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OSUR - Q3 2015 OraSure Technologies Inc Earnings Call

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## CORPORATE PARTICIPANTS

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

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

## CONFERENCE CALL PARTICIPANTS

**Eric Criscuolo** *Mizuho Securities USA - Analyst*

## PRESENTATION

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

Good afternoon, everyone, and welcome to OraSure Technologies 2015 Third Quarter Financial Results Conference Call and simultaneous webcast. As a reminder, today's conference is being recorded. (Operator Instructions)

OraSure Technologies issued a press release at approximately 4 p.m. Eastern Time today regarding its 2015 third quarter financial results and certain other matters. 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, November 11, 2015, by calling 855-859-2056 for domestic, or 404-537-3406 for international. The access code is 52009076.

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 a 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 or other financial performance, product development performance, shipments and markets, business plans, and regulatory filings and approvals. 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, 2014, its quarterly report 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 statement to reflect events or circumstances after this call. With that, I would like to turn the call over to Doug Michels.

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

Great. Thanks, Rena, and good afternoon, everyone, and welcome to our call. The third quarter continued our strong performance in 2015. Consolidated net revenues were $29.9 million, and they came in at the high end of our guidance for the quarter. The drivers for this performance were our molecular collection systems business, and continued momentum for our rapid hepatitis C test. Molecular collection systems revenues increased 7% over the prior year period. Third quarter sales of our OraQuick rapid hepatitis C test increased 62% over the third quarter of 2014, and 23% sequentially from the second quarter of this year. Together with the exclusivity payments recognized under our HCV co-promotion agreement with AbbVie, total HCV-related revenues were $6.3 million for the third quarter.

Revenue growth combined with favorable margins generated a $1.5 million net profit for the third quarter. This is the third consecutive quarter of profitable performance for the Company. Later in the call I will provide additional highlights regarding our business, but before I do that, Ron will provide more detail on our third quarter performance and expectations for the fourth quarter. So, with that, let me turn the call over to Ron.

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

Thank you, Doug, and good afternoon, everyone. Our third quarter 2015 consolidated net revenues increased 7% to $29.9 million compared to $27.8 million reported in 2014. Our consolidated net product revenues of $25.7 million increased 5%, largely as a result of higher sales of our OraQuick HCV, Intercept and molecular collection systems products partially offset by lower sales of our OraQuick HIV product.

Other revenues were $4.1 million in the current quarter, of which $3.4 million represents the recognition of exclusivity payments under the AbbVie agreement, and $750,000 represents revenue associated with Ebola-related funding we received from the Biomedical Advanced Research and Development Authority, or BARDA. Other revenues in the third quarter of 2014 included $3.4 million of AbbVie exclusivity payments.

Total HCV-related revenues including the AbbVie exclusivity payments increased 21% to $6.3 million in the third quarter of 2015 compared to $5.2 million in the third quarter of 2014. Our HCV product revenues increased 62% to $2.9 million in Q3 from $1.8 million in the prior year. Sales of our OraQuick HCV professional product in the domestic market increased 47% in the third quarter of 2015 to $1.9 million from $1.3 million in the prior year. This increase is largely due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs.

International sales of our HCV test in the third quarter of 2015 increased 104% to $957,000 from $470,000 in the same period last year primarily due to the timing of purchases by a multinational humanitarian organization. Also contributing to the higher international sales was the expansion of our HCV business in Asia.

Domestic sales of our professional HIV product decreased 23% to $5.5 million in the third quarter of 2015 compared to $7.2 million in the third quarter of 2014. This decrease was the result of customers continuing to move some of their testing to fourth-generation automated HIV immunoassays or to competitive point of care tests that are perceived to be more sensitive. We expect continued pressure on our professional HIV business for the foreseeable future.

Sales of our OraQuick in-home test increased 20% to $1.6 million in the current period from $1.4 million in the third quarter of 2014, largely due to the timing of orders placed by our retail trade customers.

Our molecular collection systems revenues, primarily representing sales of the Oragene product line in the genomics market increased 7% to $7.3 million in the third quarter of 2015 compared to $6.9 million in the third quarter of 2014. Commercial sales increased approximately 20% primarily as a result of higher sales to existing US-based customers. Sales to academic customers decreased 11%, largely due to the fulfillment of an order in 2014 for a large academic research project that did not repeat in 2015.

