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OSUR - Q3 2014 OraSure Technologies Inc Earnings Call

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PRESENTATION

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

Good afternoon everyone, and welcome to OraSure Technologies 2014 third 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 Technologies issued a press release at approximately 4:00 p.m. Eastern time today regarding its 2014 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 12, 2014 by calling 855-859-2056 for domestic or 404-537-3406 for international. The access code is 17659442.

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 remarks, 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, and other matters. Actual results could be significantly different.

Factors that could affect results are discussed more fully in the company's SEC filing, including its registration statements, its annual report on Form 10-K for the year ended December 31, 2013, its quarterly reports on Form 10-Q, and its other SEC filings. Although forward-looking statements 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.

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

Okay, thank you Rena and good afternoon everyone, and welcome to our call. I am pleased to report that we had a very successful and extremely productive third quarter. Our financial performance exceeded our guidance on both the top and bottom lines and we believe this continues the momentum that has been building for most of this year.



Consolidated net revenues for the quarter were \$27.8 million, a 13% increase from the third quarter of 2013. Our molecular collection systems business turned in another record quarter with almost \$7 million in revenues, a 38% increase over the prior year period.

Our HCV business also delivered solid results with sales growth of about 12% over the third quarter of 2013. Domestic sales revenue doubled over third quarter last year. In addition, we recorded \$3.4 million in licensing and product development revenue related to this business line as a result of our HCV collaboration with AbbVie. We are also pleased to report a consolidated net profit for the quarter of \$1.1 million.

As you might expect, a main focus during the past few months has been the launch of our collaboration with AbbVie and the co-promotion of our OraQuick HCV Rapid Antibody Test. Our initiatives in several markets are now well under way and good progress has been made to increase awareness and train potential customers on our product with the goal of stimulating additional testing. Much has been accomplished and there is still much work to be completed as we finish the year and we move into 2015.

Later in the call, I will provide more detail on our HCV collaboration activities as well as on developments at DNA Genotek. I will also touch briefly on our efforts to develop a rapid point-of-care test for Ebola on our OraQuick platform.

So with that brief introduction, let me turn the call over to Ron for his financial review.

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

Thanks Doug, and good afternoon everyone.

Our third quarter 2014 consolidated net revenues were \$27.8 million, an increase of 13% over the \$24.7 million reported in 2013. Our consolidated product revenues of \$24.5 million were unchanged when compared to the comparable period of 2013. Higher sales from our molecular collection systems business and domestic OraQuick HCV product were offset by lower sales of our OraQuick professional HIV and cryosurgical systems products, and a reduction in OraQuick In-Home HIV test sales. Licensing and product development revenues were \$3.4 million in the current quarter compared to \$147,000 in 2013.

Sales of our OraQuick HCV professional product in the domestic market increased 99% in Q3 to \$1.3 million from \$653,000 in the prior year. Higher demand among new and existing customers was the primary reason for this increase.

International sales of our HCV test in the third quarter of 2014 decreased to \$470,000 from \$924,000 in the same period last year, primarily due to reduced sales in support of a testing program with an international NGO, which made its first stocking purchase in the third quarter of 2013. We expect sales to this NGO to continue at a reduced rate in the fourth quarter.

Our overall infectious disease testing revenues decreased to 13% to \$11.2 million in the third quarter of 2014, compared to \$12.9 million in the third quarter of 2013. Domestic sales of our professional HIV product decreased to \$7.2 million in the third quarter of 2014 from \$8.1 million in the third quarter of 2013. This decrease was the result of customer migration to automated fourth generation HIV immunoassays as recommended under new testing guidelines issued by the CDC, and continued pressure on government budgets. We expect continued pressure on our professional HIV business for the foreseeable future.

International sales of our professional HIV product decreased to \$491,000 in the third quarter of 2014 from \$1.2 million in the third quarter of 2013, primarily due to the timing of product shipments in support of a significant African testing program.

