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OSUR - Q4 2017 OraSure Technologies Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, everyone, and welcome to the OraSure Technologies 2017 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 2017 fourth quarter financial results and certain other matters. The press release is available on our website at www.orasure.com or by calling (610) 882-1820. If you go to our website, the press release can be found by opening the Investor Relations page and clicking on the link for press releases.

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 statements, its annual report on Form 10-K for the year ending 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 this call over to Doug Michels.

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

Okay. Thank you, Joni, and good afternoon, everyone, and welcome to our call.

I'm pleased to report that we ended the year on a high note. We delivered outstanding results for both Q4 and the full year 2017 with record revenues and strong profitability. We are delighted with our performance. With respect to Q4, the company results were driven largely by a significant increase in molecular collection sales and continued strong growth in our HIV self-test business. There are many highlights.

Our consolidated net revenues reached an all-time high for the quarter at \$52 million, representing a 47% increase from the year ago period. Product revenue growth for Q4 was an extraordinary 75%. Our molecular business delivered another record performance. Q4 revenues reached



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\$29.8 million, which represents a 248% increase over the fourth quarter of last year. Our infectious disease revenues also rose during Q4 as a result of a 171% increase in international HIV sales, driven primarily by our HIV self-test business. The increase in international HIV sales more than offset a reduction in international HCV sales caused by the nonrenewal of a large government supply contract in countrywide HCV eradication program.

Operating income for the fourth quarter rose 44%, and we generated \$7.3 million in consolidated net income or \$0.12 per share on a fully diluted basis. For the full year, we had consolidated net income of \$30.9 million or \$0.51 per share.

We ended 2017 with \$177 million in cash and cash equivalents, which represents a \$56 million improvement from the end of 2016. By any measure, 2017 was truly an outstanding year for the company.

So let me now turn the call over to Ron, and after his financial review, I will provide some business updates and then take your questions.

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

Thanks, Doug, and good afternoon, everyone. As you can see from our press release and Doug's brief introduction, 2017 was a very successful year, with our fourth quarter revenues reaching record levels.

Our fourth quarter consolidated net revenues increased 47% to \$52 million compared to \$35.5 million reported in the fourth quarter of 2016. Notably, our consolidated net product revenues rose 75% to \$50.2 million compared to the prior year period. Higher sales of our molecular products and the OraQuick HIV self-test were the main drivers of this performance. Our molecular revenues rose 248% to \$29.8 million in the fourth quarter of 2017 compared to \$8.6 million in the fourth quarter of 2016.

Sales of our Oragene product to commercial customers increased 368% to \$26.9 million, largely due to our new \$143 million agreement to supply Oragene devices to a leading consumer genomics customer, coupled with higher sales to our other large customers.

Microbiome sales continued to gain traction and increased 180% to \$1.1 million in the fourth quarter of 2017 as compared to the fourth quarter of 2016. Academic sales decreased 29% to \$1.7 million due to customer ordering patterns.

International HIV sales increased 171% to \$3.6 million from \$1.3 million in the fourth quarter of 2016 due to higher sales of our OraQuick HIV self-test into Africa. The test shipments to Africa during the quarter were subject to the support payments under our charitable support agreement with the Gates Foundation and included countries outside of the STAR initiative. Product revenues during the fourth quarter 2017 included approximately \$589,000 of support payments associated with this agreement.

Domestic professional HIV sales decreased 9% to \$4.6 million in the fourth quarter of 2017 compared to \$5 million in the fourth quarter of 2016. This, due to factors we have previously discussed.

International HCV sales in the fourth quarter of 2017 decreased 61% to \$1.1 million from \$2.9 million in the same period of 2016, primarily due to the nonrenewal of a foreign government supply contract in support of the countrywide HCV elimination program combined with lower sales in Asia.

Domestic HCV sales rose 11% in the fourth quarter of 2017 to \$2.5 million from \$2.2 million in the prior year period, primarily due to increased HCV purchases by our public health customers.

