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OSUR - Q4 2016 OraSure Technologies Inc Earnings Call

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PRESENTATION

Rena George-Beck *- OraSure Technologies, Inc. - Investor Relations*

Good afternoon, everyone, and welcome to OraSure Technologies 2016 Fourth 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 4:00 p.m. Eastern time today regarding its 2016 Fourth Quarter Financial Results and certain other matters. The press release is available at 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.

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, regulatory filings and approvals, expectations and strategies. 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, 2015, 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 are based solely on information available to management as of today. The Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call.

With that, I would like to turn the call over to Doug Michels.

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

Thank you very much, Rena, and good afternoon everyone and welcome to our call. I am very pleased to report that the Company had a terrific fourth quarter. Our financial performance exceeded expectations and we delivered record revenues and earnings for both the fourth quarter and the full year 2016. We also moved forward on all of our strategic initiatives which will be key to continuing our growth in 2017 and beyond.

We presented our new strategy at our Analyst Day at the NASDAQ MarketSite in New York City in late November and I am very pleased with the progress we've made this quarter. Later in today's call, we will provide an update on each of the key initiatives outlined at our Analyst Day, but before that, we will provide a detailed financial review of the quarter and we will also take your questions.

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So with that, let me turn the call over to Ron for his review of our financials.

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

Thanks, Doug. Good afternoon, everyone. Our fourth quarter 2016 consolidated net revenues increased 10% to $35.5 million, compared to $32.4 million reported in the fourth quarter of 2015. Our consolidated net product revenues of $28.6 million approximated those of the prior year period. Higher international sales of our OraQuick? HIV and HCV products along with higher sales of our molecular collection systems products were largely offset by a decline in domestic sales of our OraQuick? HIV and HCV products and lower sales of our OraQuick? Ebola and InHome HIV tests.

Other Revenues were $6.9 million in the current quarter, of which $6.1 million represents the recognition of exclusivity revenue under the AbbVie HCV co-promotion agreement and $747,000 represents funding we received from BARDA related to our rapid Ebola and Zika products. Other revenues in the fourth quarter of 2015 included $3.4 million of exclusivity revenue from AbbVie and $319,000 of BARDA funding.

International sales of our HCV test in the fourth quarter of 2016 rose 123% to $2.9 million from $1.3 million in the same period of 2015, primarily due to the first shipments of product to a foreign government as well as the continued expansion of our business in Asia. Domestic OraQuick? HCV product sales decreased 18% in the fourth quarter of 2016 to $2.2 million from $2.7 million in the prior year period, primarily due to the inclusion last year of a $1.3 million order for a U.S. government HCV testing program which did not repeat in 2016. This was partially offset by an increase in both the number and size of direct orders placed by public health and other customers during the current quarter.

International sales of our [HCV] products increased 217% to $1.3 million in the fourth quarter of 2016, compared to $415,000 in the fourth quarter of 2015. This increase was due to higher sales in Africa, Asia, the Middle East, and Europe. Domestic professional HIV sales decreased 26% to $5.1 million in the fourth quarter of 2016, compared to $6.8 million in the fourth quarter of 2015, as result of customer ordering patterns, competition from other products, and budget reductions.

In 2015, we began selling our OraQuick? Ebola 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. Similar sales in the fourth quarter of 2016 were $197,000. We believe Ebola sales in future periods are likely given ongoing international surveillance efforts. Sales of our OraQuick? In-Home HIV test decreased 16% to $1.7 million in the fourth quarter of 2016, compared to $2.1 million in the fourth quarter of 2015 due to lower retail sales volumes partially offset by higher direct sales into OTC public health programs.

Our molecular collection systems revenues rose 10% to $8.6 million in the fourth quarter of 2016 compared to $7.8 million in the fourth quarter of 2015. Academic sales increased 18% primarily as a result of additional product sales to support a study on autism which commenced in 2016. Sales of our Oragene? product to commercial customers increased 4%, largely due to product shipped to a new personal genomics customer.

