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OSUR - Q3 2017 OraSure Technologies Inc Earnings Call

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PRESENTATION

Joni Messenlehner

Good afternoon, everyone, and welcome to the OraSure Technologies 2017 third quarter financial results conference call and simultaneous webcast. As a reminder, today's conference is being recorded. (Operator Instructions.]

OraSure Technologies issued a press release at approximately 4:00 p.m. Eastern Standard Time today regarding its 2017 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.

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 files and approving, 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 statements, its annual report on Form 10-K for the year ended December 31, 2016, 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.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Thank you, Joni, and good afternoon, everyone, and welcome to our call. I am pleased to report another outstanding quarter. Revenues exceeded our guidance and reached a record level. On the bottom line, our results were strong and met expectations.

The strong quarterly performance is further evidence that our products are well suited to address the large market opportunities that we're pursuing in both the molecular collection and infectious disease businesses. We continue to believe that these opportunities are in the very early stages of

development and that we are well positioned to capitalize on them. Additionally, we are making the necessary investments to increase manufacturing capacity in Bethlehem, in Canada and in Thailand to meet the growing demand for our products.

Our third quarter performance was primarily driven by growth in our molecular collection and HCV businesses. We also reported strong sales of our OraQuick HIV self-test, reflecting the impact of the World Health Organization prequalification, the expansion of the Self Testing in Africa or STAR project and our work under the Charitable Support Agreement with the Gates Foundation.

With respect to the quarter, our consolidated net revenues grew 31% compared to the year-ago period and topped $42 million for the first time. This is the second consecutive quarter of $40 million or more in revenues. Product revenue growth for Q3 was an extraordinary 62%. Our molecular business delivered another record performance. Q3 revenues reached $18.6 million, which represents a 123% increase over the third quarter of last year. Our infectious disease business also performed extremely well, with 59% revenue growth from the year-ago period. Significant increases in both international and domestic sales of our HCV product and strong growth in HIV self-test revenues were the primary contributors. On the bottom line, we generated $0.09 per share, and we ended Q3 with over $180 million in cash and cash equivalents.

In short, Q3 continued the strong growth we have seen throughout the year and represents further progress in advancing our strategic priorities. We expect this trend to continue in Q4 as well.

So with those brief comments, let me turn the call over to Ron. After his financial review, I'll provide some business updates and then we'll take your questions. So, Ron?

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

Okay, thanks, Doug, and good afternoon, everyone. As you can see from our press release and Doug's brief introduction, 2017 continues to be a very successful year. Our third quarter consolidated net revenues increased 31% to $42.3 million compared to $32.3 million reported in the third quarter of 2016. Notably, our consolidated net product revenues rose 62% to $41.2 million compared to the prior-year period. Higher sales of our molecular products, OraQuick HCV and the OraQuick HIV self-test were the main drivers of this performance.

Our molecular revenues rose 123% to $18.6 million in the third quarter of 2017 compared to $8.3 million in the third quarter of 2016. Sales of our Oragene product to commercial customers increased 157% and academic sales rose 46%, largely due to higher customer demand and customer ordering patterns.

International sales of our HCV test in the third quarter of 2017 rose 376% to $6.1 million from $1.3 million in the same period last year, primarily due to the continued shipment of product to a foreign government pursuant to a previously announced countrywide elimination program. Domestic OraQuick HCV product sales rose 24% in the third quarter of 2017 to $1.9 million from $1.5 million in the prior-year period, primarily due to increased HCV purchases by public health customers.

International sales of our HIV test increased 176% to $3.1 million from $1.1 million in the third quarter of 2016, largely due to higher sales of our OraQuick HIV self-test into Africa. The majority of tests shipped into Africa during the quarter were subject to the support payments under our Charitable Support Agreement with the Gates Foundation. Product revenues during the third quarter of 2017 included approximately $458,000 of support payments associated with this agreement.

Domestic professional HIV sales decreased 25% to $3.6 million in the third quarter of 2017 compared to $4.9 million in the third quarter of 2016 as a result of competition from other products, customer ordering patterns and some impact from recent severe weather conditions.

Other revenues were $1.2 million in the current quarter, representing $939,000 of funding we received from BARDA for our rapid Ebola and Zika products and $218,000 in reimbursement of certain nonproduct costs under our agreement with the Gates Foundation. This cost reimbursement is separate from the product support payments I previously mentioned. Other revenues in the third quarter of 2016 totaled $6.8 million and included $676,000 in BARDA funding and $6.1 million of exclusivity revenues under the AbbVie HCV co-promotion agreement, which terminated effective December 31, 2016.

