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OSUR - OraSure Technologies Inc Conference Call to provide an update on certain developments related to its OraQuick HCV

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

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Peter Lawson *Mizuho Securities - Analyst*

Jose Haresco *JMP Securities - Analyst*

Mark Massaro *Canaccord Genuity - Analyst*

Nicholas Jansen *Raymond James and Associates - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the OraSure HCV development update conference call.

(Operator Instructions)

As a reminder this conference is being recorded. I will now turn the call over to Rena George-Beck. Please go ahead.

Rena George-Beck - OraSure Technologies, Inc. - IR

Good morning, everyone, and welcome to OraSure Technologies' conference call and simultaneous webcast. As a reminder, today's conference is being recorded.

(Caller Instructions)

OraSure Technologies issued a press release at approximately 8 AM Eastern time today announcing that the Company has entered into a Co-Promotion Agreement with AbbVie with respect to the Company's OraQuick Rapid HCV Test. The press release is available 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 press 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 June 17, 2014 by calling 855-859-2056 for domestic or 404-573-3406 for international. The access code is 59796252.

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 by a brief 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, loss per share and sales and marketing plans. Actual results could be significantly different. Factors that could affect results are discussed more fully in the Company's SEC filings, including its registration statement, its annual report on Form 10-K for the year ended December 31, 2013, its quarterly reports on Form 10-Q and its other SEC filings.



Although forward-looking statements helped to provide complete information about future prospects, listener 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*

Great. Good morning and thank you, Rena. Good morning, everyone, and welcome to our call. I'm extremely pleased to share with you that our Company has entered into a Master Program Services and Co-Promotion Agreement with AbbVie, under which AbbVie and OraSure will co-promote our Company's OraQuick HCV Rapid Test in the United States.

The agreement is among the most significant in our Company's history. First and foremost it will enable us to broadly provide healthcare professionals and the patients they serve with a critically important rapid diagnostic test. Second, we believe this opportunity will be transformative for OraSure and will drive significant growth in our hepatitis C testing business.

There's never been a more critical time to know your HCV status. As we previously discussed on earnings calls, there are many positive trends occurring with respect to hepatitis C testing and treatment, not the least of which is the development of new and more effective drug therapies.

Under the new agreement, we have granted exclusive rights to AbbVie to promote with us the use of our OraQuick HCV Rapid Test in certain markets and we will provide certain services in support of HCV testing. In exchange for those rights, OraSure will receive up to \$75 million in exclusivity payments over the term of the agreement which runs through December 31, 2019. In addition, upon achievement of certain performance-based milestones, the Company will be eligible to receive additional payments ranging from \$3.5 million to \$55.5 million per year over the life of the agreement.

Hepatitis C is the most common chronic blood-borne infection in the United States and the Centers for Disease Control and Prevention estimates that 1 in 30 baby boomers, adults born between 1945 and 1965, have a chronic infection. Perhaps most alarming is that up to 75% of people infected with hepatitis C are unaware of their infection which is why the CDC, the US Preventive Services Task Forces and the American Association for the Study of Liver Diseases, have all issued guidance that recommends HCV testing for at risk individuals including all baby boomers.

It is critical that at risk individuals be tested for hepatitis C to prevent potentially serious consequences from undiagnosed and untreated infection. Hepatitis C is the leading cause of liver cancer and liver transplants. Our OraQuick Rapid HCV Test, the only FDA approved and CLIA-waived point of care test enables healthcare providers to deliver a diagnosis based on lab accurate test results in just 20 minutes using a finger stick or venipuncture blood sample. With that, let me turn the call over to Ron who can share some financial highlights associated with the agreement.

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

Thanks, Doug, and good morning, everyone. As Doug referenced, in exchange for providing exclusive co-promotion rights to AbbVie for the OraQuick HCV Test in certain markets, OraSure will receive up to \$75 million in exclusivity payments over the term of the agreement which runs through December 31, 2019. We plan on recognizing the exclusivity payments ratably on a monthly basis over the life of the agreement.

In addition, upon achievement of certain performance-based miles, the Company will be eligible to receive additional payments ranging from \$3.5 million to \$55.5 million annually over the life of the agreement. It's important to note that the first potential recognition of milestone revenues would occur during 2015 under this component of the agreement. We expect the success we have under this component of our relationship with AbbVie to ramp over time.

The agreement also contains termination, indemnification and other provisions typical for agreements of this type. Additional information about the agreement can be found in our 8-K report which was filed shortly after the start of this call.