Turning to gross margin, our gross margin for the fourth quarter of 2016 was 67% compared to 68% reported for the fourth quarter of 2015. Margin for the current quarter decreased primarily due to an unfavorable product mix and the inclusion in cost of goods sold of severance costs related to our recent corporate restructuring, partially offset by higher AbbVie exclusivity revenues and improved overhead absorption as a result of increased manufacturing activities during the current quarter.

Turning to operating expenses, our consolidated operating expenses for the fourth quarter of 2016 were $16.9 million compared to $17.8 million in the comparable period of 2015. This decrease was the result of lower costs associated with our HCV co-promotion agreement with AbbVie, lower commissions, a reduction in bad debt expense, and a decrease in research and development expenses due to a $1.4 million dispute settlement received from a supplier of raw materials. These decreases were partially offset by severance costs associated with our corporate restructuring, higher legal expenses and an increase in staffing-related costs.

From a bottom line perspective, we reported net income of $7.2 million, or $0.13 per share on a fully diluted basis for the fourth quarter of 2016, compared to net income of $4.6 million, or $0.08 per share, for the same period of 2015.

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Turning briefly to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Our cash and short-term investment balance at December 31, 2016 was $120.9 million compared to $101.3 million at December 31, 2015. Cash generated by operating activities through the full year of 2016 was $22.8 million compared to $15.8 million in the same period last year.

So turning to guidance for the first quarter of 2017, we are projecting consolidated net revenues of approximately $31.0 million to $31.5 million. As you consider this, I think some context regarding the revenue growth inherent in this projection would be useful. When you look back at the first quarter of 2016, we recorded total revenues of $29.1 million which included $3.4 million of exclusivity amortization. The remaining $25.7 million in this figure represents product revenues and BARDA funding. With the AbbVie revenues ending in 2016, our Q1 2017 guidance of between $31.0 million and $31.5 million consists entirely of product and BARDA revenues and represents growth of between 21% to 23% from the comparable revenues in the first quarter of last year.

We are also projecting consolidated net income of approximately $0.17 to $0.18 per share for the first quarter of 2017. This guidance reflects the absence of both revenues and costs associated with the AbbVie HCV co-promotion agreement as well as a lower gross margin contribution expected from increasing international revenues during the period. This net income guidance also includes the after-tax impact of the Ancestry settlement announced earlier this week.

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

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

Okay, thank you, Ron. During our Analyst Day in November, we described the focus of our long-term strategy as growing our business in two key areas, which we refer to as our growth pillars. The first pillar is our infectious disease business which includes our HCV, our HIV self-test, our Ebola, our Zika and our TB programs. The second pillar is our molecular business which consists of our personal genomics and microbiome products.

Let me first comment on the infectious disease business. The strong growth that we are realizing and that we expect in our international HCV business is attributable to country-wide or large-scale HCV elimination or testing programs. Last year, we entered into a supply contract with a foreign government for $18 million worth of both HCV and HIV products. The majority of this contract is for our OraQuick? HCV test to support a nation-wide HCV testing and treatment program. Initial shipments occurred in the fourth quarter and these will continue throughout 2017. This is the largest product supply contract in our Company's history and we believe it is just the beginning for these types of opportunities.

At the Analyst Day, we indicated that we are working with other countries that are initiating large scale HCV testing programs. As a result of these efforts, we recently received a large order for both HCV and HIV tests from one of those countries. Some initial smaller purchases were also made by another country, which is typical as a precursor to initiating a larger scale HCV testing program. The list of countries evaluating broad testing programs is growing and we believe that additional significant opportunities will emerge over time.

While our international HCV business has stolen the spotlight lately, we are equally optimistic about growth opportunities in the domestic market. We expect continued growth in HCV sales in the United States primarily due to increasing demand in the public health market and from government accounts, in addition to drug treatment and community health centers.