Turning to gross margin, our gross margin for the third quarter of 2017 was 58% compared to 70% reported for the third quarter of 2016. Margin for the current quarter decreased primarily due to the absence of AbbVie exclusivity revenues in 2017 as a result of the termination of our agreement at the end of 2016, an increase in lower-margin product sales and higher scrap and spoilage costs.

Our consolidated operating expenses for the third quarter of 2017 were $17.3 million compared to $16.5 million in the comparable period of 2016. This increase was largely due to higher staffing costs, higher external commissions paid to certain international distributors and an increase in our allowance for doubtful accounts.

Income tax expense was $1.7 million in the third quarter of 2017 compared to $400,000 in the same period last year and consists entirely of Canadian taxes due.

From a bottom line perspective, we reported net income of $5.8 million or $0.09 per share on a fully diluted basis for the third quarter of 2017 compared to net income of $6.2 million or $0.11 per share for the same period of 2016.

Turning briefly to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Our cash and investments balance at September 30, 2017, was $180.3 million compared to $120.9 million at December 31, 2016. Cash generated by operating activities for the first 9 months of 2017 was $30.4 million compared to $25.2 million in the same period of 2016.

So turning to guidance for the fourth quarter of 2017, we are projecting consolidated net revenues of approximately $45 million to $46 million. We are also projecting consolidated net income of approximately $0.08 to $0.09 per share for the fourth quarter of 2017.

As we look a bit further out to Q1 of 2018, our current thinking is that we may see a step-down in our molecular collection systems business due to seasonality associated with our expected performance in Q4 of 2017. This, together with what has been a historically lower quarter for infectious disease and cryosurgery revenues, could result in our total Q1 revenues being down sequentially while being up by about 25% when compared to the first quarter of 2017. We will be fine-tuning our expectations for Q1 2018 on our fourth quarter call, but we wanted to manage your expectations in advance.

And with that, I'll turn the call back over to Doug.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Okay, thanks, Ron. I'll now provide a few business updates, starting with our molecular business since that was the most significant contributor to our strong third quarter performance. Our molecular business performed exceptionally well in Q3, as it did during the first half of the year. Revenues in the quarter increased 123% compared to last year, and we expect this trend to continue again here in the fourth quarter.

A primary driver was continued growth in our commercial genomics business, both compared to the prior-year quarter and sequentially from Q2 of this year. Revenues grew as a result of the addition of new customers and higher sales to many of our largest customers. During the quarter 16 of our top 20 molecular customers increased their purchases over the prior-year period. And year-to-date, 19 of the top 20 customers generated higher sales when compared to last year.

Our genomics business also benefited from higher international sales and expanded adoption of our services offerings. Our international business doubled from the prior-year quarter and delivered double-digit sequential growth from Q2. Our GenoFind services business had another record quarter in the third quarter, delivering a fourfold increase from the prior-year quarter and double the revenue from the previous quarter. Growth from existing customers as well as the acquisition of new business continues to drive the strong performance of our services business.

Finally, we won a significant new contract during the third quarter to provide customized collection devices and GenoFind services for a pharmacogenomics pilot focusing on members of a statewide retirement group benefit plan. While this is a pilot program, we believe this could expand into a much broader opportunity involving a large number of retirees under the plan. In addition, it could serve as a model for adoption by other similar statewide benefit plans seeking to perform pharmacogenomic testing.

On to the microbiome business, that continued to deliver strong revenue performance during the third quarter, which represented a doubling of revenues from the prior-year quarter. The ongoing acquisition of new customers and strong repeat business from existing customers in both the academic and commercial markets are driving our microbiome revenues. A growing number of current microbiome customers are repeat purchasers, with the largest customers purchasing in more than 2 quarters during each of the past 2 years.

In addition, our microbiome services offerings are up 250% over the prior-year quarter as both academic and commercial customers leverage our endÂ–to-end offerings for sample processing and analysis. Aggregate microbiome revenues during the first three quarters now total $2.4 million, which substantially exceeds the $1.1 million recorded for all of 2016. In short, we continue to see strong interest in our microbiome products and services and are very optimistic about the future for this part of the business.

