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OSUR - Q4 2015 OraSure Technologies Inc Earnings Call

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PRESENTATION

Rena George-Beck - *OraSure - IR*

Good afternoon, everyone and welcome to OraSure Technologies 2015 fourth quarter financial results conference call and simultaneous webcast. As a reminder today's conference 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).

OraSure issued a press release earlier today regarding its 2015 fourth 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 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, February 10, 2016 by calling 855-859-2056 for domestic or 404-537-3406 for international. The access code is 20249565.

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 and 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 reports on Form 10-Q and its other SEC filings. Although forward-looking statements help to provide 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 this call over to Doug Michels.

Doug Michels - *OraSure - President, CEO*

Great. Thank you Rena. Good afternoon everyone and welcome to our call. Our fourth quarter 2015 results exceeded expectations and contributed to a record performance for the full year.

Consolidated net revenues of \$32.4 million in the fourth quarter exceeded our guidance for the quarter, driven by strong molecular collection systems and OraQuick HCV sales. Molecular collection systems revenues increased 24% from the prior year quarter. HCV sales increased 130% over

the fourth quarter of 2014 and 39% sequentially from Q3. Total HCV-related revenues, which include exclusivity payments under our HCV co-promotion agreement with AbbVie, were \$7.4 million for the fourth quarter. Strong revenue growth, combined with improved margins and lower operating expenses, generated \$4.6 million in consolidated net income for the fourth quarter. This was the fourth consecutive quarter of profitable performance for OraSure.

All of this led to full-year 2015 consolidated net revenues of \$119.7 million and consolidated net income of \$8.2 million for the year. Later in the call I will provide additional highlights regarding our business. But before I do that, Ron will discuss our Q4 financial performance in greater detail and our expectations for the first quarter of 2016.

So with that, let me turn the call over to Ron.

Ron Spair - *OraSure - COO, CFO*

Okay. Thanks Doug, and good afternoon everyone.

Our fourth quarter 2015 consolidated net revenues increased 13% to \$32.4 million, compared to \$28.7 million reported in 2014. Our consolidated net product revenues of \$28.7 million also increased 13%, largely as a result of higher sales of our OraQuick HCV, molecular collection systems, OraQuick Ebola, Intercept, and OraQuick InHome HIV products, partially offset by lower sales of our OraQuick HIV and cryosurgical systems products.

Other revenues were \$3.7 million in the current quarter, of which \$3.4 million represents the recognition of exclusivity payments under the AbbVie agreement and \$319,000 represents revenue associated with Ebola-related funding we received from the Biomedical Advanced Research and Development Authority, or BARDA. Other revenues in the fourth quarter of 2014 also included \$3.4 million of AbbVie exclusivity payments.

Our OraQuick HCV product revenues increased 130% to \$4.0 million in Q4 from \$1.7 million in the prior year. Domestic OraQuick HCV product sales increased 160% in the fourth quarter of 2015 to \$2.7 million from \$1.0 million in the prior year period. This increase was primarily due to a large order of product purchased for deployment to the federal government as part of an HCV testing program. We also saw an expansion of our core domestic HCV revenues through 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 fourth quarter of 2015 increased 85% to \$1.3 million from \$707,000 in the same period last year, primarily due to the expansion of our HCV business in Asia and the timing of purchases by a multinational humanitarian organization. Total HCV-related revenues, including the AbbVie exclusivity payments, increased 44% to \$7.4 million in the fourth quarter of 2015 compared to \$5.1 million in the fourth quarter of 2014.

In 2015, we began selling our OraQuick Ebola Rapid Antigen test to the CDC for field testing in Africa. Sales of this product contributed \$1.0 million in product revenues during the fourth quarter of 2015.

Domestic sales of our professional HIV product decreased 19%, to \$6.8 million in the fourth quarter of 2015, compared to \$8.4 million in the fourth 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 HIV tests that are perceived to be more sensitive. We expect continued pressure on our professional HIV business.