Other revenues were \$1.8 million in the current quarter, representing \$1.3 million of funding we received from BARDA for our rapid Ebola and Zika products and \$470,000 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 fourth quarter of 2016 totaled \$6.9 million and included \$747,000 in BARDA funding, and \$6.1 million of exclusivity revenues under the AbbVie HCV co-promotion agreement, which terminated effective December 31, 2016.



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Turning to gross margin. Our gross margin for the fourth quarter of 2017 was 55% compared to 67% reported for the fourth quarter of 2016. Margin for the current quarter decreased primarily due to the absence of AbbVie exclusivity revenues in 2017, an increase in lower-margin product sales and higher scrap and spoilage costs.

Turning to our operating expenses. Our consolidated operating expenses for the fourth quarter of 2017 were \$18.4 million compared to \$16.9 million in the comparable period of 2016. This increase was largely due to higher lab supplies, staffing and consulting costs and costs incurred in the fourth quarter of 2017 as a result of the nonrenewal of the foreign government HCV supply contract. In addition, fourth quarter 2016 costs were reduced by \$1.4 million as a result of the settlement payment received in connection with the dispute with the supplier of raw materials. These expense increases were partially offset by lower legal fees and the absence in Q4 2017 of costs associated with the corporate restructuring, which occurred in the fourth quarter of 2016.

Income tax expense was \$3 million in the fourth quarter of 2017 compared to an income tax benefit of \$31,000 in the same period last year and consists entirely of Canadian taxes due. Late in the fourth quarter, the Tax Cuts and Jobs Act was signed into law. In addition to lowering the U.S. corporate tax rate to 21%, other provisions of the law include a mandatory deemed repatriation tax on earnings and profits of offshore entities, a tax on global intangible low tax income, accelerated deductibility of capital expenditures and the elimination of the deductibility of executive compensation above a certain threshold. In collaboration with our outside tax advisers, we have conducted an analysis of the impact of the tax law changes on the company and have several preliminary observations.

The mandatory deemed repatriation tax calculated through 2017 on the accumulated earnings and profits of our Canadian subsidiary, DNA Genotek, has been offset through the utilization of \$24 million of our net operating losses in the United States. We are now in a position to repatriate accumulated cash at our subsidiary, subject to certain limitations without the imposition of further U.S. taxes should we elect to do so. Beginning in January 2018, our earnings and profits in Canada will be subject to the U.S. tax imposed on global intangible low tax income. Due to the rules in the U.S. tax code associated with the utilization of net operating loss carryforwards and tax credits, we will utilize our net operating losses to fully offset this tax obligation. It should be noted that for U.S. federal tax purposes, we do not envision paying cash taxes in 2018.

From a bottom line perspective, we reported net income of \$7.3 million or \$0.12 per share on a fully diluted basis for the fourth quarter of 2017 compared to net income of \$7.2 million or \$0.13 per share for the same period of 2016.

Turning to our balance sheet and cash flow. We continue to maintain a solid cash and liquidity position. Our cash and investment balance at December 31, 2017, was \$176.6 million compared to \$120.9 million at December 31, 2016. Cash generated by operating activities during 2017 was \$28.2 million compared to \$24.6 million in the same period of 2016.

Turning to our guidance. During Q1 2018, we announced the upcoming retirement of Doug Michels, our current President and CEO; the appointment of Dr. Stephen Tang as his successor; as well as my expected retirement. Charges associated with these transitions are expected to total \$6.8 million in the first quarter of 2018 and \$1.7 million in the second quarter of 2018. These charges are primarily noncash charges associated with modifications to existing stock grants made to the retiring executives and expenses associated with the onboarding of our new President and CEO. So as we look at overall Q1 2018 guidance, we currently expect revenues to range between \$40 million and \$41 million and a consolidated net loss of approximately \$0.06 per share, inclusive of our transition costs.

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

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

Okay. Great. Thanks, Ron.