In the infectious disease area, the main drivers continue to be international HCV and HIV self-test sales. Our international HCV business continued its strong growth in Q3, largely due to demand for countrywide elimination initiatives and related government supply agreements which we have previously highlighted. As Ron noted, our Q3 revenues increased 376% compared to the prior-year quarter.

We have previously mentioned our ongoing discussions with a large government customer to renew our existing supply arrangement. For some time the indication from this customer has been that the contract would likely be renewed at a volume well in excess of the existing contract. Our renewal discussions continued along these lines until just last week when, unfortunately, this customer advised us that it intends to transition its rapid HCV testing to an all laboratory-based model in the next contract period because of budget pressures.

This development came as quite a surprise, given prior discussions and negotiations with this customer. We had been engaged in discussions for a straightforward renewal and expansion of our supply arrangement, but late in the discussions the government decided to move to a tender process requiring a broader set of components to support HCV testing. We participated in this tender with our distributor. And although we were told that our rapid hepatitis C test provided the best technical solution to meet their needs, in the end this customer decided to adopt a laboratory testing solution based solely on cost. The winning bidder apparently offered pricing that was not even close to being economically viable for us. We received repeated feedback from the customer that our HCV test performed very well and that the testing program was extremely successful, which made news of the change even more surprising.

We continue to believe that our rapid hepatitis C test can and will perform a much-needed role in broad-based hepatitis C testing programs, especially where much of the testing occurs in rural or remote areas of a country. Our OraQuick HCV oral fluid test is ideal for those locations since laboratory testing requires a blood collection and more involved process to deliver samples to a laboratory. We understand that some officials in this government share this view and continue to advocate for our product, so we are hopeful that in future periods we might again participate in this government's program with the OraQuick HCV test.

In the meantime, the level of interest in HCV testing and treatment remains strong globally, and we are continuing our marketing for product for other large-scale screening programs. Although international programs are increasingly focused on cost, we believe the value proposition for a high-quality, rapid oral fluid hepatitis C test will support participation in these programs, and overall, we remain optimistic about our HCV international business model.

On the domestic side, our HCV business grew 24% compared to the prior-year quarter. This growth was driven by expansion of existing programs and the initiation of new testing programs, given growth in the public health and physician offices markets were partially offset by small declines in our hospital business. Despite continued funding challenges domestically, organizations are finding ways to channel resources from other areas into HCV testing and treatment programs.

On past calls we've mentioned our work with the Southern Cities Initiatives. This is a collaboration among OraSure, community-based organizations, advocacy groups and certain pharmaceutical companies. This goal is to expand HCV testing to high-prevalence, hard-to-reach populations in urban settings so that diagnosed individuals can be linked to care. The initial cities targeted include Columbia, South Carolina, Birmingham and Tuskegee, Alabama, and Baton Rouge and New Orleans, Louisiana. During the past 9 months, thousands of individuals have been tested with our product, and the results indicate a prevalence of almost 10% in these populations tested. We're working to expand this program into other cities.

On to international HIV self-testing, our international HIV business turned in a strong performance during the third quarter, with growth of 176% compared to the prior-year quarter. This increase was driven primarily by HIV self-testing orders for Phase II of the STAR project along with professional product sales in Africa and Asia. During our last call we indicated that Phase II of the STAR project is expected to deploy 4 million self-tests and that we expected an additional large order to be shipped prior to year end. I am pleased to report that we've received this large order and will be shipping product in the fourth quarter.

Outside of the STAR program, we are beginning to see other funding organizations start to fund scale-up of HIV self-testing in non-STAR countries. The apparent trigger for this is the receipt of WHO prequalification for our product, as we previously disclosed. We're also in discussions with a nongovernmental organization, or NGO, that expects to initiate HIV self-testing in several countries in West Africa. Although orders are not expected until 2018, this is another indication that momentum behind HIV self-testing continues to build following receipt of our WHO prequalification.

Our execution under the Charitable Support Agreement with the Gates Foundation also continues to go very well. The relevant health authorities in the 50 countries covered by the agreement have been made aware of our arrangement with Gates, and we are beginning to see more sizable orders from countries outside of those covered by the STAR project. So our HIV self-testing business continues to grow nicely, and we believe this business will be a significant contributor to our infectious disease business in future periods.