During the current quarter, net sales of our OraQuick In-Home HIV test were \$1.4 million compared to \$1.8 million in the third quarter of 2013. Net revenues for these periods were not recorded using the same revenue recognition policy and are not readily comparable. So a better way to evaluate the performance of this product is to look at the number of units purchased by consumers. Available point-of-sale data shows unit consumption remained flat in the third quarter of 2014 compared to the third quarter of 2013.

As you may recall, we previously announced that we would implement a new promotional strategy for the In-home HIV test that is focused on more cost-effective methods of building awareness and consumer adoption at retail. Under this strategy, we have largely stopped the expensive broad-based consumer advertising, and instead have adopted a lower cost and more economical promotional approach geared towards the retail or trade environment. This new approach has substantially reduced our promotional spend for this product.

Third quarter 2014 cryosurgical revenues decreased 11% to \$3.2 million from \$3.6 million in the third quarter of 2013, primarily as a result of lower sales of our professional product in both the US and international markets, partially offset by higher over the counter sales in Europe. Our domestic professional sales decreased to \$1.6 million in the third quarter of 2014 from \$1.8 million in the third quarter of 2013, due to the impact of the merger of our two largest distributors who began selling a competing private label cryo product.

Professional sales in the international markets decreased to \$43,000 from \$435,000 in the third quarter of 2014 and 2013 respectively, as we experienced delivery problems and inventory shortages as we transitioned to a new manufacturer of Histofreezer. Over the counter cryo sales increased to \$1.6 million in the third quarter of 2014 from \$1.4 million in the third quarter of 2013, largely due to customer ordering patterns.

Our molecular collection systems revenues, primarily representing sales of the Oragene product line, increased to \$6.9 million in the third quarter of 2014 compared to \$5 million last year in 2013. This 38% increase was the result of higher sales in both the academic and commercial markets.

Licensing and product development revenues were \$3.4 million in the third quarter of 2014 and represent the recognition of revenues from AbbVie under our HCV collaboration agreement. Third quarter 2013 licensing and product development revenues were \$147,000 and represent royalties paid on domestic out sales of Merck's OTC cryo wart removal product.

Turning to our gross margin, in the third quarter of 2014 it was 67% compared to 61% reported for the third quarter of 2013. The current quarter margin benefited primarily from the \$3.4 million of licensing and product development revenues recognized from our AbbVie relationship, as well as a more favorable product mix driven largely by increased DNA Genotek sales to higher margin customers.

Our consolidated operating expenses for the third quarter of 2014 increased to \$17.8 million compared to \$17 million in the third quarter of 2013. This increase was primarily related to higher R&D costs associated with qualifying a new raw material vendor and higher staffing, legal, and consulting expenses.

From a bottom line perspective, we reported net income of \$1.1 million, or \$0.02 per share on a fully diluted basis, for the third quarter of 2014, compared to a net loss of \$1.9 million, or \$0.03 per share for the same period last year.

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 September 30, 2014 was \$98.9 million compared to \$93.2 million at December 31, 2013. Cash generated by operating activities in the third quarter of 2014 was \$18.8 million compared to \$6.1 million generated in the third quarter of last year. The primary reason for this improvement was the \$15 million payment received from AbbVie in the third quarter.

So turning to guidance for the fourth quarter of 2014, we are projecting consolidated net revenues of approximately \$28 million to \$28.5 million and a consolidated net loss per share of approximately \$0.04 to \$0.05 for the quarter. The projected net loss reflects higher operating expenses driven by two main factors. First, we expect increased R&D spending during Q4 on our drug assay development program with Thermo for our next generation Intercept oral fluid collector and also on our Ebola feasibility efforts. Secondly, our Q4 sales and marketing expenses will also be up as a result of increased spending in support of the AbbVie collaboration.

As we look a little bit further out, we expect to continue somewhat higher spending as a result of the AbbVie collaboration, the next generation Intercept device, and the Ebola development work I just mentioned.

From a product revenue perspective, we anticipate that the intra-year revenue distribution for 2015 will be much like 2014 with Q1 being down sequentially and then building strongly from there.