As noted previously, our molecular business performed exceptionally well in 2017 with full year revenues more than doubling when compared to 2016. Of our top 20 customers, 17 increased their purchases year-over-year, with our top 2 accounts growing an aggregate of 371% for the full year. Our fourth quarter molecular revenues reached an all-time record of \$29.8 million, which represents a 248% increase over Q4 of last year and sequential growth over the third quarter of 61%. Our commercial genomics business continues to be the primary growth driver for our molecular

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business, with most of the growth occurring in the direct-to-consumer and clinical genetic testing markets. For the full year 2017, 14 of our top 15 commercial genomics accounts increased purchases over 2016, with triple-digit growth in 9 of these accounts and strong double-digit growth in 5. We are seeing market adoption of personal genome services on a global scale, and we believe this trend will continue and support future growth for our business.

On the international front, we continue to see strong growth, particularly in Asia, where our revenues grew approximately 93% in the fourth quarter of 2017 compared to the prior year period. The fourth quarter was our best quarter ever for sales in Japan, where revenues grew 226% compared to the fourth quarter of 2016. Revenue in China grew 114% in Q4 and 78% for the full year 2017 compared to the prior year periods.

We recently closed a large repeat order with a direct-to-consumer from China, offering whole genome sequencing using our OraGene device. We also acquired a new customer in China that will be offering one of the first genetic-based skincare products. We expect demand from these and other customers to continue to drive revenue growth in China and other parts of Asia in 2018 and beyond.

2017 microbiome revenues essentially tripled from 2016, and our fourth quarter revenues grew 180% compared to the prior year quarter. The increase in sales reflects our continued acquisition of new customers and strong repeat business from existing customers. In this regard, over 57% of our fourth quarter purchasers were repeat customers and represented 70% of our microbiome revenue for the period. We also continued to leverage our relationships with existing genomics customers, with sales for these existing customers representing 40% of our microbiome purchasers in 2017.

A key factor driving business growth has been microbiome-based discovery work, where our product is being used in support of clinical trials. During the fourth quarter, approximately 28% of our microbiome revenues were generated in support of clinical trials being conducted or sponsored by biopharma customers. The average dollar value of our microbiome-related services agreements has also doubled in size compared to 2016, and over 50% of our services customers typically return as repeat purchasers within 12 months.

An exciting new project in the microbiome spaces are collaboration with Janssen, a subsidiary of J&J and DNAnexus, to provide product to approximately 1,000 labs around the world as part of the Mosaic standards challenge project. Mosaic is a cloud-based microbiome informatics platform that provides a secure and collaborative space where researchers can develop, improve, compare and share methods in microbiome research. For this work, it's essential to start with a known sample input, which means that stabilization and standardization are critical for activities that occur downstream. Our microbiome products are uniquely qualified to meet these requirements.

We're also very happy to announce that our OMNIgene line of products has been selected by Harvard's T.P. Chan School of Public Health (sic) [Harvard's T.H. Chan School of Public Health] for a microbiome specific recollection of the nurses' health study to cohort. There are a few final details of this supply arrangement being discussed, which should be finalized very soon. Under this project, 75,000 samples are expected to be collected over a 12-month period beginning in the second quarter of this year. The samples will be housed in the newly created bio bank for microbiome research in Massachusetts. We are extremely happy that our technology has been chosen for one of the most highly regarded epidemiological studies in the world as it expands to include microbiome information.

Turning to infectious disease, our revenues grew moderately for Q4 and are up 28% for the full year compared to 2016. Our international HIV business was a major growth driver throughout 2017 and turned in another strong performance in Q4, where revenues rose 171% compared to Q4 of 2016. This growth is primarily the result of HIV self-test sales in Africa.

As discussed in prior calls, Population Services International or PSI has initiated Phase II of the self-test in Africa or STAR project, which is expected to deploy 4 million self-tests into on an expanded list of African countries, with the largest being South Africa. We've already started fulfilling orders under Phase II, and we expect this will continue throughout 2018.