On the domestic front, there's not been much change in the trending for our HIV business. The factors underlying the decline in this business are largely the same as we've seen in prior periods. These include the CDC's continued movement for use of fourth-generation automated laboratory testing equipment, price competition, funding pressures in the public health market and the timing of orders. The recent severe weather conditions also had an impact on our domestic HIV revenues in the current quarter.

Once again, the decline in our third quarter domestic HIV sales was more than offset by the growth in our HCV and our HIV self-test businesses. We expect the challenging market factors will continue to affect our domestic HIV sales in future periods.

In prior calls we indicated that the WHO was expected to issue a report regarding its technical review of sputum transport solutions for tuberculosis, including data for our OMNIgene Sputum product. This guidance report was released this past month and indicated that some data was inconclusive. Consequently, further work is required in order to receive a WHO recommendation for routine use. The report indicated that WHO supports the procurement of OMNIgene Sputum for operational research, which we view as positive. This will allow funding organizations to support interested parties doing pilots of various sizes. Going forward, we will be working with the WHO to define the additional data required to support a recommendation for routine use of OMNIgene Sputum, and we will be working with our customers to generate that data.

In the area of emerging diseases, I only have one item to address and that relates to our new Zika test. We previously indicated that we expect to submit for Emergency Use Authorization, or EUA, from the FDA in Q4 of this year. And unfortunately, because of ongoing technical challenges with the test, this submission will likely be pushed into 2018. We remain committed to obtaining EUA approval and successfully commercializing this test.

And the final area I'd like to address is our effort to expand manufacturing capacity to meet the increasing demand for our products. We've made really good progress in a number of areas. Our second automated OraQuick production line is now operational and is running on 2 shifts. Work with the supplier for our third automated OraQuick line is also progressing nicely. This equipment is now in the design phase and is expected to be installed in mid-2018, with full operation by the end of the year or early 2019.

The addition of capacity at our Thailand contractor has also progressed, and the new assembly equipment has now been installed. We expect validation of this equipment to be completed by year end, with regulatory approvals received in early 2018. Our Thailand contractor is used for the supply of non-US and non-CE marked OraQuick HIV product, primarily in developing countries. Given the strength that we are seeing in our self-testing business, we're now planning to build 2 additional lines in Thailand in 2018 to provide for additional capacity.

A new automated assembly line for Oragene DNA collection kits was put into operation in mid-October, and yet another automated line is being built and is scheduled for delivery in late December or early January, with operation expected in March or April of next year. And finally, we also

recently signed a lease for a new warehouse near our Bethlehem facility as part of our capacity expansion project. Construction of the warehouse is expected to be completed by February 1, 2018, and should be fully functional no later than April 1 of 2018.

So in summary, our Q3 performance was very strong. We will continue to focus on expanding the use of our products around the globe, consistent with our strategic priorities. We are making the necessary investments in our manufacturing capacity to meet future demands and to capitalize on the many opportunities before us, and we expect the recent trends in our business will continue through the remainder of 2017, and we expect to enter 2018 with solid momentum.

So with that, we can now take your questions, operator, if you will proceed.

QUESTIONS AND ANSWERS

Operator

[Operator Instructions.] Our first question comes from the line of Brandon Couillard from Jefferies. Sir, your line is now open.

Samuel Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

Doug, with respect to the single large countrywide elimination contract that you spoke about, could you give us a sense of whether that development has changed how you're thinking about your capacity expansion plans and how you would characterize your level of visibility around potentially signing one or more other contracts to fill that hole that you'll be facing next year?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Obviously, it was a disappointment that that contract was not renewed despite the fact that we had been in renewal discussions for quite some time and we were told that we should expect a renewal. And actually, we were shown documents that represented the request from the Ministry of Health to the finance authorities for not only renewal, but a substantial increase in the number of tests that we'd likely be contracted for. So it was quite a surprise, unfortunately, that we received last week.

That being said, it doesn't dampen our enthusiasm for hepatitis C eradication programs and the use of our product in those programs, and we continue to be engaged with a number of different countries on their program design and what they're anticipating to do. Certainly, as we've indicated previously, the challenge is funding in many cases, and the timing is always very, very challenging because of everything that has to be put in place to execute one of these programs. It's not just about screening, but it's also about getting the confirmatory testing completed. It's also critically important that the drugs are available to the individuals who are diagnosed positive, and all that has to come together in these eradication programs. So we continue to be enthusiastic and optimistic. Our test is ideally designed for these kinds of programs, and we're going to continue to pursue them.

