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OSUR - Q1 2017 OraSure Technologies Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, everyone, and welcome to the OraSure Technologies 2017 First 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 first 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 the press release.

With us today are Doug Michels, President and Chief Executive Officer; and Ron Spair, Chief Operating Officer and Chief Financial Officer. Doug and Ron will begin with opening statements, which will be followed with a question-and-answer session.

Before I turn the call over to Doug, you should know that this call may contain certain forward-looking statements, including statements with respect to revenues, expenses, profitability, earnings or loss per share and other financial performance, product development performance, shipments and markets, business plans, regulatory filings and approvals, expectations and strategies.

Actual results could be significantly different. Factors that could affect results are discussed more fully in the company's SEC filings, including its registration statement, its annual report on Form 10-K for the year ended December 31, 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*

Okay. Thank you, Michelle, and good afternoon, everyone, and welcome to our call. I'm very pleased to report that we delivered another strong quarter and the year is off to a terrific start. Demand for our products is strong, and we're excited about the future prospects for our business.

On last quarter's call, I encourage those who missed our Analyst Day in November of last year, to consider reviewing our commentary from that day. It provides a helpful road map of the numerous opportunities available in our various businesses. As you will hear today, we're making great progress on the opportunities that we highlighted at the Analyst Day.

One of our goals was to communicate to the investment community why we believe OraSure is in the early stages of several large market opportunities and very well positioned to capitalize on them. One example of this, which I'm happy to share this afternoon, is the recent signing of another large contract, this time with a genomics customer to supply them with over $20 million worth of our molecular collection devices over a period greater than 12 months. This is the largest contract in the history of our molecular business. There is no shortage of potential opportunities, and we're pursuing them across our businesses.

So moving on to the quarter, as indicated in our earnings release, we delivered a strong first quarter. Both our top and bottom lines exceeded expectations with 12% revenue growth and a $10 million improvement in net income compared to the year-ago quarter.

Product revenue growth was 25%, truly outstanding. We achieved these results despite the absence of AbbVie exclusivity revenues, which as you know, ended in 2016. These revenues were $3.4 million in Q1 of last year. Leading the way in the first quarter was a record performance by our molecular business where revenues grew 55% and topped $10 million for the first time.

Our infectious-disease business also performed very well with 28% revenue growth from the year-ago period. Significant increases in international sales of our HIV self-test and our HCV products were the primary growth drivers. Not surprisingly, our balance sheet improved with over $20 million in cash added during the quarter. We ended the quarter with more than $140 million in cash on hand.

So with that brief introduction, let me turn the call over to Ron for his financial review. I'll then provide some business updates after which we'll take your questions. So Ron?

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

Okay. Thanks, Doug, and good afternoon, everyone.

We certainly are off to a great start for 2017. Our first quarter consolidated net revenues increased 12% to $32.5 million compared to $29.1 million reported in the first quarter of 2016. Notably, our consolidated net product revenues rose 25% to $31.4 million compared to the prior year period. Higher sales of our molecular products along with higher international sales of our OraQuick HIV self-test and OraQuick HCV products were partially offset by decline in domestic sales of our OraQuick HIV and HCV products and lower cryo sales.

Other revenues were $1.1 million in the current quarter, representing funding we received from BARDA for our rapid Ebola and Zika products. Other revenues in the first quarter of 2016 totaled $3.8 million and included $482,000 in BARDA funding and $3.4 million of exclusivity revenues under the AbbVie HCV co-promotion agreement, which terminated effective December 31, 2016.

Our molecular revenues rose 55% to $10.7 million in the first quarter of 2017 compared to $6.9 million in the first quarter of 2016. Sales of our Oragene products to commercial customers increased 119%, largely due to higher customer demand and the increased sales from new customer accounts won in the second half of last year. Academic sales decreased 20%, largely due to customer ordering patterns and the absence of a onetime order of almost $400,000 by the World Health Organization for an epidemiology study, which occurred in the first quarter of 2016, and won't repeat in 2017.

International sales of our HCV tests in the first quarter of 2017 rose 340% to $4.4 million from $1 million in the same period of 2016, primarily due to the continued shipments of products to a foreign government pursuant to a previously announced countrywide elimination program as well as increased shipments for large-scale screening programs. Domestic OraQuick HCV product sales decreased 10% in the first quarter of 2017 to $1.7 million from $1.9 million in the prior year period, primarily due to customer ordering patterns.