Sales of our OraQuick In-Home test rose 38% to \$2.1 million in the current period from \$1.5 million in the fourth quarter of 2014, largely due to an increase in sales volume in the period immediately following a celebrity's announcement that he had tested positive for the HIV virus, a price increase implemented last August, and 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 24% to \$7.8 million in the fourth quarter of 2015 compared to \$6.3 million in the fourth quarter of 2014. Commercial sales increased 37% primarily as a result of higher sales into the personal genome service market, partially offset by a decline in sales to two other commercial customers. Sales to our academic customers decreased 11%. This was largely due to customer ordering patterns.

In our substance abuse testing, it rose 19% to \$2.7 million in the fourth quarter of 2015 compared to \$2.3 million in 2014. This increase is largely due to higher sales of our Intercept device into the workplace testing market.

Fourth quarter 2015 cryo revenues decreased 12% to \$3.0 million from \$3.4 million in the fourth quarter of 2014. Domestic sales of our professional product decreased 51% to \$1 million in the fourth quarter of 2015 compared to \$2.1 million in the fourth quarter of 2014 due to distributor consolidation, competition from new private label brands, and a large purchase in the fourth quarter of 2014 by one of our distributors that did not repeat in 2015. Sales of our OTC products in the international markets increased 66% to \$1.7 million in the fourth quarter of 2015 compared to \$1 million in the fourth quarter of 2014, primarily due to ordering patterns of our European distributor.

Turning to our gross margin -- gross margin for the fourth quarter of 2015 was 68% compared to 63% reported for the fourth quarter of 2014. Margin for the current quarter benefited from reductions in royalty expenses along with scrap and spoilage costs.

Turning to operating expenses, our consolidated operating expenses for the fourth quarter of 2015 were \$17.8 million compared to \$20.5 million in the comparable period of 2014. This decrease was the result of lower detailing costs associated with our HCV co-promotion agreement with AbbVie, lower research and development spending, and a favorable change in the exchange rate between the Canadian and US dollars.

From a bottom line perspective, we reported net income of \$4.6 million, or \$0.08 per share on a fully diluted basis, for the fourth quarter of 2015, compared to a net loss of \$2.7 million, or \$0.05 per share, for the same period of 2014.

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 December 31, 2015 was \$101.3 million compared to \$97.9 million at December 31, 2014. Cash generated by operating activities in the fourth quarter of 2015 was \$667,000 compared to \$858,000 used in operating activities in the fourth quarter of 2014. During the fourth quarter of 2015, we used \$4.9 million in cash to buy back stock under our previously authorized repurchase program.

Turning to guidance for the first quarter of 2016, we are projecting consolidated net revenues of approximately \$28.5 million to \$29.0 million. We are also projecting consolidated net income of approximately \$0.01 to \$0.02 per share. Our expectations for Q1 include a \$1.1 million order for OraQuick HIV and HCV devices that had been received from a public health jurisdiction that normally orders at the end of their fiscal year. As you call, we had mentioned this order on the last call as potentially being realized in Q4 2015.

And with that, I will now turn the call back over to Doug.

Doug Michels - *OraSure - President, CEO*

Thanks, Ron. As noted earlier in the call, DNA Genotek continued the strong performance delivered in prior periods. Full-year revenues of \$29.9 million increased 26% over 2014.

As discussed previously, the bulk of our molecular collection systems revenues are generated in the genomics market, which consists of both academic research and commercial customers. Historically, these revenues have been split approximately 65% commercial and 35% academic, and this pattern continued in 2015. Q4 revenue growth was driven almost entirely from sales into the US commercial market. The continued growth in the genomics market has been driven by sales to existing customers and an increasing amount of new opportunities. In fact, our business is developing a much more diversified base of accounts in this market, which we believe is very promising.

Some examples -- in 2015, we were chosen to provide collection kits, custom packaging, and fulfillment services for a large study on autism. The aim of this study is to build the largest genomic database for autism research in the world. Recruitment of participants for this study is expected to begin in 2016. We are also selling products to a personal genomics company providing services to the people of China. Our product line will be used to conduct genetic analysis of ancestral traits, health risks, disease screening, drug reactions, genetic characteristics and nutrition metabolism. We are really excited about this opportunity and the chance to expand our business in this important marketplace. Finally, we are participating in a major longitudinal study on the epidemiology of aging, which has been collecting data since 2002 on adults aged 50 and over from nationally representative samples in several countries. Data collection has included a number of components and now a genetic component will be added

through the use of our OraGene kit. These are just a few examples of some of the increasingly diverse revenue opportunities we are seeing in the genomics marketplace.