Substance abuse testing revenues rose 38% to $3 million in the third quarter of 2015 compared to $2.1 million in 2014. This increase is largely due to higher sales of our Intercept device as a result of the recovery of customers previously lost to competition, improved domestic employment conditions, and an increase in oral fluid testing due to certain customers recognizing the advantage of its ability to detect recent drug use.

Our third quarter 2015 cryo revenues increased 7% to $3.5 million from $3.2 million in the third quarter of 2014. Domestic sales of our professional product remains largely unchanged at $1.6 million. International sales of our professional product increased to $258,000 in the third quarter compared to $43,000 due to the reintroduction of our product into the Asian marketplace.

Sales of our over-the-counter products in the international markets decreased 9% to $1.5 million in the third quarter of 2015 compared to $1.6 million in the third quarter of 2014 primarily due to distributor ordering patterns.

So, turning to gross margin, our gross margin for the third quarter of 2015 was 69%, compared to 67% reported for the third quarter of 2014. Margin for the current quarter benefited from a reduction in royalty expense and the increase in other revenues largely offset by the impact of a less favorable product mix.

Looking at operating expenses, our consolidated operating expenses for the third quarter of 2015 were $19.1 million compared to $17.8 million in the comparable period of 2014. During the current quarter, higher detailing costs associated with our HCV co-promotion agreement with AbbVie

and increased legal [expenses] were partially offset by lower R&D spending and a favorable change in the exchange rate between the Canadian and US dollar.

From a bottom line perspective, we reported net income of $1.5 million, or $0.03 per share on a fully diluted basis for the third quarter of 2015 compared to $1.1 million or $0.02 per share for the same period of 2014.

So, turning briefly to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Cash and short-term investment balance at September 30 was $108.2 million compared to $97.9 million at December 31, 2014. Cash generated by operating activities in the third quarter of 2015 was $18.5 million compared to $18.8 million generated in the third quarter of last year.

Turning to guidance for the fourth quarter of 2015, we are projecting consolidated net revenues of approximately $29.5 million to $30 million. We are also projecting consolidated net income of approximately $0.03 to $0.04 per share. Our current expectations for Q4 exclude a $1.1 million order for OraQuick HIV and HCV devices that has been received from a public health jurisdiction that normally orders at the end of their fiscal year. Given certain constraints surrounding the warehousing of inventory by this customer, we were not comfortable in assuming that they will take delivery of the product before year-end, which would be required to recognize the revenue.

As we look further ahead to Q1 of next year, it is important to remember that the first quarter of the calendar year is historically our softest quarter for revenues. We do expect this pattern to continue in 2016. An additional item to note is that our existing universal shelf registration statement that became effective in 2012 is set to expire during the fourth quarter of 2015. We intend to file a new universal shelf registration statement consistent with our previously communicated practice of always having a shelf registration statement in effect. And with that, I will turn the call back over to Doug.

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

Okay, thanks, Ron. As noted earlier in the call, DNA Genotek had another very strong quarter. The $7.3 million in current quarter revenues represents the second highest quarterly revenue total in DNA Genotek?s history. Through the end of September 2015, DNA Genotek generated more than $22 million of revenue, which represents growth of over 25% compared to the first nine months of 2014. The revenue split for the third quarter was largely consistent with prior quarters, with commercial customers representing 60% of the total, and academic customers contributing the remaining 40%. Commercial revenues were up 20% year-over-year in the third quarter.

The largest contributor to the growth of our commercial revenues was 23andMe, which delivered $1.7 million of revenue for the quarter. This represents more than 200% growth over the third quarter 2014, when 23andMe was dealing with certain regulatory issues. You will note that DNA Genotek's third quarter revenues were down sequentially from the second quarter, as expected, primarily as a result of the ordering pattern of a large breast cancer genetic testing company. This customer made its initial purchase in second quarter to deploy our Oragene DNA sample collection product into its large network of collection centers. This initial purchase contributed to DNA Genotek?s record revenue performance in Q2. Although this customer purchased additional product in Q3, the amount purchased was naturally down from the initial stocking order last quarter. Overall, third quarter performance across a number of commercial customers was strong, and we are very pleased with the advances we have made in this market.