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

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

Great. Thank you, Ron. I'd like to begin our business discussion with HCV. Implementing our HCV collaboration with AbbVie continues to be a top priority. You may recall that our co-promotion efforts are focused on several key markets in the United States and we are pleased with the progress to date.

One of our largest initiatives is focused on primary care and specialty physicians, and was launched approximately 10 weeks ago. Over that time period, the AbbVie sales force has been detailing our OraQuick HCV test to physicians and we have launched a comprehensive training program for this customer segment.

Our detailing efforts to date have resulted in well over 1,000 physicians indicating a strong interest in the product. We are seeing a high rate of purchase intent once a physician or physician's office completes our training program. Our representatives are tasked with making sure product pull through occurs following the completion of customer training. It has been our experience that once a physician's office expresses interest in our product, it takes somewhere between three to four weeks to schedule training. And then following the training, it then takes another three to four weeks for the first product order and the commencement of testing.

Consequently, we are just beginning to see the impact from these efforts on our sales line. Our expectation is that sales will continue to grow, but meaningful results will not materialize until 2015. I want to emphasize that we are extremely encouraged by the results we are seeing in this initiative so far.

We are also encouraged by the fact that product interest is being generated across a variety of practices, ranging from multi-site physician offices, internal medicine practices, practices that serve HIV patients, corrections facilities, and community health centers. In addition, we are finding that the prevalence rate for HCV runs higher in some practices than the average for the baby boomer population of 3%. In a pilot conducted in one large US jail system, we saw a prevalence of 7%.

Similarly, offices that serve HIV patients have substantially higher HCV prevalence rates. We are also seeing testing volumes at some of these customers range from 10,000 to 20,000 tests annually, which approaches the volumes of some of our larger public health accounts. We certainly believe we are off to a solid start with this initiative. And our representatives will continue to coordinate with their AbbVie counterparts on all aspects of this physician co-promotion initiative.

The second primary initiative targets employers or employer groups with employees that are at high risk for hepatitis C. The initial focus here has been on commercial long-haul truck drivers. We have been working closely with the Healthy Trucking Association of America, or HTAA, along with an organization known as Rolling Strong. Both of these groups collaborate and focus on improving the health and wellness of professional truck drivers. OraSure and AbbVie are specifically promoting the use of our test in physician offices, health clinics and retail pharmacies where truckers receive their health care, at driving schools where newly-hired drivers are required to take and pass a physical exam, and at health events sponsored by HTAA and Rolling Strong where truckers can take advantage of a variety of health and wellness services. We are also engaging in discussions with large fleet owners. We have assembled a Fleet Advisory Board and will hold our first meeting next week. We have also assembled a Clinical Advisory Board for this effort and that group will meet in early December.

Our co-promotion efforts geared towards truckers began in earnest with a major awareness and testing event at the Great American Truck Show in Dallas, Texas in late August. More recently, we have conducted other testing events at some of the larger truck stops in the United States, including stops located in Carlisle, Pennsylvania and in Bordentown, New Jersey. Yesterday, we had an event at a large truck stop in Tampa, Florida and another event is planned later this year in Ontario, California. Similar events are expected throughout 2015.

The primary objective of these trucker shows is to educate and build awareness about HCV and to offer on-site rapid HCV testing along with the AbbVie patient support program. In conjunction with these events, OraSure and AbbVie are also in discussions with several physician groups and organizations who provide health care services to a significant number of truck drivers.



A third major market segment consists of national and regional retail pharmacies and retail clinics. With the increased focus on expanding health and diagnostic services to consumers, we believe local retail pharmacy outlets are an important growth area for our hepatitis C collaboration. OraSure and AbbVie are continuing discussions with several major retailer -- retail pharmacies and health providers about increasing hepatitis awareness and making our OraQuick HCV test, along with AbbVie's Patient Care Model available through retail outlets. Good discussions continue with a number of retailers and we hope to share more definitive progress updates in the months to come.