Another area of focus for our molecular collection business has been the microbiome market, through the offering of our OMNIgene Gut product. During 2015, we received CE mark approval and completed design validation on a high-throughput automated processing system for this product. Several technical manuscripts with academic and biotech groups are also in process, which will report on the ability of this product to "snapshot" microbiome communities at the point of collection. We sold our collection kit to over 100 customers in 2015 and generated over \$500,000 of revenue. Many of these customers were known to us through our genomics business and thus demonstrates the value of our broad brand recognition and pre-existing relationships.

In order to gain further insight into the microbiome market, we recently appointed Dr. Dan Knight as a scientific advisor to our DNA Genotek team. Dr. Knight is a computational microbiologist and a leading authority in the application of machine learning to discovering linkages between microbiome, environment, and human disease. Dan is an assistant professor at the University of Minnesota and received a Ph. D. from the University of Colorado with post-doctoral fellowships at M.I.T. and Harvard. We believe Dr. Knight's insight and assistance will be invaluable as we work to expand our microbiome product and service offerings.

We are very excited about the microbiome market and, in fact, we see similarities to our genomics business, where there was initially a strong academic research opportunity early in the market's development followed by commercial applications as the market matures. We believe there is a significant long-term opportunity in the microbiome market.

A final market our team at DNA Genotek is pursuing falls under the infectious disease umbrella and is focused on tuberculosis. Products offered in this space include the OMNIgene Sputum and PrepIT MAX products. Healthcare providers from more than 60 countries -- that's six-zero -- have expressed interest in evaluating these products and more than 20 entities, ranging from Ministries of Health, non-government organizations, donor agencies and diagnostic test developers, have begun their evaluations of our product offerings.

A major milestone in 2015 was a collaboration among various organizations to support future World Health Organization endorsement of our tuberculosis products. Once secured, this endorsement will enable countries to purchase our products with funding provided by the Global Fund and other international funding agencies. Our tuberculosis products are well-positioned to support the National Action Plan for combatting multidrug-resistant tuberculosis, recently announced by the Obama Administration, by providing much-needed solutions to developing countries that are at the highest risk for multidrug-resistant tuberculosis.

We are excited about the potential opportunities in this market, and we are realistic about the complexity involved in achieving commercial success. It will likely take some time for this opportunity to translate into meaningful financial results.

Turning more broadly to our core infectious disease testing business, revenues were up 15% compared to the fourth quarter of 2014. As Ron explained, strong growth in OraQuick HCV sales more than offset declines in our domestic professional HIV business. Although the trends in our HIV business are likely to continue, we do see opportunities for growth, primarily in the international marketplace.

During the past several years, we have been working to develop a lower cost version of our HIV self-test for use in certain countries. We now have a working model that has the same robust diagnostic capabilities of our US-approved test. Specifically, we are working with Population Services International -- PSI -- a leading global health organization, along with UNITAID, the World Health Organization and health officials from Malawi, Zambia and Zimbabwe to launch the UNITAID-PSI HIV Self-Testing in Africa, or "STAR", project.

As part of STAR, PSI is implementing a four-year pilot program funded by UNITAID which will utilize a self-test that we have specifically tailored for the developing marketplace. The purpose of the STAR project is to generate crucial information about how best to deliver HIV self-testing, how to generate demand for HIV testing in this manner and what the potential public health impact of self-testing will be. Initial research indicates that the rates of people accepting a self-testing approach in Africa are much higher than traditional HIV testing programs. Our test was chosen for the PSI pilot because of its quality, its ease of use, and the oral fluid testing option. We expect initial shipments to PSI during the first quarter of 2016.



As noted earlier, HCV sales for the quarter grew nicely, with total revenues up 130% from the fourth quarter of 2014. Fourth quarter revenues were also up 39% sequentially from the third quarter of 2015. From a full-year perspective, our total HCV product revenues grew 57% compared to the prior year.