On our last call we discussed DNA Genotek?s new product initiatives in microbiome and tuberculosis, and I am pleased to report that these initiatives are progressing as expected. We continue to acquire new customers in the microbiome space. We are also continuing to execute the trials and the validation studies through partners and prospective customers to demonstrate the capabilities and value of our tuberculosis products.

Turning to infectious disease testing, revenues from this part of the business were up 1% compared to the third quarter of 2014. Lower sales resulting from the continued challenges impacting our professional HIV business were largely offset by continued growth in revenues from our OraQuick HCV test. We expect both of these trends to continue for the foreseeable future.

With respect to HCV, this part of our business continues to show promising growth. As previously mentioned, total HCV revenues were up 62% during the third quarter compared to 2014 and were up 23% sequentially from the second quarter of this year. These results were driven by strong growth in both the domestic and international markets. We expect continued growth and also anticipate sequential growth in the fourth quarter.

As noted during our last several calls, a major focus continues to be our co-promotion agreement with AbbVie. Our efforts in the physician office market have included refreshed training for both the AbbVie and OraSure field sales teams, improved messaging for customers, and increased detailing by AbbVie.

In the retail market, the pilot program mentioned on prior calls has continued in order to help assess the effectiveness of using our test to identify positive patients and link them to care. We will continue to look for ways to maximize the benefit of this collaboration on our HCV business.

The final area I will address is our ongoing efforts to commercialize the OraQuick Rapid Ebola Antigen Test. In the quarter we announced significant progress toward the commercialization of this product. In September, BARDA exercised an option to provide an additional $7.2 million in funding, primarily for clinical and regulatory activities required to obtain US FDA 510(k) clearance. This option is part of the $10.4 million aggregate funding contract between OraSure and BARDA that was announced in June 2015.

The Company also announced that the CDC will purchase approximately $1.5 million of the Company's OraQuick Ebola Test. The CDC purchase is expected to be fulfilled by the end of this year with approximately $500,000 in revenue recognized in the third quarter, and the remainder expected here in Q4. The CDC is purchasing the OraQuick Ebola Test for field testing in West Africa. This is the second such purchase of this product for field testing made by the CDC. We will continue to focus on the completion of regulatory activities and on securing sustainable purchase commitments for this product.

So, in conclusion, our financial performance for the third quarter was strong, with solid revenues and another quarter of profitability. Our molecular collection systems and HCV businesses continue to be the growth drivers for the Company, and we expect that to continue for the foreseeable future. We are also making good progress on the commercialization of our OraQuick Ebola Test, and we look forward to wrapping up a record 2015 with a solid fourth quarter, and we look forward to continued growth in 2016. And with that, I will now open the floor to your questions. Operator, if you would please proceed.

## QUESTIONS AND ANSWERS

**Operator**

Thank you. (Operator Instructions) And our first question comes from the line of Brandon Coulliard with Jefferies. Your line is open, please go ahead.

**Unidentified Participant**

This is actually Kate in for Brandon. Could you maybe give a little more detail on the impact of AbbVie detailing what you saw in the quarter and how you expect detailing, the level of detailing to trend into 4Q? And just to clarify, do you expect domestic HCV up sequentially? Thanks.

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

This is Doug. Hi, Kate. Answer the last question first, so we indeed expect domestic HCV revenues to be up sequentially in Q4, so that's high confidence there. Relative to AbbVie detailing, Abbvie detailing was at a peak in the third quarter, so I think it remains to be seen if that level of detailing continues into Q4. We will obviously monitor that closely. As I think Ron emphasized, expenses in the third quarter were impacted by an increase in AbbVie detailing expenses, and actually at this point in time, we have exhausted our obligation from a financial perspective to AbbVie detailing. So, we should see a sequential decrease in expenses associated with AbbVie detailing in the fourth quarter. That doesn't mean that their

detailing will necessarily -- their detailing activity will be necessarily reduced, it just means that our financial obligation as it relates to AbbVie detailing will be reduced substantially in the fourth quarter.