A second growth driver for our infectious disease business is HIV self-testing. We have previously discussed our ongoing work with Population Services International, or PSI, in support of a pilot program known as the "Self-Testing in Africa" or "STAR" project. This pilot is being funded by UNITAID and is designed to deploy approximately 750,000 OraQuick? HIV self-tests in Sub-Saharan Africa during the first phase. Continued sales under this program are expected in 2017. We recently received an additional order from PSI for approximately 350,000 tests, which we are preparing for shipment here in the first quarter.

Our HIV self-tests are now being successfully deployed in Malawi, Zambia and Zimbabwe and field reports on the use of our tests continue to be positive and we believe our product is fully meeting the needs of the STAR project. We are also working with several countries outside of STAR that have initiated studies as a precursor to implementing community based HIV self-testing programs. To ensure the long-term success and sustainability of our international HIV self-testing business, we are pursuing the prequalification of our product by the World Health Organization. Our submission

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is under active review and we expect to receive feedback later this month. WHO prequalification will enable countries purchasing our test to access global funding sources such as the Global Fund, UNITAID and PEPFAR.

Another infectious disease growth driver is in the area of emerging diseases, where our two focus programs are Ebola and Zika. Our OraQuick? Ebola test is being used in several West African countries as a part of ongoing surveillance efforts. We shipped a small quantity of product in the fourth quarter and an additional small order here in the first quarter. We have additional orders planned for later in 2017. Our product remains the only rapid Ebola test with indications of use for both live patients and cadavers.

Our clinical work for this product remains on track for a 510(k) submission to the FDA in late 2017 or early 2018. Given the history of the Ebola epidemic, the sporadic cluster outbreaks in 2016, and the ongoing transportation and infrastructure improvements in Africa that facilitated the last outbreak, we believe it is unlikely that we have seen the last of Ebola. We expect our product will be an important global health tool in the future.

With respect to Zika, our efforts to optimize our test are progressing. We remain on track to submit for Emergency Use Authorization, or EUA, from the FDA as early as the second quarter of this year. We are committed to expediting the required optimization and clinical work wherever possible. An active Zika virus transmission unfortunately continues in Central and South America, with sporadic cases of travel-related transmission still being reported in Florida. We anticipate that outbreaks similar to those experienced in the U.S. in 2016, particularly in Florida, Texas, Hawaii, California and other states and territories, will likely occur in 2017.

A final growth driver for the infectious disease business is our tuberculosis product. The clinical studies being performed by the Foundation for Innovative New Diagnostics, or FIND, in support of WHO endorsement of our OMNIgene? Sputum product were completed in December. FIND has indicated they expect to issue a final data dossier to the WHO by the end of February. The WHO has indicated that it will review the FIND data and issue a broader review of all commercial sputum transport reagents later this year. As you know, WHO endorsement is critical to enable future customers to access global funding sources for product purchase.

We also continue to make progress on commercializing this product while pursuing WHO endorsement. DNA Genotek is negotiating with two foreign Ministries of Health in countries with high TB prevalence for the deployment of our OMNIgene? Sputum on a national scale.

In addition, a major and successful evaluation which funded by USAID was completed in late 2016 and the results were presented to another Health Ministry, to USAID, and to several surrounding countries to inform national testing laboratories on the routine use of OMNIgene? Sputum. Discussions with these countries and USAID are continuing.

Finally, a National Tuberculosis and Leprosy Control Program in Africa has begun planning a nationwide pilot of OMNIgene? Sputum as a follow-up to a prior laboratory assessment which singled out sputum transport as a major area for improvement. As you can see, there is a lot of activity occurring with respect to TB and we remain very optimistic about the prospects for this part of our business.

I'm going to turn now to our molecular growth pillar where there are two primary drivers, our genomics business and the microbiome market. During the fourth quarter, there were several developments in our genomics business, some of which we previewed at the Analyst Day. As you know, we announced a new contract with Helix for the supply of ORAgene? Dx collection devices and our GenoFIND fulfillment services.