As we look out over the balance of this year, in addition to recognizing incremental revenues, we will be investing in various promotional programs that we will pursue with AbbVie. These programs will require bringing on additional personnel to staff new initiatives and incurring programmatic expenses. We will be disclosing more details of the specific programs as they are launched over the next several months.

Consequently, we are revising our guidance for the second quarter to include the anticipated new revenues and expenses from the AbbVie collaboration. We now are projecting consolidated net revenues of between \$26 million and \$26.5 million and a consolidated net loss in the range of \$0.08 to \$0.09 per share for the second quarter.

As we take a somewhat longer view of the business, this exciting opportunity with AbbVie along with the changes that we have announced with our HIV OTC program and the expected termination of certain patent royalties on sales of our professional and OTC HIV products beginning in early 2015, are expected to drive the Company to full-year profitability in 2015. And with that, I'll now turn the call back over to Doug.

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

Thank you, Ron. This is truly a significant milestone for our Company and a major step in achieving our vision for this amazing product. I would like to thank all the people at AbbVie and OraSure who worked so hard to make this agreement a reality. It is a great achievement for each of our respective companies.

More importantly, we now have the opportunity to make a significant impact on those patients at risk for HCV, especially those who are unaware they are infected and face potentially serious health consequences from going undiagnosed and/or untreated. And with that, I'll now open the floor to your questions. Operator, please proceed.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Brandon Couillard, Jefferies.

Brandon Couillard - *Jefferies & Co. - Analyst*

Doug, why go the exclusive route with AbbVie here? Could you elaborate on how you expect them to go to market in terms of which specific certain markets they will have rights? And perhaps quantify the size of the sales force that they'll be promoting with?

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

Let me first talk a little bit about the exclusive nature of this and understand that it is specific to the United States and to specific markets here in the United States. For quite some time, we've had discussions with each of the major hepatitis C therapeutic manufacturers. And as it turns out, our discussions with AbbVie progressed the furthest and developed into the most broad-based relationship that this agreement represents.

I think that as we continue discussions with AbbVie and others it became very clear that there was a clear strategic alignment between our two Companies, with the primary focus first of all on the patient. And secondarily on the providers and the caregivers supporting those patients and ultimately shared commitment to be the best at what we're trying to do here and to win in the marketplace.

That developed into the agreement that we're announcing today. I think it's an extraordinary agreement for both Companies and for the patients that we serve. And we expect it to really be a home run for all of us.



As it relates to the specifics of the programs and the initiatives and the go-to-market strategies, we'd love to be more specific about those today, but unfortunately we cannot. You can be sure that as we mentioned in our prepared remarks, that as we launched the specific programs and initiatives that are contemplated in this agreement, that we will then give more color to those specific initiatives and our specific responsibilities.

I think you should bear in mind that OraSure has a significant incentive to achieve the performance-based milestones in this agreement. And these milestones are directly related to the specific programs and initiatives that we refer to here. And to disclose the details of these strategies today, before we're ready to announce them to the market, I believe would potentially compromise our competitive advantage and compromise our ability to earn or to maximize these performance-based milestone payments.

So you can be sure that given the magnitude of the incentive opportunity that these are significant programs and we've outlined several major initiatives that we intend to announce over the next several months. And I look forward to sharing the details of those with you when we are prepared to disclose them.

Brandon Couillard - *Jefferies & Co. - Analyst*

Okay, fair enough. And will -- would you expect AbbVie to begin promoting trying to find patients prior to its launch or its PDUFA date in the US later this year? And then Ron, could you remind us the type of gross margin you capture on HCV tests?

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

I'll handle the first part of that and then let Ron handle the margin piece. The co-promotion agreement is effective immediately, and our objective together with AbbVie is to educate providers and patients about HCV, about the importance of diagnosis and about the availability of our Rapid hepatitis C test. We share a common goal to increase awareness and to identify as many undiagnosed hepatitis C patients as we possibly can.

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

So responding to your question on gross margin, I would suggest it's based obviously on the channel into which we sell the product. But for modeling purposes it's -- the incremental revenues would generate a gross margin better than our corporate average and probably more skewed towards the higher end of 60%.

Brandon Couillard - *Jefferies & Co. - Analyst*

Super. Thank you.

Operator

Shaun Rodriguez, Cowen and Company.