Our fourth quarter HCV sales reflect strong growth in both the domestic and international markets. Higher domestic sales were driven by expansion of existing testing programs, new programs in the public health market, and new pilot initiatives in populations with high prevalence. As Ron mentioned, we also filled a large order that will be deployed for a federal government screening initiative. It is not clear whether purchases for this program will repeat in 2016. On the international front, we experienced higher sales in Asia and we received additional orders from the large multinational healthcare organization we have been supplying product to in prior periods.

Turning briefly to our HIV In-Home Test, we are pleased with the performance of this product line, particularly its full-year contribution. Full-year sales increased 8% from 2014 and, more importantly, this brand generated a net profit contribution of \$1.5 million for the year. Throughout 2015, we focused on developing programs for deployment in the public health market, and at least one major public health customer has launched such a program and we expect continued revenues from this customer and possibly others in 2016.

Finally, we are pleased to see that our Ebola product contributed a total of \$4.0 million in revenues in 2015, which includes BARDA funding and initial product sales to the CDC. More importantly, this product represents a crucial new diagnostic tool that the CDC is now using in West Africa in support of ongoing surveillance efforts. It is important to note that while great strides have been made to contain the Ebola epidemic, new cases unfortunately continue to appear and deaths continue to occur. There is an ongoing need for surveillance and as a result, we believe the role for an accurate, rapid point-of-care Ebola test is just as important as ever. We are working to expand the claims and related regulatory approvals for our Ebola test and will continue to seek sustainable and substantial product purchase commitments throughout 2016.

So in closing, 2015 was a great year for OraSure. Strong revenue growth, full-year profitability and continued improvement of our molecular collection systems and OraQuick HCV businesses were the major highlights. We expect the momentum in these segments to continue. Opportunities for additional growth also exist in the microbiome and tuberculosis markets and, possibly, for our rapid Ebola test. We will continue to build upon our success in 2015 by driving deeper penetration in our existing markets and executing on exciting new market opportunities in 2016.

So I want to thank you again for your continued interest in our work. And with that, I will now open the floor to your questions. So operator, if you would please proceed.

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions). Our first question comes from the line of Brandon Couillard with Jefferies. Your line is now open.

Brandon Couillard - Jefferies - Analyst

Thanks, good afternoon. Doug, back on the DNA Genotek business, can you give us a sense of the total number of customers at the end of the year, perhaps how that compared relative to the end of 2014? And I think it's safe to say that the total addressable market has expanded considerably beyond where you -- it likely was when you first bought the business. Do you have, by chance, an updated view of how you frame the team as it exists today largely around genomics?

Doug Michels - OraSure - President, CEO

Thanks for the question, Brandon. Certainly since we've acquired the business, the business has changed in complexion, much like we expected. If you go back a few years, when we acquired the business, the majority of revenues were generated out of the academic research market. I think

at the time of acquisition it was 60% academic research and 40% commercial. And that's completely flipped now, with the majority of business, 65% being generated out of the commercial market.

We continue to serve the academic research market. And that market itself has the majority of number of customers, research institutions all around the world. I don't have, off the top of my head, the precise number of served customers. We can provide that at a later time. But suffice it so say -- I would say in both the academic as well as the commercial space, the number of customers that we have signed has expanded significantly.

I mentioned in the call we're certainly benefiting now with new products that we're able to introduce into the research market. We're benefiting from the relationship that we have had with those customers for so long. And now the interest they have in exploring new areas of research in microbiome and the like.

Our revenue mix from a geography perspective has stayed pretty consistent. Approximately 75% of our revenues in 2015 were generated here in North America, with about 25% outside the United States. So that's been relatively consistent.

I would also add on the commercial front, over the last several years as the commercial business has expanded significantly, we have really diversified our customer base. And I think that pays great dividends for the company, both in terms of growth opportunities as well as diversifying some risks. So the business has just really performed super. I'm so proud of the team up in Ottawa and around the world, promoting those products. So we're looking forward to a great 2016 as well.

Brandon Couillard - *Jefferies - Analyst*

Thanks. That's helpful. And then one for Ron, just in terms of understanding you don't really provide full year guidance -- but could you speak to sort of the outlook in terms of profitability for the year, and perhaps the magnitude of incremental OpEx investments that might be on tap for the year?