We are not sure if investors fully appreciate the potential for this opportunity, so let me elaborate just a bit. We started providing kits and services in connection with Helix's official launch of its consumer genetic information service in November and we expect sales to ramp in 2017. We are very excited about this new relationship and we expect Helix to be a strong contributor in 2017 and beyond. Just based on public information about Helix and its business model, we think sales will likely grow substantially over time. As new partners are added to its service offerings menu, there is a greater chance that Helix will attract new consumers not already in its database. And this is where OraSure benefits as all those new consumers will require a DNA collection device. So as Helix grows so does the growth opportunity for OraSure.

During the fourth quarter, we added a significant number of new commercial accounts, most of which are providers of diagnostic tests. Our commercial customers provide a more predictable revenue stream than academic accounts which generally purchase based on grant funding

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cycles. The addition of these new commercial accounts will continue to diversify our revenues and reduce customer concentration over time. Our business in China showed a strong increase in the fourth quarter, and I emphasize we are still in the early stages of penetrating this market. We are now seeing repeat orders from multiple customers. In addition, as you also may have seen, DNA Genotek recently announced a new multi-year supply agreement with WeGene, a company offering genetic testing and personalized healthcare services in Asia. We expect to start shipping against this contract in the second quarter, and we are very excited about this new market and its large potential.

There were also several new contracts obtained from academic customers. We were awarded a contract with a major bio bank in Europe for collecting samples from youths. We were also awarded a multi-year contract to provide kits for a large-scale research study in neuropsychiatric disorders in African populations. We are very pleased to see these types of new academic opportunities develop.

Our microbiome business also continues to develop nicely. The number of microbiome kits sold in Q4 increased by 47% over the prior quarter, Q3, and 91% over Q4 of 2015. We expect our microbiome business to double in 2017 from the roughly $1.1 million in revenues recorded in 2016. The majority of our microbiome revenues have been derived from gut or stool sample collection kits and related services with a smaller percentage derived from kits for other sample types. Academic customers continue to provide the vast majority of our microbiome sales, although the proportion of sales to commercial customers is growing.

We are acquiring new commercial customers across several market segments, including direct-to-consumer firms, clinical stage biotechs and pharmaceutical companies that utilize both our kits and the related order fulfillment, wet lab and analytical services we offer. Academic and clinical research scientists are also demonstrating a continued need for standardization in their case control and longitudinal studies with both segments generating repeat business for both our kits and our microbiome services.

And then a final area I want to discuss is the significant work in our Operations Department to meet the increasing demand for our diagnostic products. As discussed on the last call, our second automated production line for the assembly of OraQuick? products has been delivered and installed and is now being validated. This equipment will supplement our current automated and manual production lines. The second line will be capable of producing all OraQuick? platform products and will initially manufacture our HIV and HCV products. When fully operational in mid-2017, this year, the equipment will be able to produce approximately 8 million additional devices per year.

Because of the substantial growth projected in international markets where pricing is sometimes lower, we have initiated an effort to evaluate our global manufacturing. We have hired a very capable and well-known consulting firm to help us optimize the global footprint for the manufacture of our products that will align with our projections in international markets, that minimize our cost of goods and logistics expenses, and will maintain the highest levels of product quality and customer service. This effort is well under way and we expect completion sometime in the middle of this year. And after potential strategies are identified and evaluated, we will then make final decisions and begin implementation.

So, in summary, it was a highly productive end to 2016. We delivered a strong financial performance in the fourth quarter and advanced our key strategic objectives. Our international HIV and HCV products and our molecular collection systems business continue to fuel strong growth for OraSure and we believe the recent trends in these businesses will continue and will provide for solid growth in 2017.

If you missed our Analyst Day, I would like to emphasize the key take away from that day and that is that OraSure is in the very early stages of multiple large market opportunities. Through product innovation and the development of additional ways for customers to use our products, the door has opened to several new and large opportunities that did not exist for us even a few years ago. We are very excited about OraSure's prospects and we believe that we are extremely well positioned to capitalize on these opportunities. These are definitely exciting times for the Company. And with that, I will now open the floor to your questions. So, Operator, could you just please proceed.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Brandon Couillard, Jefferies.