Shaun Rodriguez - *Cowen and Company - Analyst*

So first somewhat of a followup, but can you say what the specific markets are where this exclusivity applies? And I guess what I'm getting at is when you think about the various channels as you've described them for this product with public health, physician office, hospitals and alternative sites, where will AbbVie be focused? Or asked another way, what's the incremental portion of the market opportunity that this allows you to address?

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

Without speaking to the specifics, because we're not prepared to disclose that today, you can be sure that it is across a very broad cross section of those markets that you described.

Shaun Rodriguez - *Cowen and Company - Analyst*

Okay. So then on the economics. So the increased guidance for Q2, at least for revenue less than \$1 million or so. So is that non product up front payment, milestone payment revenue that as it's recognized?

And then think you said the potential earn out components start in 2015, but on the exclusivity payments, is there more coming this year in 2014?

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

Yes. Yes there is, Shaun. And in fact the incremental step up from our prior guidance we leased on the earnings call is representing the amortization of the exclusivity payments specifically for the portion of June that is relevant here, which amounts to about in the range of about \$800,000.

And then going forward, we would be recognizing the exclusivity payments on a monthly basis and that monthly revenue is approximately \$1.1 million. And that would be through the life of the agreement which runs as we've indicated through the end of 2019.

Shaun Rodriguez - *Cowen and Company - Analyst*

Okay. But to be clear, I think the press release says that even the exclusivity is up to \$75 million through the end of the deal. So is there a guaranteed minimum of that number?

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

There are payments that we will be receiving shortly and over the next several years, but as we indicate in our 8-K and in our prepared remarks here, the contract is subject to standard termination provisions that are included in it.

Shaun Rodriguez - *Cowen and Company - Analyst*

Okay. So it's reasonable to assume that you do ultimately realize that exclusivity payment through the end of the contract period. Okay, thank you.

Operator

Peter Lawson, Mizuho.

Peter Lawson - *Mizuho Securities - Analyst*

Ron, are there potentially other partners you could gain outside these specific markets with AbbVie?

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

So the agreement was structured to ensure that if -- that our test would be available through distribution to anyone who wanted access to it. So our specific and exclusive co-promotion activities with AbbVie as we said are specific to these markets here in the United States. This is a domestic



agreement, and so for now there are no obligations to AbbVie nor anyone else in the international markets and obviously that represents another opportunity for OraSure down the road.

Peter Lawson - *Mizuho Securities - Analyst*

And the exclusivity in the US, is that -- sounds like that's part of the US or is it parts of particular channels in the US?

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

As we speak to the specific programs and initiatives, that will become crystal clear as to what markets and what segments that exclusivity applies to.

Peter Lawson - *Mizuho Securities - Analyst*

Great. Thanks so much.

Operator

Jose Haresco, JMP Securities.

Jose Haresco - *JMP Securities - Analyst*

Hello, guys, good morning and congratulations on the announcement.

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

Thanks, Jose.

Jose Haresco - *JMP Securities - Analyst*

Could you give us a sense of you've mentioned that you'll be incurring expenses. I think we can assume that AbbVie will be ramping up some activity ahead of the PDUFA date.

What can we expect on your side terms of expenses? And in general how should we think about the expenses associated with this revenue stream going forward?

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

Sure. I would suggest that with the initiation of this program, we will be incurring staffing expenses as well as programmatic expenses related to the initiatives that will be announced over the next several months. And there will -- those are more front-end loaded then they are back-end loaded, so I would model the expenditures to be somewhat in the approximate range of the revenues that are being recognized over the initial part of the agreement from the amortization of the exclusivity payments, Jose.



Jose Haresco - *JMP Securities - Analyst*

Okay.

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

Jose, I can add just a little bit to that. From a resource perspective, we will be adding people in the marketing area as you might expect, in the customer training area and in the program management area because there are multiple programs and initiatives that are going to have to be orchestrated between both Companies.

As it relates to additional services that we'll be providing, which I referenced in the release, we're going to be providing training to customers beginning to use our product. Obviously customer support, complaint management services and then other specific services related to the programs and initiatives that we'll describe once they're launched. So again, it's a very comprehensive program and relationship that we're entering into with AbbVie.

I think it's important too that everybody appreciates there's really three sources of revenue as it relates to this relationship. One is the exclusivity fees which Ron spoke about and how we're going to recognize those.

The second is test revenues. We are going to continue to sell the test directly into all markets. And so as we go out and promote the test together with AbbVie, our expectation is we're going to secure new customers and they're going to begin ordering the HCV product and we expect to see significant growth as a result of these promotional efforts.