Ron Spair - *OraSure - COO, CFO*

Sure. Thank you, Brandon. No problem. We do expect not only increasing revenues in 2016 but we also expect increasing profitability over the levels that we have attained in 2014. Without giving any point estimates, but that would be our expectations. And as far as our operating expenditures, we want to do everything we can to bring them in and to manage them effectively and efficiently. So I don't see that we're looking at any substantive increases if any at all in OpEx for 2016 over the levels of 2015.

Brandon Couillard - *Jefferies - Analyst*

And just one more. On -- in terms of just the balance sheet -- I mean, the cash continues to build. Any updates on potential uses for the excess capital or an update kind of on anything brewing on the M&A pipeline?

Ron Spair - *OraSure - COO, CFO*

Well, we continue to be -- to work very hard on looking at M&A opportunities and partnering opportunities, licensing opportunities. And you may have noted in the remarks that I made earlier that we did buy back some shares, OraSure common stock in the quarter, expending approximately \$4.9 million of cash to buy back common stock through December 31.

Brandon Couillard - *Jefferies - Analyst*

Super. Thank you.

Operator

Thank you. And our next question comes from the line of Nicholas Jansen with Raymond James. Your line is now open.

Nicholas Jansen - Raymond James - Analyst

Hey, guys, nice quarter. I just wanted to get a little bit more color on Hep C. Obviously that market has evolved over the last 12 months, maybe a little bit differently from what you originally thought when you signed the AbbVie agreement. I just wanted to get your thoughts on the progress so far as their detailing efforts, your expectation for revenue contribution of those detailing efforts in 2016 and maybe how you're thinking about the exit -- the call-out or claw back end of 2016 with the option for either you or AbbVie for you to get out of the exclusive agreement. Thanks.

Doug Michels - OraSure - President, CEO

Thanks, Nick. And the great results in the quarter, a big contributor to those was our HCV business. We saw great growth as we mentioned on both the domestic and international front, 78% year-on-year growth in the domestic market. And that's the result of active discussion and work with current customers as they expand their testing programs, and then of course a lot of activity with prospective customers and trying to get new customers to begin testing.

Our work with AbbVie continues. We continue to work together on our co-promotion activities as well as on the special programs. And that's going to continue through 2016. We've got a meeting with them in a couple of weeks to review the 2016 plans and make sure we're aligned on those.

And we're seeing new entrants into the therapy space, and I think that from our perspective, that's expected, right? That's no surprise. And I think that the fact that more of the therapy providers are competing for patients, that's going to continue to create demand for diagnostics. And I think that we're in a great position to continue to capitalize on that.

You mentioned the future prospects that we have to work with AbbVie. We're completely focused on building the AbbVie relationship and making it successful. You're probably aware that, as outlined in the redacted copy of the AbbVie co-promotion agreement which was filed with our previously filed 10-Q, that we both have termination rights which could be exercised at the end of 2016. But that's neither here nor there for what we're doing today and our intent for 2016, and we're looking forward to working with AbbVie and making the effort successful.

Nicholas Jansen - Raymond James - Analyst

Thanks for that. And then secondly, just wasn't sure if there was any update on the ancestry.com litigation, any updated timeline there. Maybe there's going to be more disclosure in the 10-K and maybe we'll just wait till that's filed. But is there anything that you can comment there from a timeline perspective?

Doug Michels - OraSure - President, CEO

It's our policy not to comment on litigation. And so really at this point in time we really have nothing to say with regard to that other than we continue to assert our IP and our contractual -- our contracts and we'll just continue in the process.

Nicholas Jansen - Raymond James - Analyst

Okay. And then my last question would be on HIV professional. It's been quite impressive this year that you have been able to grow so well, even with a 17% or so reduction in your base domestic HIV business. And I just wanted to get your views on how we should think about that reduction going forward. Certainly I know you're calling on that to continue to decline -- the patient decline certainly accelerated in 2015 compared to the,



let's call it the mid-to-high single-digits we have seen in the prior years. I wanted to get your views on your ability to continue to navigate through that ongoing pressure. Thanks.

Doug Michels - *OraSure - President, CEO*

I think we're going to continue to have some headwinds there in 2016, although the team is working diligently to stabilize that business and I think we're going to make some progress in that regard in 2016.