As previously discussed, the effort required to adequately address these market segments is substantial. A great deal of work is required to build awareness, promote our test and implement the various support services that are needed, including product training, co-payment assistance and patient support. We are implementing this collaboration as quickly as possible, and substantial progress has been made since we signed the AbbVie agreement in June. As I mentioned previously, we expect to see increased revenues from the collaboration in the fourth quarter, but we are not projecting a significant financial impact from these efforts until 2015.

In addition to the AbbVie collaboration, we continue to drive improvement in our existing HCV business. We achieved another record in Q3 with \$1.3 million in domestic revenues. We shipped product to over 460 customers during the quarter, with 82% of our shipments being delivered to repeat customers. We also added over 80 new customers during this period.

So as we look forward, we anticipate continued progress in our HCV business. We expect product sales to continue to grow, especially here in the US, and we expect to achieve some of the performance goals under our HCV collaboration with AbbVie next year.

Another area I'd like to address this evening is our molecular collection systems business. As noted earlier in the call, DNA Genotek delivered another record quarter in Q3, with \$6.9 million in revenues, a 38% increase over the third quarter of last year. DNA Genotek's revenues for the quarter were fairly evenly split between sales to the academic and commercial markets. Academic revenue grew over 80% compared to the year ago period, while commercial revenue grew approximately 16%. We are extremely pleased with the performance of our molecular collection systems business.

During our last call, we discussed two new product development initiatives underway at DNA Genotek. The first product, Omnigene Gut, will enable academic researchers to collect and stabilize fecal samples for gut microbiome analyses.

The second product line, consisting of Omnigene Sputum and a preparation reagent called PreplT Max, are designed to improve collection, transport, stabilization, and processing of sputum samples used for tuberculosis testing. Much of our activities for these products are centered around ensuring that early versions are being provided to key opinion leaders in the relevant markets, which is exactly what is happening.

DNA Genotek employees have been connecting with many key opinion leaders around the world and the feedback to date on these new products is very positive. We believe these products represent promising new opportunities and we expect both will make important contributions to the future of our molecular collection systems business.

A final area I want to discuss are our efforts to develop a rapid test for Ebola. As you may have heard, Dr. Margaret Hamburg, the Commissioner of the United States FDA visited our offices a couple of weeks ago to recognize the collaborative work that OraSure has with the FDA over the years in bringing innovative HIV and HCV tests to market. This meeting had been set up some time ago and was not related to the development of an Ebola test.

However, towards the end of our meeting several members of the media interviewed Dr. Hamburg and me, and a question was asked if we had plans to develop an Ebola test. In response, I explained that we had been recently contacted by certain public and private entities about developing such a test and that we were evaluating whether our technology platform could deliver the performance levels required for this product.

As I'm sure you can appreciate, OraSure is interested in doing whatever it can to benefit the public health, especially with something as urgent and critical as Ebola. We have formed a cross-functional team to manage this product -- this project, and we're actively assessing the technical feasibility of an Ebola test on our OraQuick platform.

Studies indicate that oral fluid is a good carrier of the Ebola antigen, so we are optimistic about our ability to develop a product that will deliver the appropriate performance characteristics, while bringing the benefits of rapid, oral fluid based diagnostics to this situation. We have been actively engaged with several government and other organizations, including the FDA, the CDC, the NIH, the World Health Organization and certain non-profit foundations, regarding all aspects of developing, validating, gaining emergency regulatory approvals, and deploying a rapid diagnostic for Ebola. In cooperation with these organizations and others, we are also assessing the commercial opportunity represented by this test.

We expect to achieve several key milestones on this project during the fourth quarter of this year and we will provide an update on our progress at the appropriate time.

So as you've just heard, there is absolutely no shortage of opportunities available to the Company, and you can be sure that we are keenly focused on the successful execution of the initiatives that I have outlined today. We continue to be extremely enthusiastic about our molecular collection systems business and its growth opportunities. Our HCV business posted a solid performance in Q3 and is poised for substantial growth in 2015 and beyond.