International sales of our HIV products increased 210% to $2.6 million in the first quarter of 2017 compared to $854,000 in the first quarter of 2017, excuse me, that's first quarter of 2016. This increase was due to the continued shipment of product, in support of an HIV self-testing program in Africa, and higher sales in the Middle East.

Domestic professional HIV sales decreased 33% to $3.8 million in the first quarter of 2017 compared to $5.7 million in the first quarter of 2016 as a result of customer ordering patterns and competition from other products. Sales of our cryo products decreased 21% to $3.1 million in the first quarter of 2017 from $3.9 million in the first quarter of 2016, largely due to lower sales of our international over-the-counter products.

Turning to gross margins. Gross margin for the first quarter of 2017 was 62% compared to 70%, reported for the first quarter of last year. Margins for the current quarter decreased, primarily due to the absence of the AbbVie exclusivity revenues in 2017 as a result of the termination of our agreement at the end of 2016; a less favorable product mix and increased scrap and spoilage costs in the quarter.

Our consolidated operating expenses for the first quarter of 2017 were $4.4 million compared to $17.6 million in the comparable period of 2016. This decrease was largely due to the inclusion of a $12.5 million pretax gain related to our Ancestry litigation settlement, the absence of costs associated with our terminated HCV co-promotion agreement with AbbVie and lower legal costs.

Income tax expense was $3.9 million in the first quarter of 2017 compared to $61,000 in the same period last year. Taxes for the current period included the additional Canadian taxes due as a result of the litigation settlement gain of $12.5 million. From a bottom line perspective, we reported net income of $12.4 million or $0.21 per share on a fully diluted basis for the first quarter of 2017, compared to net income of $2.4 million or $0.04 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 March 31, 2017, was $141.5 million compared to $120.9 million at December 31, 2016.

Cash generated by operating activities for the first 3 months of 2017 was $12.6 million compared to $4.7 million in the same period of 2016.

Turning to our guidance for the second quarter of 2017. We are projecting consolidated net revenues of approximately $36.5 million to $37 million. We are also projecting consolidated net income of approximately $0.07 to $0.08 per share for Q2 of 2017.

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

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

Okay. Thanks, Ron. As you know, our growth strategy is focused on our infectious-disease business, which includes our HCV, our HIV, Ebola, Zika and TB programs and our molecular business, which includes our genomics and microbiome programs. The story line in infectious disease continues to be strong international growth. The largest first quarter revenue increases came from international HCV sales, in support of large-scale HCV elimination or testing programs, including the large government supply contract, which we previously highlighted. That initiative has been going well, and we expect to continue supplying product to this government customer through the remainder of 2017.

In addition, this customer has an option to renew the contract and purchase up to 100% of the original quantities of product on the same terms and conditions as provided in the original contract. We are starting discussions on a potential renewal this week.

The level of interest in foreign HCV testing and treatment programs continues to be strong. Orders have been received from 2 other countries that have indicated an intent to start testing programs. These orders have been filled, and we anticipate additional orders from these countries later this year.

As we reported during our Analyst Day last November, the WHO has announced its goal of eliminating hepatitis C by the year 2030. To date, 36 countries have developed national programs to combat hepatitis and 33 additional countries are developing similar plans. While this doesn't guarantee available funding or that large-scale HCV testing programs will occur in all cases, it does evidence the increased focused by high-prevalence countries on the need to take action with respect to hepatitis. We believe this bodes well for the future of our HCV business.

The other main growth driver internationally was our OraQuick HIV self-test. We indicated on the last call that an additional order had been received from Population Services International or PSI in support of the self-testing in Africa or STAR project. This additional order was for approximately 350,000 tests, and we filled that order during the first quarter.

To date, we've shipped over 700,000 tests as part of the initial phase of the STAR project. Field reports remained positive on the use and performance of our tests. And a second phase of this program is now being discussed with both PSI and its funding source UNITAID. We expect more details on the timing and scope of Phase II in the next few months, and we expect additional orders throughout 2017 and beyond.

The international focus on HIV self-testing is increasing, and the STAR program is just part of the story. In November 2016, UNITAID issued a -- what they described as call for proposals for the purpose of accelerating the demand for and widespread adoption of HIV self-testing programs in low- and middle-income countries. As part of this request, UNITAID specifically mentioned the success of the STAR project that has been using our product.

The closing date for submissions to UNITAID was March 31. These additional programs, assuming they are approved and funded, are expected to be incremental to the STAR program. In addition, we continue to see high-interest levels from a number of public health departments or ministries and nongovernmental organizations in numerous countries.

We are currently engaged with approximately 20 countries that have taken or are planning concrete steps to begin implementation of self-testing. And these include many countries outside the current STAR pilot program.