We continue to benefit from our charitable support agreement with the Gates Foundation as the more favorable pricing we can now offer is stimulating additional demand. We expect to ship 30% to 40% more HIV self-tests in Q1 2018 than we did in Q4 of this past year.

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Importantly, we are also seeing increasing self-test demand outside of the STAR project. As an example, we expect to begin deploying tests in the second half of 2018 under a new initiative funded by a large NGO. This program will target the Francophone countries, and we expect this initiative will be large, although not as comprehensive as the STAR project.

We are also participating in pilot programs initiated by PSI to provide our self-tests into the pharmacy market in sub-Saharan Africa. The pharmacy channel will be important in order to fully realize the benefit of self-testing in these markets.

Our international HIV sales more than offset the declines in our U.S. HIV business. We are continuing to experience the same domestic trend seen in the past, with declines resulting from the CDC's preference for a fourth-generation automated laboratory testing solution and some price competition and funding pressures in the public health market. Nevertheless, we continue to implement programs to mitigate the impact of these factors on our business.

As Ron noted, our Q4 HCV revenues declined when compared to the fourth quarter of 2016, although our overall HCV business performed very well for the full year. The main reason for the Q4 decline was the nonrenewal of a foreign government supply contract in support of a countrywide HCV eradication program, which we discussed at length during our last earnings call.

Our HCV Domestic business increased revenues 11% in the fourth quarter compared to the year ago period. This growth reflects contribution from all 3 of the major markets in this (inaudible), which include public health, hospitals and the physician's office. Our customers continue to find the resources needed to support HCV testing and treatment programs despite continued funding challenges domestically.

Turning to operations. We've continued the capacity expansion efforts described in prior calls. The second manufacturing and packaging room at our Thailand contractor, which was previously installed, has now been validated. This doubles the manufacturing capacity of the site and will be used for the supply of non-U.S. and non-CE-marked OraQuick product. During 2018, we plan to build additional capacity in Thailand to meet the demand forecasted for 2019 and beyond.

As noted on our last call, a fourth automated assembly line for OraGene collection kits has been built and is expected to be fully operational in April of this year.

And lastly, construction of the new leased warehouse here in Bethlehem is progressing on schedule. After completion of environmental qualification and submission for regulatory approval, we expect the new warehouse to be operational in April.

A final point I want to address is the recent addition to our Board of Directors. Dr. Aradhana Sarin has been appointed as a Class 2 Director, with her initial term expiring at the company's 2020 Annual Meeting of Stockholders. Aradhana currently serves as the Head of Business Development at Alexion Pharmaceuticals, a global biopharmaceutical company. She has over 20 years of professional experience in global health care, primarily with large financial institutions that include Citi Global Banking, UBS and JPMorgan. Aradhana is a physician, and early in her career, she practiced for several years in both India and Africa. And I can say, without a doubt, we could not be more pleased to have Aradhana join our board.

So in conclusion, we delivered excellent financial results for both Q4 and the full year 2017. The molecular collections business and the OraQuick HIV self-test were the primary drivers of this performance. We expect the continued strength in these businesses will be a big part of our performance in 2018, and we're also making the necessary investments in our manufacturing capacity to meet the expected future demand for our products.

I'm confident that as you come to know Steve Tang, you will understand why he was chosen to lead the company. He is an impressive individual and a very talented executive. I fully expect that he will take OraSure to new heights.

So in summary, our business has never been stronger, and we're starting the new year with significant momentum. We expect 2018 will be another successful year for OraSure.

So with that, we'll now take your questions. Operator, if you'd please proceed.



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QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Brandon Couillard with Jefferies.

Brandon Couillard - Jefferies LLC, Research Division - Equity Analyst

Doug, I appreciate all the details around the Asians customers and the DNA Genotek business. I guess 2-part question there. Could you give us a relative sense of how big the top 5 customers are as a percent of revenue for that segment? And then, secondly, anything you can share in terms of the mix between U.S. and o-U.S. customers just so we can sort of think about where Asia is in sort of the part of the overall size of that business today?