We believe in our strategy to further advance each of these parts of our business and I am pleased with our overall progress and encouraged that we are on the right track towards maximizing the value of the opportunities before us. I look forward to a successful fourth quarter as well as moving to full-year profitability in 2015.

So with that, I'll now open the floor to your questions. Operator, if you'd please proceed.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first questions from Brandon Couillard with Jefferies. Your line is open.

Brandon Couillard - Jefferies & Company - Analyst

Doug, with respect to the DNA Genotek business and the period, were there any discrete orders driving that growth. Maybe could you give us -- remind us what the academic business grew in the first half of the year and whether I guess this run rate is sustainable over the coming periods?

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

Well, I'll let Ron handle the academic growth rate, but let me just make a couple comments about the quarter's revenue. So we did see nice growth in the quarter, in the academic space. The mix of business was pretty much 50/50 academic versus commercial and that compares to previous quarters where we had a little higher revenue contribution coming from commercial customers.

We still expect that the full year mix of revenue contribution will skew slightly more towards commercial, I'd say probably more like we've seen historically over the last few quarters, more like 60% commercial, 40% academic. We did see -- driving that growth on the academic front, we did see nice contributions from an academic study that contributed from the EU, as well as another large study that came out of Australia. But we also, on the commercial front, we saw a real solid contribution from some of our larger historical commercial customers, continued growth, if you will, same-store growth. So nice balanced performance across the entire business and just couldn't be more pleased.

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

Right, so with respect to the growth in the academic marketplace specifically, as Doug pointed out in his prepared comments that that space grew for us 80% compared to the year ago period. And I think it did benefit from the contribution from a couple of orders that were received. We expect



that to continue, but I think realistically an expectation of that level of growth is probably higher than what we're going to be able to deliver going forward. That said, the academic business certainly has been a fine contributor to the revenues for the year. And I think overall, we will close out the 2014 year with an academic business contributing approaching half of the total revenues for the business as a whole.

So very pleased with how that's going, but I think overall, Brandon, as you look out into 2015, 2016 and beyond, the expectations would be that the commercial side of the business would be the one that would really move the needle for us going forward.

Brandon Couillard - *Jefferies & Company - Analyst*

Super. That's helpful. And then on the domestic HCV business, is it fair to say that the current revenue run rate does not really capture any meaningful contribution from the AbbVie program thus far? And can you give us some color around how we should be modeling the ramp in those revenues kind of over the next few periods?

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

Yes, I think that's a fair characterization at least for Q3 given the way I just described. We've been out detailing for about 10 weeks and despite the fact that we've had very encouraging interests from the provider community, once we get that expression of interest then there is a process that takes some time to get them scheduled for training. Once they're trained, some time passes by until they order the product and they get up and running.

So I don't -- we really haven't seen a material impact from those efforts yet in Q3 and we'll see some impact in Q4, but I think the real impact is going to be felt in 2015. We did see on the core HCV business, as we mentioned, double from a year ago period and it's up across the board, whether that's growth in the public health segment, in hospital, and in the physician's office on a year to date basis. So we just continue to see more interest and adherence to the recommended guidelines. There is more money being allocated towards HCV prevention efforts in the public sector and we expect that will continue.

Operator

Our next question comes from Shaun Rodriguez with Cowen and Company. Your line is open.

Shaun Rodriguez - *Cowen & Co. - Analyst*

So maybe one or two on the guidance. So in terms of the revenue guidance, if we have non-product revenue about flat sequentially from Q3 to Q4, can you just talk or walk us through the sequential assumptions that net out at what you're guiding to, which is I think about \$500,000 up sequentially, virtually flat from Q3 to Q4.

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

Right, so I would -- without getting too far into the details here, because there are a lot of moving parts and there are some assumptions around the different sensitivities on different line items. But I would venture to say that the one that moves down sequentially that could cause us a little bit of reduced revenues would be in the cryo business. And so the cryo business is down in the fourth quarter versus the third quarter, which is not uncommon given the seasonality associated with the cryo business and some of the difficult to predict ordering patterns that we have in the international marketplace.