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Brandon Couillard - *Jefferies - Analyst*

Thanks. Good afternoon. I guess, Doug, first one for you. With respect to the HCV countrywide testing programs, you mentioned you received another large order from another country in the period. Any chance you could give us some sense of the magnitude of that program and when you expect to begin initial shipments? Than one for you, Doug, on the same topic, how much revenue contribution is baked in from that $18 million order in the first quarter revenue guidance?

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

I'll let Ron speak to the guidance question. Let me comment I guess more broadly on the HCV elimination program effort and what we're doing there. It's extremely exciting, the level of interest that we're seeing in the HCV product and its utility in these elimination programs. We mentioned in the prepared remarks that we shipped into the large order that we received in 2016, we made shipments in the fourth quarter and we'll be shipping against that throughout 2017.

During the Analyst Day, we also highlighted several additional countries there were in various stages of either evaluating the product or elimination programs or that were planning to deploy and they are at various stages of development. One of them has placed a significant order for delivery in the first quarter. We fulfilled most of that already. We do expect there will be additional orders from this second country and they are significant. They're not to the level of the first country that we spoke about, but they are going to be meaningful in future periods.

I want to also emphasize that we've said we are engaged with several other countries. And one of the additional countries has made a public statement that says they intend to eliminate HCV from their country by 2020. They have planned a pilot that's going to begin in the first quarter with a local drug supplier and, assuming that pilot is successful, which we have every reason to believe it will, they are going to be another, we would expect they will be another elimination program that will likely begin in Q2 or Q3 with volume. And we have several other discussions ongoing with additional countries. So this is going to be an ongoing, developing effort, but it's going to be a meaningful contributor to our revenues and revenue growth in 2017 and beyond.

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

Coming back to the second part of your question, Brandon, regarding the contribution from that large contract in the first quarter, our expectations are that we will record approximately $2.9 million worth of revenue split between primarily HCV, but some component of HIV tests in the first quarter of 2017.

Brandon Couillard - *Jefferies - Analyst*

That's helpful. And then on the DNA Genotek business, any chance you could help us understand what the growth of that segment would have been if you kind of back out the two customers that went bankrupt? And when do we begin to normalize or lap the headwinds from that dynamic?

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

That's a great question. I don't have that metric off the top of my head here. Let me see what I could do to derive something and come back to you on that, either on the call here or after the fact. But suffice to say that the contributions from those two companies that went out of business were significant for 2016. And we are, as I think we've mentioned previously, expecting that one of them will be back as a customer in 2017 having emerged from bankruptcy. But the other did go into liquidation and our expectations are that they will not be a customer for DNA Genotek in 2017. I'll come back as soon as I can on the other component.

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Brandon Couillard - *Jefferies - Analyst*

Thanks. I'll hop back in the queue. Appreciate it.

Operator

Andrew Cooper. Raymond James.

Andrew Cooper - *Raymond James - Analyst*

Hey, guys, thanks for taking the question. Starting I guess with DNA Genotek again, can you give us any color to help frame the Ancestry royalty opportunity and what that could be over time as they continue to grow that business?

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

Yeah, so unfortunately we're precluded from giving detail on either the royalty rate or the expected volumes. That's proprietary and covered under confidentiality of the agreement. Expected royalties would begin in 2018 pursuant to the settlement agreement.

Andrew Cooper - *Raymond James - Analyst*

Okay, thanks. And just one more for me then. As we look at HIV, it looks like the core domestic market still continued to trend downwards. Just wanted to get your thoughts on where you think the floor might be or what you might expect for 2017 in that market in terms of any potential rebound.

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

Yeah, thanks for that question. So we would expect we're going to continue to face some headwinds in the domestic HIV market in 2017. Although I think that decline is going to moderate somewhat year on year. I want to emphasize that any decline in that business is going to be more than offset by international growth and we expect the total HCV business in 2017 to grow in strong single digits and perhaps even higher growth rate than that.