Relative to our capacity expansion plans, this doesn't dampen those whatsoever. We continue to expect increased demand for both hepatitis C and our HIV testing products, both domestic as well as internationally, and we're going to continue to execute on expanding our capacities to be prepared for that increased demand. And that's only part of it, because the other component is the expansion of our molecular capacity, and all those programs are going along really well.

Samuel Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

Okay, and then maybe a 2-part question for Ron, if I can. If we look in the third quarter, the international HCV revenues -- I believe the third quarter, if we look back in terms of the $18 million contract, the third quarter was supposed to be the largest in terms of contribution from that contract.

Could you give us an update on how much of that you booked in the third quarter? And then as we look into the fourth, in terms of the revenue and EPS, is that probably like another step down sequentially in terms of gross margins?

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

Right. So in the third quarter of 2017, we recognized approximately $4.7 million worth of revenues from the large countrywide elimination -- eradication program in revenues. And in the fourth quarter of 2017 here, we are not forecasting any revenues in our guidance of $45 million to $46 million. We do have probably a small, de minimis amount of shipments that we will have made to that country in Q4, but it's very small.

Operator

And our next question comes from the line of Andrew Cooper from Raymond James. Sir, your line is now open.

Andrew Cooper

I just wanted to look at DNA Genotek. As we think about kind of where the growth has come from, could you remind us the breakout of academic versus commercial? And then as we think about moving forward this year and beyond, what sort of seasonality we might expect, given that I know you had 23andMe, a very successful prime day, for example, in July, and obviously, the holiday season with a special little bit of spike. So I just wanted to get a little bit of your thoughts on that, please.

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

Yes, so we do see that the academic, as we mentioned, picked up approximately 46% over the prior quarter, the prior year's quarter. And we also had quite a large step up in our commercial revenues for the third quarter over the comparable period. And as Doug mentioned, microbiome was also up well in excess of where our performance was.

Looking forward into the fourth quarter, we do sense, although we don't know definitively, but we do sense that there is some seasonality associated with some of the consumer genetic testing opportunities that are being pursued by a number of our customers. And we expect that to accelerate over the next couple of months here and then likely not be replicated in the first quarter of 2018, although I think we still reserve the right, obviously, to come back to you with further color on the first quarter of 2018 as we actually move into that period. And we'll update you on our fourth quarter call in February. So I think it's a bit of a learning experience for us, as this is really the first year where we have a significant number of customers operating in that space, and we're anxious to see their successes and want to be fully supportive of their needs as we move through the balance of 2017 here.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

It's really one of the -- just to add to that -- it's really one of the reasons why in our last call we forecasted sequential growth from Q3 to Q4, and it's one of the reasons why we wanted to give you some commentary on Q1 so that our expectations are somewhat aligned. But as Ron indicated, I think we'll have a better perspective a year from now, again, as we see these businesses go through different cycles. But nonetheless, across both the commercial as well as academic customer set, the molecular business is doing really, really well.

A small tidbit I mentioned, because I went back and looked historically, the $3.2 million that we delivered in Q3 is the best quarter ever for our academic business. Going back to the first quarter of 2016, it was the only 1 quarter where we did a little bit better. We did $3.3 million. So it kind of gives you a perspective. The academic business is performing really well. Obviously, the commercial business is killing it, and the microbiome business continues to perform. So it really gives us a lot of confidence and very enthusiastic about how that business is going to deliver, not just in the fourth quarter but in 2018 as well.

Samuel Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

Great, that's really helpful. And then just one quick one on gross margins. I know you called out a little bit of spoilage in the press release, but if you could maybe help us size how much of the -- that was a little shy versus what we thought -- how much of that is spoilage versus just a mixed dynamic, or if there was anything else going on underlying?

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

Yes, that's a great question and happy to share a little bit more color on that with you. We did have a production issue in the third quarter of 2017 that involved our HCV product and a component that was being used in our production process that unknowingly was a defective piece of equipment that had been supplied to us. And because of certain reactions that were occurring with our product and this piece of equipment, we ended up scrapping many lots of product and totaled about $600,000 worth of scrap in the quarter. And so it was a pretty significant negative contributor to our gross margin performance in the third quarter.