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

Yes. We -- thanks, Brandon. We don't break out our customers by business or by business segment. So unfortunately, I can't give you that level of granularity in terms of our top 5 customers. I think you certainly got a sense from our prepared remarks that we're seeing broad-based growth across our top customers, across the whole genomics business with our commercial customers. The majority of our revenues today can continue to be generated in the United States, although the International business is growing significantly. Obviously, it's smaller. So growing as a significant percentage for sure. We do believe that the Asian market represents a very significant opportunity, and we also believe that it's perhaps several years behind the development of the U.S. market. And so consequently, we believe that there is going to be significant future growth coming out of Asia.

Brandon Couillard - Jefferies LLC, Research Division - Equity Analyst

Two-part question for Ron. Number one, the DSO spike in the fourth quarter. Any color you can add there? And then number two, the gross margin deterioration year-over-year. Could you help us bridge the step down year-over-year in terms of the contribution from mix? Any other factors? I would think given the growth in the DNA Genotek business, that'd be at a higher-margin business that actually would have been helpful in the fourth quarter.

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

Right, right. So addressing the DSOs, so we did have a pretty significant amount of revenues as we move through the quarter. So as we got into the holiday season, Brandon, and into -- then through Christmas, there were a lot of demands put on us as far as our -- from our customers, which had us with a significant balance of receivables at year-end, which we have, for the most part, subsequently, collected. So I was checking on that just today, and a fair amount of cash has already come in here. So I would imagine that at March 31, the DSOs will be down pretty significantly from where they sit today. From a gross margin perspective, biggest single driver in the gross margin reduction from the fourth quarter of last year to the fourth quarter this year was the AbbVie exclusivity amortization. That amount -- that accounted for approximately 600 basis points. Then we also had, I think we telegraphed in our last quarter call, charges associated with the nonrenewal of our contract for the HCV eradication program and also the discontinuation of a product that we had been selling for some time, and that's the Western Blot product, and we wrote that off in the fourth quarter. That accounted for another about 250 basis points of margin, and so there are -- they are items -- all of those actually are items that we don't anticipate going forward. And we expect, as we move into and through Q1 here, that we will see more of an uptick in our gross margin from the approximate 55% that we recorded. We also, as Doug pointed out, enjoyed higher sales of our HIV self-test in the fourth quarter compared to the year ago quarter. And if you recall, our objective with that test is to drive operating income and concede on the gross margin line, and so that accounted for approximately 170 basis points of margin loss. And that's something we'll need to keep our eye on as our revenues are



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expected to grow well in 2018 over levels that we achieved in 2017. But again, all in, I think we'll see a pickup in gross margin in Q1 over where we ended in Q4. Hope that's helpful.

Operator

Our next question comes from Nicholas Jansen with Raymond James.

Nicholas Michael Jansen - Raymond James & Associates, Inc., Research Division - Analyst

First on the DNA Genotek side. Certainly, the demand in 2017 surprised everyone. And so I guess I'm just trying to get a sense of your level of visibility today based on the ordering patterns of your biggest customers. How do we feel about the near-term, the medium-term kind of growth trajectory off of that phenomenal growth that we saw in the year? Any color there would be appreciated. I'm sure you're expanding capacity right now in preparation for growth, but any color on visibility would be helpful.

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

All right. I think that's certainly an indicator of how bullish we are on the molecular business. I think our first quarter guidance from a revenue perspective, again, doesn't have any HCV revenues related to the countrywide eradication program. So we anticipate continued strong demand across our molecular as well as our HIV self-testing business. One of the things that we telegraphed and certainly enjoyed was the seasonal impact that we saw in our molecular collections business in the fourth quarter. Obviously, we expect that will continue in 2018. We're going to have to continue to learn how that plays out across our different consumer DTC genomics customers both here in the United States as well as abroad. So continue to stay tuned on that. But the bottom line is, as you saw based on the stats that we shared, we're seeing broad-based growth across our molecular business.

