 US cities, including New York, Philadelphia, DC, Newark, Durham, Chicago, Baltimore, Baton Rouge, Detroit, and Los Angeles. Our awareness efforts have not been limited to the US market. For example, we recently participated in several testing initiatives in recognition of World Hepatitis Day, which was founded by the World Health Organization, and occurred this year on July 28. These initiatives took place in New York, Chicago, and Washington, DC, and in several foreign countries.

In recognition of this date, we also closed the NASDAQ stock market, and organized a publicly webcast panel discussion, which included representatives from public health, hospitals, and community-based organization on best practices for incorporating HCV into testing programs. We believe all of these activities will encourage people to get tested for hepatitis C, including the use of our OraQuick test. Finally, we've discussed our HCV collaboration with Merck on prior calls, and particularly Merck's detailing efforts directed at the physician office market. While these detailing efforts have been helpful, we now believe it is in our best interests to focus on our new distribution relationships and the types of initiatives and collaborations described in my earlier remarks.

As a result, our domestic agreement with Merck, which has an initial term expiring in September of this year, will not be renewed. As you may know, this agreement contains exclusivity restrictions, which will terminate with this expiration. This will allow us more freedom to pursue potential collaborations with other companies in the HCV therapeutic marketplace. At this time, the international agreement with Merck will remain in place. Now turning to molecular collection systems, the second quarter financial performance for this segment of our business also came in as expected. There was continued purchasing from a number of repeat customers, including a large reorder from a relatively new customer acquired during the first quarter.

Several of DNA Genotek's commercial customers are starting to grow their businesses as their tests become more widely known in the marketplace, particularly here in the United States, and there was also continued purchasing from DNA Genotek's worldwide academic customer base. On the intellectual property front, in July DNA Genotek announced the issuance of a key US patent covering the physical design of its Oragene DNA sample collection kit. A similar patent has previously issued in several European countries, Mexico, Hong Kong, and China.

In the second quarter DNA Genotek also received notice that several key chemistry patents related to its product were issued in Canada, Australia, and India. We believe these newly-issued patents further build what was already a strong IP portfolio. So in conclusion, we're well prepared for the commercial launch of our OraQuick In-Home HIV Test, the first and only FDA approved rapid test for consumers. This is an extremely exciting time for our Company, and we intend to build on our performance during the first six months of 2012 as we finish the year and move into 2013. So with that. I'll now open the floor to your questions. Operator, you can proceed.

QUESTIONS AND ANSWERS

Operator

Thank you.

(Operator Instructions)

To allow time for as many questioners as possible, we ask that you limit yourself to a single question, and no more than one follow-up question related to the same topic. Charles Duncan. JMP Securities.

Charles Duncan - *JMP Securities - Analyst*

This is Roy in for Charles. Thanks for taking the question. Quick question on the HCV screening guidelines from the CDC that are coming up. The initiatives you guys have announced are pretty impressive. What do you think the market opportunity is in the population covered by these CDC guidelines, and what do you expect it to be outside the guidelines?

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

Well, so the draft CDC guidelines were issued and the comment period for response to those draft guidelines closed in early June. Our expectation is that we'll see the revised guidelines sometime soon, hopefully it'll be within weeks, but certainly we would expect sometime during this quarter, the third quarter. This is really a critical step in terms of expanding hepatitis C testing here in the United States. I mean, obviously the fact that 80 million or so individuals were born between 1945 and 1965 highlights the significant population that these guidelines are directed toward.

The prevalence of hepatitis C within this population of 3.25% is significant, and we know that the government is focussed on this because they believe that implementation of the guidelines will mean a very high yield of newly diagnosed, chronically infected hepatitis C patients who are candidates for therapy, who can go on therapy and be cured, and reduce not only the public health impact of this disease, but also the growing economic burden that later stage chronically infected patients represent to the health care system.

So this is a win-win-win for everybody, and I know that the federal government, our federal government officials, are focussed on this, they're committed to this. Obviously, we're looking forward to seeing increased funding being made available to jurisdictions as a result of this, the grant that was made, or the request for proposals that went out to the public health community earlier this year, we expect those are going to be awarded here before the end of September, and that should have an impact for our business in the fourth quarter. Obviously that's just the beginning of what we would hope will be significantly increased funding for hepatitis C prevention.

Charles Duncan - *JMP Securities - Analyst*

Okay, thank you. If I could ask a follow-up on international HCV, could you remind me, sorry if it's a naive question,, but remind me how the test is sold ex-US. Is it also considered a, I guess, a kind of a CLIA waive test? Is it available over the counter? I'm sure it differs market to market but in most of the international markets, what's the usage like, is it public health, things like that? Thank you.

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

So internationally it's all sold through distribution. It is not sold over-the-counter. It's only available in the professional market, and the primary purchasers have been for more public health applications.

Charles Duncan - *JMP Securities - Analyst*

Great, thank you.

Operator

Bob Nielsen, ThinkEquity.

Charles Duncan - *JMP Securities - Analyst*

This is Mary. I just have a quick question about the impact that you observed, if any, as a result of the recent HIV government sponsored testing initiatives, in terms of giving you a firmer or more tangible figure for the actual size of the end user market upon the launch of the HIV test?