The good news is that the team did an exhaustive job of tracking down the root cause of this production problem and we have switched out the piece of equipment that was being used. And we are currently in discussions to recoup what we can on the cost that we experienced here during the third quarter and actually some in the second quarter of 2017. So more to come on that, but that's some additional color for impacts on gross margin in Q3.

Samuel Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

And did that issue have any potential impact on timing of shipments or any sort of delays that could have maybe impacted the big eradication contract or no, everything was still shipped on time, just at a higher cost to you?

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

No, thankfully not. We did not have implications on our shipment schedule nor receipted a product by the folks in country.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Let me just add to that. This was an issue that was identified through our quality control program. We have a robust quality management system, so it detects any issues well before a product is approved for release to customers. And so kudos to our quality team and our operations team for identifying a problem. Unfortunately, it did cause us to scrap a fair amount of product and incur that cost, as Ron described. But no impact to deliveries, no impact to quality to our customers whatsoever.

Samuel Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

Congrats on the good quarter and I'll follow up offline.

Operator

Our next question comes from the line of Drew Jones from Stephens. Your line is now open.

Andrew Luten Jones - *Stephens Inc., Research Division - Research Analyst*

Looking at the 4Q guidance, what's implied there as far as HIV self-test?

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

Yes, we generally do not drill down into the individual product contributions from a revenue perspective, but I will say it certainly is a step up from our third quarter performance, as we're beginning to build traction in that marketplace, and we're very excited about the opportunities that have now accrued to us as a result of WHO prequalification, the implementation of the Gates agreement and just the broad dissemination of the product's availability to the countries that are being targeted. So we're seeing a good pull-through of product there, and Q4 does represent a substantial step up. But I really don't want to quantify the precise amount.

Andrew Luten Jones - *Stephens Inc., Research Division - Research Analyst*

Understood. And then transitioning over to Hep C and eradication programs, I think you guys have said in the past that you were in discussions with 6 of the 50 countries that were pursuing eradication programs. Can you give us an update on how have those discussions progressed, and have you expanded discussions to other countries?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

We continue to be engaged with at least 6. There are actually more that we're in discussions with. And like I said previously, the challenge is to predict when those are going to translate into substantial orders. But as I mentioned, there's a large number of countries that both have developed hepatitis eradication programs and are considering and actually planning for broad-based hepatitis C screening programs, and we're in discussions with those. As we have more to say about specific opportunities as they come our way, we'll certainly update you.

Operator

[Operator Instructions.] Our next question comes from the line of David Westenberg from CL King. Your line is now open.

David Michael Westenberg - *CL King & Associates, Inc., Research Division - Senior VP & Senior Equity Analyst*

Congrats. So just on the HIV business, the domestic business, I know that just the trends in HIV testing in -- domestically have not necessarily been very good tailwinds. Obviously, they've been headwinds. But trending down a lot further than me, so can you just discuss what might sort of be the new normal here in terms of what we should expect in that business?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Yes, I think there's a little bit of ordering patterns in what you saw in the third quarter results. I think we're going to see some improvement in Q4 in the domestic HIV business, but it doesn't change what we've described as a difficult market where overall HIV testing volumes are down, where we're seeing pressure on rapid HIV testing and a shift to laboratory-based HIV testing, primarily to capitalize on the benefit of the fourth-generation automated laboratory tests that are available.

So all we can really say is those pressures are going to continue, although we will see some improvement in Q4.

David Michael Westenberg - *CL King & Associates, Inc., Research Division - Senior VP & Senior Equity Analyst*

Got it, thanks. And can you run through the process of when you're engaging -- the steps that you're in for getting a country. You named 6 countries that you're in discussion with. Just kind of give us kind of a play-by-play on how it works. And I understand that most countries are going to be different. And what I'm really going after here is you have the baseline business from 2016 and then you have this deal that you had for the majority of 2017. I'm trying to just figure out, in the context of not renewing this deal, but you have other deals that are, or other arrangements that you're working on, I just want to -- just run us through the process so we can kind of understand how to model or how to think about that business as you engage with other countries and organizations.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Dave, I wish there was a playbook. These are new programs that are being contemplated and they vary by the size of the country, the population, the prevalence of hepatitis C, the budget dollars that are available. I can't answer it. I can say that in all cases, there has to be a provision for the drug, there has to be a budget and an expected way to deploy these tests. Those are the discussions that we engage with in at the country level, both at the political and policymaker level, all the way down to the organizations within countries that are charged with deploying these tests, whether it's in an urban area or in a more rural area. And you've seen one, you've seen one. And that's just the way it is. We've got good folks on the ground that are working and engaged in these discussions, but given the complex nature of these, it's an involved process. And I know you'd like a cookie-cutter approach to it. Unfortunately, it just doesn't exist.