So the exclusivity fees, additional test revenues, and then as Ron talked about, beginning in 2015, assuming we achieved the specific performance objectives then we'll see on top of that revenue from the performance-based milestone payments.

Jose Haresco - *JMP Securities - Analyst*

Okay. Could you -- to be clear on the performance metrics, that's tied to kit volume or your revenue and to -- there's no regulatory milestones associated with that, it's purely on volume right or is it mix?

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

It's tied to the specific performance objectives of each of those objectives of those programs that we spoke about earlier. So we'll talk about that once we begin to launch those programs.

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

But to be clear, there are no regulatory milestones that need to be achieved to trigger them.

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

That's correct.

Jose Haresco - *JMP Securities - Analyst*

Okay, great. Thanks very much.

Operator

Mark Massaro, Canaccord Genuity.

Mark Massaro - *Canaccord Genuity - Analyst*

Congratulations on the announcement. I wanted to maybe see, Ron, if you could add a little more color. I think you mentioned that you're on track to achieve profitability by the end of 2015. Is it safe to say that the incremental revenue from this deal will likely offset some of the expenses but still put you on a path to profitability by the end of 2015?

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

Yes, so our expectation is that as I talked about the combination of all the factors in our prepared remarks, this arrangement with AbbVie, the previously announced recalibration of expenditures for HIV OTC, the expected rolling off of royalties that occur in the early part of 2015, all of those in concert work to get us to full-year profitability for 2015. And I'll further take it to say that that's -- without including any contribution from the fee for service or the success payments associated with our performance under AbbVie agreement. So we're feeling very good about the trajectory that we're on and looking to drive the Company to profitability.

Mark Massaro - *Canaccord Genuity - Analyst*

Great, thanks. And obviously the \$3.5 million to \$55.5 million incentive payments are quite a wide range. If you could maybe provide any color at all about to what extent that is based on geographic penetration versus volumes in the US that would be helpful. Thanks.

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

So this is really a US deal, Mark. And so all of the performance milestones and parameters are derived from execution here in the US marketplace without any reference to our international performance.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. Thanks, guys.

Operator

(Operator Instructions)

Nicholas Jansen, Raymond James and Associates.

Nicholas Jansen - *Raymond James and Associates - Analyst*

Hey, guys, congrats on the deal. One quick question or follow up. Thinking about this agreement relative to the one that you had previously the exclusive agreement you had with Merck that was canceled back in 2012, was wondering if you could point out any major differences or advantages with the AbbVie deal relative to what you guys were standing back then? Thanks.

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

Well completely different agreement structure. This agreement with AbbVie is much more comprehensive than anything we had with Merck. You recall Merck's commitments were to detail the product into the physician's office market and that was the extent of that relationship other than they supported some of the development in the early days of the product.

This AbbVie co-promotion agreement has multiple components across the entire, virtually the entire US market. And as we roll out those different programs and initiatives, you'll fully appreciate it. Clearly the economics of this deal are much more significant and comprehensive than anything we've had with Merck. And I think their representative of the size and scope and breadth of this relationship as you'll find out. So very, very different agreement.

And clearly with all the other developments in the marketplace with heightened awareness about HCV, the market factors that are in place now to promote hepatitis C testing and diagnosis and now with new therapies in the market and soon to be introduced to the market, it's a completely different time and opportunity for the Company. So thanks for asking the question, but we are really stoked about this opportunity, and we expect to hit the ball out of the park.

Nicholas Jansen - *Raymond James and Associates - Analyst*

Great. And then one follow up maybe for Ron. The \$1.1 million monthly payment, so that's about \$3 million plus a quarter and you mentioned that the expenses are more front-end loaded. So that we all don't get ahead of ourselves in terms of modeling, are we expecting the expense ramp to be similar in the first or at least in the back half of the year so we can get a sense of this is not really necessarily adding a whole lot of earnings at least over the next quarter or two but more meaningful in 2015 and beyond?

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

I think that's a fair way of looking at it, Nick, yes.

Nicholas Jansen - *Raymond James and Associates - Analyst*

Thanks so much.

Operator

I'm showing no further questions, I will now turn the call back to Doug Michels for closing remarks.

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

Okay, hey listen thanks, everybody, for coming on the call so early this morning. We appreciate your continued interest and support in the Company. We look forward to speaking to you about our success with this relationship in future calls. Have a great day, everybody.

Operator

Ladies and gentlemen, that does conclude today's conference. You may all disconnect and everyone have a great day.



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