Nicholas Michael Jansen - Raymond James & Associates, Inc., Research Division - Analyst

That's helpful. And maybe just thinking about -- and this might be a better question for Steve Tang. But just thinking about the portfolio of the company, the Cryosurgical and substance abuse continue to be somewhat drags on growth. You're now sitting on a record cash pile. It sounds like DSO is coming down [at once] you would give even more [credence] to that cash pile growing. So I'm just trying to get a sense of how we should be thinking about strategically putting that capital to work or, perhaps, looking to maybe divesting some of the noncore stuff to plow back into what could be a very differentiated molecular collections opportunity.

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

Right. So I think that's all part of a process that Steve and the team will undertake as we move through the early part of 2018 here in a strategy refresh that is being conducted, and that will involve using outside advisers as well as our own internal folks to take a look at the whole business and determine the path forward. And certainly, all of that is fair game and up for discussion. So I think probably more on that to come down the road, Nick. A little premature at the moment, but it's certainly something that's under consideration. And also we'll drive some additional costs in the first quarter, so just as a heads-up.

Operator

Our next question comes from David Westenberg with CL King.

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

Congrats on the retirement, and great to work with you guys. So I know I asked this on a prior call, but I am still trying to kind of figure out that baseline for HCV. Can you talk about the -- you mentioned there was a little bit of step-down in HCV ordering in Asia. Can you give us a sense in terms of the magnitude and the step-down of ordering in Asia and what you might expect in terms of coming back? And as a kind of a follow-up to that question, how is it going with other kinds of HCV projects in maybe that region?

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

Yes. So relative to the step-down in Asia, that was primarily related to our business in Korea. We do anticipate that, that's going to improve in 2018, and we're working to make that happen. That's been the primary contributor there. We continue to be focused on opportunities globally. Like I've said multiple times since our last call, we've basically stripped out some of these large countrywide eradication programs given the difficulty we have in predicting when they're going to translate into significant contribution to revenues and to the P&L. Doesn't mean we're not working on opportunities, and we're in discussions with a number of different governments. But right now, I don't have anything substantive to report on that, or at least I can't predict when that may translate into future revenues. So it's out of our guidance at this point in time. And at the same time, you see our projections for total revenue growth for the businesses is quite handsome, and we expect 2018 is going to be a good growth year for OraSure.

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

All right. Well, I'm not picky on that. So I know you're -- we're only a month into it, but can you give us a sense in what the licensing payment might look like, well, if you legally can?

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

We're precluded from providing that level of detail on our settlement with Ancestry. It'll be -- those revenues will be recorded in other income. We will report on total other income for the first quarter in our first quarter call in May. And we do provide some granularity in other income, specifically as it relates to other income received from BARDA and those gates, income items, that are not product subsidy-related. So you'll get some sense of what the total revenues are related to royalty payments, but we can't be specific on that either in terms of the specific dollars or the royalty rate. We're just precluded from sharing that by the contract.

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

Perfect. But I would, in that particular payment, assume that it would probably have the same sort of cadence as the rest of the consumer genomics industry.

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

I would anticipate that there will be some element of seasonality associated with that. Again, we'll have to learn through experience.

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

And then I'll just squeeze in one more, if I can. Is there any updates on the pipeline whether with Zika or Ebola? And when we should expect kind of the next -- if there would be anything after that?

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

Well, certainly, we expect to continue to benefit from the BARDA contract through 2018 and beyond for both of those products. The Ebola revenues that we received from BARDA are going to be primarily related to the payment for clinical studies that we're conducting this year to secure 510(k) approval. On the Zika front, revenues are primarily directed to paying for the development cost. We did make some good progress on the Zika development during the fourth quarter. We mentioned previously that we had a couple of technical issues that appear to be largely resolved right now, so we're moving that into further development where we can build some clinical lots that will be used as the basis for our submission for emergency use authorization on the Zika test. Beyond that, as it relates to other emerging diseases, I think Ron indicated that we've got the strategy refresh activities in process right now. And certainly, as we look across-the-board, our R&D strategies, new product development strategies, that will be one area of focus in that effort.