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

I'm sorry, Mary. You broke up part way through your question. So it was?

Charles Duncan - *JMP Securities - Analyst*

Well, just with the recent government sponsored testing initiatives, we're wondering if that's given you a firmer number as far as how big the HIV testing market will be upon launch? Did that shed any light on it, those initiatives that have been happening recently?

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

Are you talking specifically about the pharmacy testing initiative that was discussed?

Charles Duncan - *JMP Securities - Analyst*

Yes.

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

Okay, great. Thanks for the question. That initiative is a pilot program to evaluate whether pharmacists, whether it's an effective deployment model for pharmacists to actually administer our professional test.

Charles Duncan - *JMP Securities - Analyst*

Okay.

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

In a retail pharmacy. It is not related to our over-the-counter HIV test, which will be on shelf in the retail pharmacy. This is a two- or three-year pilot program. It was rolled out, I believe, in either 25 or 40 pharmacies across the country. I don't think that we'll get any kind of information from that which would give us any indication how our over-the-counter HIV test is going to be deployed. I think it's, the government, CDC and others, are looking for as many ways as we can possibly make HIV testing available to consumers, and this is just another deployment model that's being evaluated. You should know that in virtually all of these sites, they're using the OraQuick HIV test, both because it's so simple to administer, as well as the oral fluid application makes ideal for that kind of an application.

Charles Duncan - *JMP Securities - Analyst*

Okay, thank you.

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

You're welcome.

Charles Duncan - *JMP Securities - Analyst*

Then maybe just following up to that, what are your expectations for second half in regards to the factors that will figure most prominently into the acceleration of the HIV market once it is launched? You talked about a lot of different things that you're doing, but which ones do you think will figure most prominently?

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

Well, certainly the launch is going to -- we'll be shipping to retailers in mid-September. The product'll be available on shelf in and around October 1, and coincident with that, we'll begin all of our consumer communications strategies. So we won't realize the impact of that from a revenue perspective until the fourth quarter, and when I get done with some of my comments maybe Ron can just talk about the revenue recognition component here, because it's going to be a little bit different. We're going to realize revenue as it scans at retail. Upon launch, we're going to be executing a pretty massive public relations campaign, both at the national as well as regional level.

We're going to be leveraging targeted communications against those sub-populations that I mentioned, whether it is MSM, whether it is the Latino population, or whether it is the African-American population, we're going to coincide a lot of that work with. For example, on September 27, the National Gay Men's HIV/AIDS Awareness Day, on October 4, a lot of activity around African-American events, on October 15, the National Latino AIDS Awareness Day. So we've got a lot of activities that are coordinated with these other broader national recognition programs. Our retailers will also be activating their consumer communication strategies as well, through circulars that they put out on a weekly basis. That will begin coincident with launch, right around September 30, and they have a very broad reach.

So Walgreen's, as an example, reaches about 65 million consumers, CVS about 55 million, Rite Aid about 30 million. Then each of the retailers will also be activating their own communication and promotional strategies with newsletters, with employee magazines, with shelf signage, with health and wellness displays. At the same time, we'll be launching, as I mentioned in the script, some of our professional communication plans with physician journal ads in September and October, with a pharmacists' mailing in September. I mentioned our website, expanded website, going live right at launch. So just extensive, extensive public relations and advertising campaigns directed to our target audience, and obviously that's all going to be supported by the work I mentioned with the retailers. It's going to be very exciting. We're going to see increased spending in the third and fourth quarter to support this, but the whole objective is to get out there so that we have an extremely successful launch in the fourth quarter, carrying on into 2013 where we're going to see a big impact from this product. That's the plan.

Charles Duncan - *JMP Securities - Analyst*

Thanks for taking the question.

Operator

Jeff Frelick, Canaccord.

Jeff Frelick - *Canaccord Genuity - Analyst*

Hey, Doug, so with respect to your Merck partnership, if a new pharma partner is something you guys are going to pursue, what should we, I guess, kind of expect in any kind of new detailed strategy that you're seeking? How would that look, how would that evolve?

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

So as we've talked about before, the whole Merck relationship, we're very pleased with. One of the challenges with it was that it did restrict our ability to work, in similar fashion with other potential partners, and equally important, there's been a perception amongst other potential pharma partners that we could not work with them at all, and I think, that that's had an impact. So as we look to the future, we would prefer to have more of an open relationship and more flexibility to work with those potential partners that might make sense at any given time, and we all know that the whole HCV space is pretty fluid right now.

A key objective for us is to build awareness and drive adoption in the physician office, and obviously I talked a little bit ago about the importance of the guideline change in helping us to do that. I can tell you, the physician office distributors right now, the Henry Schein, PSS, and McKesson are all over this. They see a great opportunity for their organizations to build revenue in an area that they haven't had access to before. Each of them are actively involved now in helping us to drive awareness in the segment.