Plus, as you may have noted from our remarks, we are -- we changed over a manufacturer from our cryo product in the professional marketplace and we will expect to have affected that transition in the fourth quarter, and get that business back rolling again later on this year and into 2015.



So I would say that that would be an area that we would see some diminution of revenues where with the infectious disease business overall, our expectations are that that will be up sequentially.

Shaun Rodriguez - *Cowen & Co. - Analyst*

Okay, that's helpful. And actually, related to that, on the P&L assumptions within the Q4 guidance, I understand that R&D and SG&A will tick up and understand the basis for that, but does your guidance also reflect that gross margin moderates relative to Q3? And if so, is that just reflective of the mix assumptions, some of which you just touched on?

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

I think that's a good point, Shawn, and yes, we will see a slight moderation because sequentially our revenues from DNA Genotek are expected to be down, and that is a higher gross margin profile for the business. And we'll likely see some step up in contribution from the 23andMe business within the fourth quarter, which also is a lower gross margin profile.

Shaun Rodriguez - *Cowen & Co. - Analyst*

Okay, thank you for that. And on HIV Professional, so I understand the pressures you called out there. Clearly, the CDC changing the algorithms is not new, but I guess I'm trying to understand what you're saying about the outlook. So it looks like US Professional HIV is down about 10% year to date. So is what you're suggesting when you say you expect it to remain under pressure for the foreseeable future, are you signaling an acceleration of the rate of declines? Stable declines at around these levels or moderation? How should we think about it given that this still is obviously an important franchise for us to think about when we model.

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

Yes, I think that you can look at most of the pressure being applied in the public health space and I think if you model those declines in that segment, consistent with our most recent experience, I think at least for the near term that's a reasonable expectation. I think you should also highlight that the hospital business has been quite stable, actually, and our physician office business is up for the year and will likely finish up in the mid to high double-digits, in 15% to 20% range.

For the full year, physician office business could be up in the 30 plus percent range year-on-year. So you kind of have to look at it by segment. Our HIV International business is going to be down year-on-year slightly and that is due largely to some of these large African orders that are a little bit lumpy and hard to predict, more a timing issue than any kind of major business degradation.

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

Then Shaun, just to point out, in the fourth quarter we're going to be up against a pretty tough comp for the overall infectious disease business because if you recall, in last year's fourth quarter we had the revenue recognition change, which generated about \$2.5 million worth of revenue on the OTC HIV line, which we will not have the benefit of in the fourth quarter of 2014.

Shaun Rodriguez - *Cowen & Co. - Analyst*

Oh, right. Yes, that's helpful. Thanks, Ron. Okay. Thanks, guys. That's it for me.



Operator

Our next question comes from Peter Lawson with Mizuho Securities. Your line is open.

Peter Lawson - Mizuho Securities - Analyst

Just on the DNA Genotek business, how many commercial partners do you have now that are meaningful and if you could give us some details about how broad that growth was in the commercial business. Is that coming from many partners or just a few?

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

I would say it's coming from many and the number of large commercial customers continues to grow significantly year-on-year. And when we kind of evaluating our definition of a large commercial customer for this business, it'd be a customer in the \$250,000 plus revenue range. And we have many of those right now, versus what we had in 2013 and certainly in 2012.

Peter Lawson - Mizuho Securities - Analyst

And so when you look out with that business, how sustainable do you think that kind of 20% to 30%, even 40% growth rate is?

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

I don't think we want to get out into speculating on the sustainable levels of growth other than to say that it is certainly our expectation that after this next quarter here that we will continue to see growth for the years ahead in the collection business that we currently enjoy, but also as we bring on the new products, Peter, like Doug spoke of the, Omnigene Gut, the Omnigene Sputum, the Preplt Max product and our HEMAgene product that was developed there.

So that can benefit from not only the domestic successes but the geographic expansion and more customers coming on board, and just generally more DNA testing being conducted around the world. So I think it's a business that has a significant potential over the long-term.

Peter Lawson - Mizuho Securities - Analyst

Thank you, and just on the Ebola test, do you have all the right components, capabilities, and reagents internal if you were to develop a test for Ebola? Or would that have to be a commercial partner as well to help you?