I think it's also important to understand that in addition to some of the comments we made in our prepared remarks, that total testing for HIV is down in the markets that we serve here in the United States. So obviously being the market leader in rapid HIV testing here in the US, we're disproportionately impacted when testing volumes decrease. For reasons that I think are well-known, funding has been decreased, the number of undiagnosed individuals continues to go down, Which is a good thing, not necessarily for a testing company like us. But this is data that we get from the National Association of State and Territorial Directors in their 2016 report that said that total volume, total HIV testing volume, is down 16% from 2011 to 2014. So these are some of the factors that have impacted us. And it's actually one of the key reasons why we pivoted to the significant opportunities we have outside the United States to not only make up for some of the declines we're seeing domestically, but to really get this business back on a growth track. And that's what we're beginning to see and that's what we're going to see in 2017 and beyond.

Andrew Cooper - *Raymond James - Analyst*

Great, thanks. I'll hop back in the queue.

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

Yeah, so just in the meantime while we're waiting for the next question, Brandon, to follow up on your question regarding the contribution from the two labs that had financial troubles last year, we did not record any revenues in 2016 from either one of them. So those comps should be clean for 2017 going forward.

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

And the magnitude of their collective purchases in 2015 was north of $2 million collectively. So you can pro forma that out and you see that the DNA Genotek business in total grew in very strong double digits on a pro forma basis with those two customers taken out of the equation. Near 20%.

Operator

Mark Massaro, Canaccord Genuity.

Mark Massaro - *Canaccord Genuity - Analyst*

Hey, guys, congratulations and thanks for taking the question. The first question is on the BARDA funding. I think the total BARDA funding that I believe that you've been awarded is $16.6 million. So maybe the first question is, how much funding is imbedded in your Q1 2017 guidance?

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

So just to step back, the total BARDA funding to date that's been awarded is approximately $27 million and that's split between the Ebola of a little over $10 million with the balance being for Zika. So we're executing against those contracts. And for our first quarter, I would say it is approximately $1 million worth of BARDA funding for the first quarter that we have in our guidance, and for the year our expectations are in and around the $5 million mark.

Mark Massaro - *Canaccord Genuity - Analyst*

Excellent. My second question is on WeGene. Is there any way that you could size the opportunity or can you maybe discuss the agreement, keeping it at a high level? Is there any, one, is it exclusive? And two, are there any minimums or can you discuss maybe the size of the contract?

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

I'd love to, unfortunately I'm precluded from dimensionalizing that by our contract with WeGene. It is a multiyear agreement and the revenues are significant. I would also say that while we've framed those in our contractual relationship and there's a commitment there, how quickly this ramps is a TBD. Their goal is to help all agents better understand and benefit from their genetic information. They are going to be providing both health reports plus they're the first and only ancestry service in China right now. So they are well positioned to capitalize on these opportunities just like other commercial entities here in the United States have capitalized on these opportunities. In a huge market. So we're very excited about WeGene selecting our technology. I think it again reinforces what we know from other experiences, that our customers value the quality and integrity of our product, the fact that we collect a large volume of DNA, high quality DNA. And obviously like the recent settlement highlights, people know that we've got a strong proprietary position, intellectual property and we're going to defend that. So we're really excited about that.

I'll just say also, WeGene is just one of a bunch of opportunities. We've got a relationship with WuXi, WuXi NextCODE. Our academic business is growing and we captured some nice new accounts on the academic front which we highlighted some of those, at least described the businesses

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there. And we're also working to develop the academic channel in China right now which we believe can be significant. So lots of opportunities across the molecular collection business.

Mark Massaro - *Canaccord Genuity - Analyst*

Excellent. And if I can sneak one last one in, on Helix, my understanding is that they are targeting a full-blown launch around the summer of 2017. Are you seeing any, or do you even have any visibility on any ordering ahead of the launch just for maybe new genomics companies that are potentially validating their tests ahead of the consumer launch?