At the same time, I mentioned opportunities we had to grow our professional HIV business, particularly in the international space. We are super excited about the work we are doing with PSI and UNITAID in Africa and I mentioned the three countries that are specific to the STAR initiative -- that's Zimbabwe, Malawi and Zambia, but we're also working with several other African countries as well as some Asian countries to roll out a similar kind of pilot programs. And these are really designed for high-prevalence countries where today's routine HIV testing just aren't reaching the affected population as effectively as these governments would like. This is a very large pilot that's being initiated in Africa with PSI and UNITAD and there's plans to scale this significantly in the out year.

We're, like I said, very excited about it. Our product is ideally suited for this application -- The ease of use, the accuracy, the oral fluid application. And we have a lot of learnings from our in-home HIV test here in the United States that we have now transferred to a simple, low-cost, easy to use device that can be deployed into these developing markets. So more on that to come. But we wanted to highlight that in our call this evening.

Nicholas Jansen - *Raymond James - Analyst*

Thanks, guys. That's it for me. Nice job for the end of the year.

Doug Michels - *OraSure - President, CEO*

Thank you.

Operator

Thank you. And our next question comes from the line of Mark Massaro with Canaccord Genuity. Your line is now open.

Mark Massaro - *Canaccord Genuity - Analyst*

Hey, guys. Congratulations on a great quarter.

Doug Michels - *OraSure - President, CEO*

Thank you, Mark.

Mark Massaro - *Canaccord Genuity - Analyst*

I wanted to start with 23andMe. I think, if I look back to the prior year, the revenue, if I recall correctly, was \$1.1 million in Q4 in the prior period. I know that they got expanded claims intraquarter and doubled the price of their test, which would lead me to believe that maybe the ordering levels might have dipped with a 2X increase in the price of the test. Could you call out what the 23andMe revenue was, and do you have any reason to believe that the trajectory could increase throughout 2016?



Doug Michels - *OraSure - President, CEO*

Yes. Thanks for the question, Mark. And you probably noticed that we didn't speak specifically to 23andMe in the prepared remarks today, and that's really for some competitive reasons. And so we're going to try to refrain from doing that in future calls, much like we don't really speak to specific accounts in other parts of our business, as a general rule.

With that said, our sales to entities that are in the personal genomics space have been very strong in 2015 and they were a significant contributor in 2014. And we continue to supply product to 23andMe and work very closely with them, as you can imagine, and it's been a very productive relationship, I think, for both parties. And we expect it will continue to be.

Mark Massaro - *Canaccord Genuity - Analyst*

Okay. Great. And unfortunately Ebola is still a problem. And I was maybe positively surprised to see \$1 million in the quarter. Is there a reason to believe that you expect continuous ordering from the CDC in 2016 so long as there is Ebola to monitor?

Doug Michels - *OraSure - President, CEO*

So the very fact that Ebola is still out there, the unfortunate fact that these countries over the last at least couple of quarters have declared their countries Ebola-free only to have to update that declaration and announce that there's new cases and people dying suggests that this is going to be an issue for quite some time, and highlight the fact that these countries are going to need to perform surveillance to understand if there's new cases, where might those cases have originated? They had people who are diagnosed infected. There's contact testing or tracings that go on. And of course a rapid test is ideal for those applications.

As we previously mentioned, the product sales that we've made to date have been to the CDC for both clinical studies as well as deployment in the field for this kind of application. While that's been going on we've also been pursuing WHO pre-qualification. And we've submitted data to the WHO for such. WHO pre-qualification is important because that authorization allows different countries to purchase the product using Global Fund and other public provider third party funding. So hopefully in the early part or first part of 2015[sic] we'll see WHO pre-qualification. And then that will hopefully open up additional purchase opportunities for the product. And we're also continuing in discussions with different entities about stockpiling the product. We don't have anything to report on that right now. But it's another important pursuit of the company.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. And I don't think you commented on the Zika virus. Have you had any discussions to potentially develop a test for that virus? And is there anything you can comment about the challenges of developing a test to help that current problem?

Doug Michels - *OraSure - President, CEO*

We were waiting for that question, for sure. Because there's no doubt it's all over the news. We're all being inundated with that. And we have had multiple discussions with the leadership of different organizations in the US government as well as around the globe, about the need for accurate diagnostic tools to deal with Zika. It reminds me of some discussions we had a year ago or more when the Ebola crisis was raging.