Operator

(Operator Instructions) Our next question comes from Mark Massaro with Canaccordia.

Mark Anthony Massaro - *Canaccord Genuity Limited, Research Division - Senior Analyst*

It's Mark Massaro from Canaccord. Doug, best of luck in retirement.

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

Thank you, Mark.

Mark Anthony Massaro - *Canaccord Genuity Limited, Research Division - Senior Analyst*

First question is on HCV eradication. I know there's a lot of questions on the other parts of the business. But Doug, where are we in terms of the number of countries that continue to evaluate your rapid hep C product? I know in the past, it was at least maybe half of a dozen or so. And would just love an update as to whether or not you expect to deliver another hep C eradication later this year.

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

We continue to be engaged with the vast majority of those governments that we've spoken about previously. And like I said, we'll give you more color and more specifics when we've got something substantive to say about those. At this point in time, we don't. And so I prefer to keep the focus on those other parts of the businesses that, frankly, are a little easier to model and project as to when the significant revenues are going to come, like the molecular business, like our HIV self-testing business.

Mark Anthony Massaro - *Canaccord Genuity Limited, Research Division - Senior Analyst*

Got it. Okay. The gut microbiome of \$1.1 million is a record at your company. I feel like it's very much underappreciated. I think a lot of people don't even know what it is. You did provide a lot of examples of contracts that you're involved in. As I think about this bucket in context to your larger molecular collections business, obviously, the vast majority of that revenue is coming from commercial customers. But can you just speak to your confidence of maybe the academic or even the pharma piece with the clinical trial development? But specifically on the academic side, do you expect microbiome research to expand to other bio banks as you contemplate this product over the next year?



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

Yes. So thanks, Mark. I think it's important just to be clear, most of our microbiome revenues are coming out of either the academic research market or the pharmaceutical commercial research market. But still, even in pharma, it's largely either applications and clinical studies or clinical trials, right? And we think that's going to continue for sure. We had a great year with our microbiome business in 2017, more than tripling the business year-on-year. We've indicated publicly that we believe that we can do in excess of \$6 million in 2018, so that's off \$3.5 million now, so almost doubling again. Hopefully, we'll do better than that. Some of the commentary that we've provided in our prepared remarks: inclusion in the Harvard nurses' study cohort; inclusion in this Mosaic project, where thought leaders in the space are choosing our technology for all the benefits that were highlighted in the human longevity study that was published in Nature in 2016, that it's critically important that samples are collected and stabilized so that you get the most benefit out of this comparative research. And we're in discussions actually with some of the largest pharmas, talking about the utilization of our microbiome products to standardize their specimen collection across their multiple programs that they have going on. Our goal in this space is to establish OMNIgene as the gold standard in specimen collection and stabilization for comparative research, and I think that the examples we put out there highlight that we're making good progress in that regard. And we're going to continue to support the research community, so that once these applications move out of research and into commercial opportunities, there's going to be no question they're going to use OMNIgene. So we're very excited about it like it sounds, like you are, Mark. And even though it's a relatively small part of our genomics business, it's growing substantially, and we believe it can be a big contributor down the road.

Operator

I'm showing no further questions in queue, so I'd like to turn the call back over to Mr. Michels for closing comments.

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

Okay. Thanks, everybody, for being on the call all with us tonight, for your support in 2017. We're looking forward to delivering just a super 2018 and look forward to future calls. Have a good evening and afternoon, everyone.

Operator

Thank you, ladies and gentlemen. That does conclude today's conference. Thank you very much for your participation. You may all disconnect. Have a wonderful day.

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