Those activities involve everything from making not only the OraQuick HCV, but also the OraQuick HIV in combination an important part of their sales reps' compensation, driving direct mail programs in both, not only July and August, but in the months to come, focusing on community health centers and federally qualified health centers, developing custom information materials promoting the probable issuance of these new CDC guidelines, and obviously they've got tremendous reach into the physician office market. So we're pretty encouraged by that. Then as we evaluate other opportunities to develop relationships with other pharmaceutical potential partners, we'll be evaluating that, as well, and when there's something to report on that, we'll certainly share it.

Jeff Frelick - *Canaccord Genuity - Analyst*

Doug, do you think that distributor partners will be able to detail the HCV, HIV tests, and close it with the physician office practices, or do you think they'll be required more to bring in the OraSure manufacturer rep to detail it and close it?

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

I think it is a combination of both. I think in some cases they'll be perfectly fine. I mean, the good news is, is we've got the manufacturers' reps right behind them, working closely with them, to assist in the follow-up, and depending on the size of the group practice, we can always work with our local reps, too, to assist in the efforts. So in all cases, even when Merck was detailing the product, that demand was being fulfilled through the physician office distributor. So we think this is very efficient right now, and I can't emphasize enough, this represents incremental revenue to those physician office distributor reps, and so there's a nice incentive for them to drive this business.

Jeff Frelick - *Canaccord Genuity - Analyst*

Okay. Then just a quick follow-up for Ron, With respect to the 3Q guidance, basically flat sequentially, maybe you can just kind of point to where you're basically displaying some caution. I'm just kind of curious, where do you think that is. Is it on the traditional HIV side or is it somewhere else?

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

It's in different pockets of the business, Jeff. I would say that we still are going through with substance abuse, some of the impacts that we've had from one of our large laboratory distributors adopting a in-house product for a drugs of abuse testing. That's going to impact our revenues, we believe, in Q3 sequentially from Q2. wWe are not likely to see the same level of cryo business in Q3 as we did in Q2, particularly related to the over-the-counter contribution., as you begin to work through some of the seasonal effects in that business.

Then, of course, as we've talked about previously, there are some headwinds there in the infectious disease business in HIV, related to particularly government funding, and the impact that it's having on some of the testing initiatives at the various jurisdictions. Then if we go back all the way

to DNA Genotek, that business, given the high focus on research, there's typically a little bit of a lull in research funding and spending over the summertime, and that typically, that's their historical pattern. So that's where we would see the pockets of conservatism in the Q3 number.

Jeff Frelick - *Canaccord Genuity - Analyst*

Okay. Thanks, Ron.

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

Sure.

Operator

(Operator Instructions)

Charles Duncan, JMP Securities.

Charles Duncan - *JMP Securities - Analyst*

Hi guys, just a quick follow-up. I realize you have your hands pretty full with the HIV and the HCV initiatives, but a couple of questions. Do you have any plans for a CLIA waiver for the oral fluid for HCV, and what's the outlook on that? Then a kind of nebulous question, I apologize if it's hard to answer, but I guess outside of the home HIV and the CLIA waived HCV test, what do you see as the most compelling growth area for the Company if you had to pick one? Thank you.

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

All right, okay. So relative to CLIA waiver for an oral fluid application, we first have to have the oral approval from the FDA, and we haven't yet gotten clarity on the path forward yet with the FDA on that. When we do have that, as I mentioned, I'll share that. Relative to opportunities beyond HCV and the over-the-counter opportunity here in the United States, we believe there's many, so many that we've talked about this previously, we've been doing some strategy work in terms of our next development priorities. Certainly this is isn't necessarily a development priority, but what we believe is a significant commercial opportunity, and that is to expand globally the availability of an in-home HIV test.

Now, we've done some preliminary market research as to what markets would be the likely next countries or regions that we would pursue in over-the-counter HIV test. We've had a number of direct inquiries from different countries. We want to do a little bit more quantitative market research to make sure that we're real clear on what the unit demand we might expect, as well as the pricing for an over-the-counter HIV test in the different geographies, and our objective is to work on that between now and the end of the year so that we can pursue this in earnest in 2013 on a priority basis. Now that we've created a road map for FDA approval of a self-test for an infectious disease, we're going to look at other opportunities, including the possibility of home test for hepatitis C.

More work needs to be done on that in terms of evaluating just what that market opportunity might look like in terms of units here in the United States, but now that we've got a road map, I think there's no question we're going to evaluate that. Then we're looking at other opportunities, both in terms of internally developed products, as well as constantly on the lookout for other products that might be complimentary to our sales organizations that are calling on public health market, calling on hospitals in the emergency department, and the like. So we're not short on opportunities. We want to obviously execute on these investments that we've made, and that we're in a great position to capitalize on right now, but we'll say more about our development priorities as we look to 2013 in future calls.

Charles Duncan - *JMP Securities - Analyst*

Great, thank you.

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

You're welcome.

Operator

Thank you. That brings us to the end of the Q&A session of today's call. I would now like to turn the call over to Doug Michels for closing remarks.

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

Okay. I just want to thank you all again for being on the call this afternoon, and your continued interest in the Company, and we've got a lot of exciting things we're executing on. We look forward to updating you on how that work goes in subsequent discussions. Have a great afternoon and evening, everyone. Thank you.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the program. You may now disconnect, and have a wonderful day.