I think it's important to understand that it's a little different than Ebola. I don't think that it's as well understood. And health authorities around the world are in discussions and collaborating on what they believe is the right next step with regard to both diagnostics and therapeutics and really just what to do with -- in this current outbreak.

I'll emphasize that our approach to this is going to be very similar to what we did in response to the Ebola crisis -- number one, if we're capable of developing a diagnostic, and that's what health authorities say they want and need, then we're willing to do that, provided that there's some



support for that development as well as some commitment to ongoing purchase, much like we were able to secure with the Ebola project. I don't have anything to report on that right now. But should anything develop, obviously we would make an announcement in that regard.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. Thanks very much.

Doug Michels - *OraSure - President, CEO*

Thank you.

Operator

Thank you. (Operator Instructions). Our next question comes from the line of Eric Criscuolo with Mizuho. Your line is now open.

Eric Criscuolo - *Mizuho - Analyst*

Hey, guys. Good afternoon.

Doug Michels - *OraSure - President, CEO*

Hey, Eric.

Eric Criscuolo - *Mizuho - Analyst*

On the government order for the HCV test this quarter, how much of an impact was that?

Doug Michels - *OraSure - President, CEO*

I'm sorry, I didn't catch the end of that.

Eric Criscuolo - *Mizuho - Analyst*

How much of an impact was the federal government order for HCV that you called out?

Doug Michels - *OraSure - President, CEO*

We haven't dimensionalized that publicly but it was a nice contributor to our, to fourth quarter revenues.

Eric Criscuolo - *Mizuho - Analyst*

Okay. And staying with HCV, can you maybe talk about what type of demand for testing you're seeing coming out of the physician offices versus public health testing facilities and labs, and maybe kind of segment the test market that way?



Doug Michels - *OraSure - President, CEO*

Yes, we haven't broken that out. I will say demand continues to be very high in the public health market. And that's where we continue to see the greatest demand for the product, largely because they have large budgets, and they're able to deploy some of their HIV prevention monies to hepatitis prevention under the CDC and other state and local grants. So that's been the biggest contributor to our growth in the HCV market, along with the international contribution, of course.

Eric Criscuolo - *Mizuho - Analyst*

So have you seen any physician programs try to deal with the fact that what we've seen are several studies and articles pointing out that HCV testing is not being done on the correct population and that it needs to be increased, etc., etc.? Are you seeing any kind of like groundswell from physicians or patient advocacy groups in that regard?

Doug Michels - *OraSure - President, CEO*

The patient advocacy organizations have been very active across all the market segments. That's for sure. Because, I think, of some of the constraints that have been put on therapy and you know the payers' desire to stage patients and in some respects carefully allow, or on the flip side, restrict access to these drugs because of their cost. So the advocacy effort continues to grow and I think will continue to grow as the effectiveness of these new therapies and awareness about Hepatitis C continues to build among the consuming public.

One thing that we are seeing that I think is very interesting, and I think this will come out down the road, I think health care providers are finding a higher prevalence of Hepatitis C infection in young adults, particularly individuals 18 to 45 years old. And this increase in HCV incidence is believed to be driven by the significant increase in injection drug use in America. And so we're seeing some pretty significant prevalence rates in the different testing programs that we see in the public health market and in different hospital or other large group screening programs. And again we're happy that we have got a tool that can be used in those situations, and delighted that there's therapies that can treat these people but it's a big issue, I believe, and I think we're going to hear more about that down the road.

Eric Criscuolo - *Mizuho - Analyst*

That's an interesting insight there. Thank you.

Doug Michels - *OraSure - President, CEO*

Um-hm.

Operator

Thank you. That brings to an end the question and answer session of today's call. I will now turn the call over to Doug Michels for closing remarks.

Doug Michels - *OraSure - President, CEO*

Okay. I just want to thank you all again for your interest in the company and your support and I look forward to updating you in a few months on our first quarter performance. Thanks again for joining us, everyone. Have a great afternoon and evening.



Operator

Ladies and gentlemen, thank you for participating in today's conference. That does conclude the call. You may all disconnect. Everyone have a wonderful evening.

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