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

Well, so as you can imagine, there's many aspects to the development of a test like this. We certainly believe our testing platform is robust and we -- obviously we've demonstrated that through the development of our original HIV OraQuick assay and enhancements to that, and the hepatitis C product, and the like.

So those components and materials are well characterized. We have them in-house. We have different forms of those in-house and they'll all go into the development of the prototype test. The actual biological material, the monoclonal antibodies, the antigens, and the like are being sourced externally and we have multiple sources for those reagents from both the private, as well as the public sector. And I mentioned a number of the organizations and agencies that we've been in discussions with. The spirit of collaboration and cooperation is of the charts. And we've been receiving raw materials for the last couple of weeks.



And those are being evaluated and put into the development effort, which our expectation is will lead to functional prototypes, at which time we'll validate those, both analytically as well as clinically. All that work will also be done together with potential partners, and as we make progress on that, that warrants communication, we'll certainly share that.

Peter Lawson - *Mizuho Securities - Analyst*

When could you have a test for Ebola?

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

I wouldn't speculate on that because this is development. But there's a tremendous level of urgency both here and in the Company, and that urgency is shared by these partners that we've been in discussions with. And I think if any company can develop highly effective, accurate diagnostic in this space, OraSure is extremely well positioned to do it, both with our platform capability, our organization technical capability, and the resources that we have available to do it.

But again, it's science. So we're on it and we'll share our success or lack thereof with you at the appropriate time.

Operator

(Operator Instructions) Our next question comes from Mark Massaro with Canaccord Genuity. Your line is open.

Mark Massaro - *Canaccord Genuity - Analyst*

Maybe could you comment on whether or not you think you can obtain some of the benefits on the milestone payments in the first half of 2015 versus the second half of 2015? And what I'm referring to is the \$3.5 million to \$55.5 million of additional opportunity on the AbbVie opportunity.

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

Right, we've indicated, and I want to be clear both from things we've communicated previously as what we've tried to reinforce here. We do expect profitability from the entire business in 2015 and that expectation for profitability is exclusive of us earning some of those performance payments as part of the AbbVie agreement. We've also indicated that we do expect to achieve some of those performance payments in 2015. I don't think at this point in time, we're prepared to forecast or predict when in the year we'll begin to achieve those payments.

Mark Massaro - *Canaccord Genuity - Analyst*

Okay. And I think I heard you guys say that you thought that 23andMe could pick up a bit in Q4. Can you give us an update on some of the conversations you've had with them and maybe an update on their regulatory update?

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

Yes, so I'll hand the regulatory component to the extent that I'm able to share. They have responded to the FDA's concerns. They -- and we believe that the FDA has given them feedback on their submission. I do not have an update beyond that as to whether they responded to the FDA's feedback. We did announce or they announced in the quarter that they launched the full service offering in Canada, and we are aware that they expect to launch in additional countries both in the fourth quarter, as well as they have plans for launching in additional geographies in 2015. So we're excited about that and look forward to continuing to work with them both in terms of global expansion, as well as to support them in whatever way they can so that they can get back on the US market with a broader product service offering.



Mark Massaro - *Canaccord Genuity - Analyst*

Thanks, and I know the AbbVie US agreement is clearly large and significant for you. Doug, can you comment if you are continuing conversations with a partnership outside the US?

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

We are and those discussion are ongoing, but I don't have anything substantive to report on that at this time.

Mark Massaro - *Canaccord Genuity - Analyst*

Great, and maybe the last one from me. With \$100 million in cash, is there -- do you have any thoughts on potentially deploying that and in any does that deviate from the last year or two?

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

No, I think we're still going down the path of exploring business development opportunities that would identify products, technologies, companies that would be attractive to bring in under the OraSure umbrella.

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, well, I just want to thank everyone for joining us on the call this afternoon and this evening. Look forward to speaking with you on the next call and talk about Q4. Thanks everybody and have a great evening.

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