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**Unidentified Participant**

Great, thanks. And just one question on Genotek. Did you have a comment on Genotek's current capacity utilization and what type of impact will the capacity expansion planned for next year, I believe, have on gross margins? Thank you.

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

Kate, we apologize, but we missed a large part of that question. Could you repeat that, please?

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

Yes, we're getting a lot of echo on your line, Kate. So, I don't know if you're on a speaker or if you can pick up?

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**Unidentified Participant**

Sorry about that, guys. I was just wondering, could you comment on Genotek's current capacity utilization and what type of impact will the capacity expansion plan for next year, I believe, have on gross margins, if any? Thank you.

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

So, DNA Genotek has plenty of capacity to meet existing demand and expanded demand. We are going to be increasing capacity, and that new capacity is going to come online in the first quarter of 2016. So, we do not expect any issues from a capacity constraint either in the near term or into 2016.

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

And we don't expect any effect on our gross margin profile, Kate, from bringing online that additional capacity.

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**Unidentified Participant**

Okay, great. Thanks. I'll jump back in the queue.

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**Operator**

(Operator Instructions) Our next question comes from the line of Eric Criscuolo with Mizuho Securities. Your line is open, please go ahead.

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**Eric Criscuolo** - *Mizuho Securities USA - Analyst*

Did the relaunch of the 23andMe tests that just occurred, did that have any impact on the quarter? Was there any inventory stocking from them, or do you expect this to affect more the quarters going forward?

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

So, they just recently relaunched their program here in the US for carrier screening, and we certainly have been coordinating our activities with them to make sure that we have sufficient product for them to accommodate what needs they may have. But I wouldn't say that we have seen any extraordinary purchasing from them in advance of the launch, but we certainly are prepared to support them in every way we can to make that launch successful and to have products available to respond to their needs.

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**Eric Criscuolo** - *Mizuho Securities USA - Analyst*

Gotcha. Okay, thank you. And the HCV international purchase that you referenced, I think it was the NGO, is that the same customer that you've been speaking about for the past year or two?

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

Yes, it is, Eric. In addition to that customer purchasing more than they typically have done in the quarter, I think in large part due to timing, we have seen nice growth in the Asian marketplace for our HCV test, and that, too, was a contributing factor to increased HCV revenues in the international space.

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**Eric Criscuolo** - *Mizuho Securities USA - Analyst*

Okay, gotcha. Thanks. And then just lastly on the Ebola program, and specifically the $7.2 million from the BARDA funding, can you remind me how that is going to be recognized by you?

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

Right. So, that $7.2 million, as Doug indicated, is there and available to fund our activities in support of securing 510(k) clearance for our rapid Ebola antigen test. And those activities include the finalization and locking in of the actual product itself, validating that, scaling that up from a manufacturing perspective, having sufficient product to conduct clinical trials in support of the 510(k) claim, and then filing. And so all the costs associated with that, whether it be from R&D, clinical and regulatory, that will be reimbursed by BARDA as we progress through that phase of development. That is likely to take us out through the 2017 timeline, and so we will recognize revenue coincident with the incurring of costs associated with that program. And we will give visibility as to how that is going to roll out as we move through time, but as you might suspect, the conduct of the clinical trials, the amount of money that we're going to spend for those clinicals, the accrual of patients, all is somewhat vague at the moment as far as timing and expense levels. But we will endeavor to give you as much visibility as we can as we move through the process.

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**Eric Criscuolo** - *Mizuho Securities USA - Analyst*

Oh, great. Thanks for the color there. That is certainly helpful. And then, I'm sorry, just one more on -- the expectations are still for not recognizing any performance fees from AbbVie; is that correct?

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

Yes, that is correct.

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**Eric Criscuolo** - *Mizuho Securities USA - Analyst*

Right, okay. That's it. Thanks, guys.

**Operator**

Thank you. And I'm showing no further questions at this time and I would like to turn the call back over to Doug Michels for any closing remarks.

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

Okay. I just want to thank everybody for being on the call this afternoon and look forward to talking to you again at the conclusion of Q4. Have a good afternoon and evening, everyone. Goodnight.

**Operator**

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program and you may all disconnect. Everyone, have a great day.