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

I think you're probably reading some of the same materials that we have access to and that's what we see. You know, we're in close communications with Helix on their plans. We have a plan for 2017. I really can't tell you the dimension of that. But the Helix deal that we have with them is a multiyear, it's a multimillion dollar contract. And like I tried to emphasize in the prepared remarks, they have a very different business model than anything that's out there in the marketplace right now. And as they add these new partners in different market segments, they are going to represent new consumers that are all going to need to be sequenced. And with each one of those comes opportunity for OraSure. So we're going to grow with Helix and looking forward to supporting their growth initiatives.

Operator

(Operator Instructions). Dave Westenberg, CL King.

Dave Westenberg - *CL King - Analyst*

Hey, guys, congrats on the good quarter. So you've talked about the three countries in HCV elimination pilot programs. And you talked about behind that you have a number of countries that you're in discussion with. Can you talk about the process and sort of the timing of moving a country from discussion into a more formal pilot kind of program?

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

Yeah, I wish there was a defined process. I think if you know one, you know one because each one is going to be different. A lot is going to depend on what they've done in Hepatitis C historically. What their testing programs have looked like, what kind of infrastructure they have in place, both on the laboratory or in the public health front. Do they have a process for managing a patient from the point of initial screening through confirmation and linking that patient to treatment? Because this is all about eliminating Hepatitis C, so the screening is up at the frontend.

One of the valuable advantages that we have in this space is that generally speaking we've been working with these ministries, these Ministers of Health in HIV or in some early stages of Hepatitis C. And so we're able now, because our technology has been chosen for some of these lead countries, we're in the position to be able to advise and consult with these countries and to help them navigate through this process. It doesn't happen overnight. So it's generally months and oftentimes the countries are going to want to do a pilot program in a city or a region or with a different population. Once again, it really depends on the state of the epidemic or prevalence of the disease in their country and what kind of infrastructure they have in place to roll these things out.

Ultimately, too, it's going to depend on funding. And sometimes they may develop the greatest plan and then they've got to work with their government officials to identify the funding that's going to be available to execute on those plans. They may start out slowly and then increase funding as they realize more success. So I wish I had a cookie cutter answer for you. I don't. But I hope you can tell from my response that we understand how to work through this process and I think our expertise is going to continue to grow and we'll be able to accelerate the process wherever it's possible.

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Dave Westenberg - *CL King - Analyst*

Good, that was actually very helpful. So there appears to be some competitive shifts or maybe some price undercutting in that HCV market domestically. What might some of that impact be if there is some of that increased pricing competition that's coming in and coming in actually a lot stronger than Gilead might have thought initially?

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

So you're taking on the therapeutic front, Dave?

Dave Westenberg - *CL King - Analyst*

On the therapeutic front, yes.

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

Yeah, so I know as certainly when AbbVie entered the market, they introduced pricing lower than Gilead. I know that Gilead largely matched their pricing, less or more. I know through negotiation the different drug companies also enter into other discount programs with large purchasers. I don't have privy to what that looks like, but I am aware that those kinds of arrangements exist. I think the reality is, prices have absolutely come down for a cure here in the United States and they've come down dramatically outside the United States as Gilead in essence licensed a number of different generic manufacturers in the developing markets. And that's what's really fueling this interest in countrywide elimination programs. Because now they actually can cure someone who has been infected for less than $1,000 in as little as 8 to 12 weeks. So they can identify the patients, they can get them on drug, and it's going to be well tolerated and it's going to lead to a cure. It's great stuff.

Operator

That brings to an end the Q&A session of today's call. I will now turn the call over to Doug Michels for closing remarks.

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

Okay, I just want to thank everybody for coming on the call this afternoon, this evening. As you can tell, we're very excited about the position we're in and we're looking forward to delivering a really terrific 2017 starting with the first quarter and we look forward to getting back together with you in a few months and talking about our progress. Thanks again, everybody.

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.

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