David Michael Westenberg - *CL King & Associates, Inc., Research Division - Senior VP & Senior Equity Analyst*

Let me ask this question another way. In terms of what you see for 2018 relative to what you saw in 2016 before this deal in the HCV business, is it a better business today than it was in 2016 internationally? You don't need to necessarily quantify specifically, but just the way we think about that in terms of should we be looking, is that a more steady business on a go-forward basis or is it just going to be so bullet and lumpy that it's not even -- or not even worth it to really dive too deep?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

So absent the renewal of this large government contract, our enthusiasm for the other opportunities, I would say, remains intact, so no less -- no change in that regard. We believe it's a large opportunity. Governments have these policies in place, and an increasing number of governments are putting them in place to develop hepatitis elimination programs, and we're just going to continue to pursue them. We believe we'll be able to capture them.

David Michael Westenberg - *CL King & Associates, Inc., Research Division - Senior VP & Senior Equity Analyst*

All right, great, great. And then I'll just ask one more on -- would you be willing to break out the contribution from microbiome, or is it still too early to really want you to quantify it yet?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

No, it's easily quantified. We did about $1.1 million in 2016. We've done well more than that. We're on track to deliver about $3 million for the full year here, 2017. As we look ahead, so we're going to more than double our microbiome revenues this year. I think we see a path to doubling them again in 2018. And there's a number of drivers that give us a lot of encouragement for that, not the least of which is increased funding at the NIH level for microbiome research. Microbiome research continues to capture a larger percentage of the total genomics research business.

There's interest in new sample types, which we're pursuing. Despite the fact that gut microbiome, or fecal samples, continue to be the dominant specimen type and the largest, fastest-growing specimen type, we're well positioned to capitalize on the interest in new sample types. We look at

patent filings as an indicator of where the business is heading, and we see a continuous increase in patent filings over the last 4 or 5 years. We monitor the number of active clinical studies that are going on around the world. That continues to increase. And interestingly enough, over 80% of them include stool samples as a specimen type. And I think as the cost of sequencing comes down, what we're also seeing is a larger average clinical study size in the microbiome space. So there's a lot of drivers that we see that really put wind in the sails of our microbiome business, and we're really well positioned to capitalize on that.

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

And Dave, Doug indicated in the call that we've done $2.4 million in microbiome revenues year-to-date.

David Michael Westenberg - *CL King & Associates, Inc., Research Division - Senior VP & Senior Equity Analyst*

Thank you very much and congrats on a good quarter.

Operator

Our next question comes from the line of Mark Massaro from Canaccord Genuity. Sir, your line's now open.

Max Masucci

Max Masucci on for Mark. Can you speak to the strength in your Q4 guidance? Is this mainly driven by a favorable seasonality in personal genomics? And also looking forward, do you expect to fulfill the complete $18 million from the original HCV eradication contract?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Okay, so the Q4 guidance is strength pretty much across the board. We see it in our infectious disease business, our molecular business is particularly strong and we are anticipating a good uplift from the seasonality that we see in our commercial business. It's a big driver. We see a little bit of improvement in our cryosurgery business. And as Ron mentioned specific to additional revenues expected from the large government contract, we don't have any significant revenues in the fourth quarter from that agreement.

Max Masucci

Okay, great. So just looking for some additional color on gross margins, I know we saw a slight dip quarter-over-quarter. What portion of this was due to what you identified as scrap and spoilage costs, and what portion was due to mix? Any color there would be great.

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

So I think as we talked about earlier in response to a question posed, we recorded a little over $600,000 worth of charges associated with the specific issue that we had related to the HCV product and the equipment. And I would say that beyond that, you're looking, really, at mix as a potential contributor to the gross margin profile in the quarter, as the self-test revenues increased as well as we had a nice recurring bolus of revenue from the HCV product sales into the countrywide eradication program. So they were other contributors for our gross margin step-down in Q3.

Operator

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

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Okay, just thanks again, everybody, for being on the call with us this evening, this afternoon, and we look forward to delivering a real strong Q4 and close out 2017 in great form and look forward to updating you all on our next call. Have a good evening.

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.