During the first quarter, we announced that our HIV self-test was designated as eligible for procurement by purchasing entities entitled to access Global Fund resources. Our product was classified by the Global Fund's Expert Review Panel for Diagnostics or ERPD as CATEGORY-2, which permits product procurement for 12 months with Global Fund monies. This designation is important in that it permits funded purchases, even though our product has not yet received WHO prequalification. And on that front, our efforts to obtain prequalification have also progressed.

During our last call, we indicated that our submission was under active review, and we expected to receive feedback during the first quarter. Well, we did receive that feedback, and we're now in the process of completing additional data collection that we expect to submit to the WHO in early June. WHO prequalification is important in that it will enable countries to purchase our tests with monies from large funding organizations, such as UNITAID, PEPFAR and the Global Fund.

So we remain very optimistic about HIV self-testing, and we believe this business will be an important source of future growth for the infectious disease business.

The strong international sales during the first quarter more than offset declines in our domestic businesses. The magnitude of the first quarter decline in HIV sales was driven primarily by the timing of customer orders, including in particular a very large order from a public health jurisdiction and by competition.

In the past, this large public health jurisdiction had placed their orders during the first quarter. However, beginning in 2017, the customer decided to spread its orders out more evenly throughout the full year. While the pressure on our HIV domestic business is expected to continue, we do not anticipate the steep decline in Q1 to repeat in future periods.

Timing of purchases was a key factor in the performance of our domestic hepatitis C business as well. We remain confident in the future growth of our domestic HCV sales. As public health budgets continued to be pressured, a number of jurisdictions are shifting funding to HCV from other areas of their budgets, and one of our largest customers recently provided a forecast doubling their deployment of HCV tests in 2017.

In addition, as you may know, public health jurisdictions are attempting to respond to the opioid epidemic. Since injection drug use remains the most common risk factor for hep C infection in the United States, and in fact, accounts for more than 50% of all new infections, we're beginning to see drug treatment centers increase the deployment of hepatitis C testing programs. And as a result, we expect our domestic hepatitis C business to resume more normal revenue patterns and return to year-over-year quarterly growth, beginning here in Q2.

On the tuberculosis front, as we indicated in our last call, clinical study use our -- using our TB products, have been completed by the Foundation for Innovative New Diagnostics or FIND, in support of WHO endorsement of our OMNIgene SPUTUM product. FIND has issued its final data dossier on our product, and the WHO has indicated it will review the FIND data and issue a broader review of all commercial SPUTUM transport reagents later this year.

In the meantime, commercial discussions with foreign Ministries of Health for deployment of our products are progressing as are discussions with The National Tuberculosis and Leprosy Control Programme in Africa. These initiatives and other activities are expected to generate expanded sales in 2018.

Turning briefly to emerging diseases. There have been a number of activities that continued to progress. With respect to our OraQuick Ebola Test, the CDC is currently assessing its product needs for 2017, and we should have better visibility of future orders once that assessment is completed. Our clinical work on the Ebola product also continues. We've had further dialogue with the FDA, and we received input on the additional clinical work required for 510(k) clearance. We expect this work will result in a mid-year 2018 submission to the FDA.

And finally, our progress -- our efforts to progress clinical activities for our new Zika tests continue. We're still planning to submit for Emergency Use Authorization from the FDA later this year. Zika remains an important public health risk, and we believe our new tests can play an important role in combating this disease.

On to molecular. So as Ron explained, our molecular business turned in a truly exceptional first quarter performance with 55% growth over the prior year quarter and 25% growth sequentially from Q4 of last year. We expect continued strong performance from this part of our business with strong double-digit growth in Q2 from the prior year quarter as well.

During Q1, there are a number of developments in the genomics market. Revenues from our top 20 genomics accounts more than doubled compared to the year-ago quarter. Our top 5 commercial accounts contributed significant growth in Q1, both sequentially and from the year-ago quarter with numerous repeat orders.

Our business in China continues to grow with a 100% increase in Q1 revenues compared to the year-ago quarter. And during the last call, we discussed a new multiyear supply agreement with WeGene, a company that offers genetic testing and personalized health care services in Asia. And we will continue shipping against the WeGene contract in Q2.

Overall, we're now seeing a record level of product orders in our molecular business. And additionally, you may have seen a recent announcement that 23andMe has received FDA clearance to begin marketing their health risk tests for 10 diseases or conditions using our Oragene collection device. We certainly congratulate 23andMe and believe this is a very positive development for their business and hopefully, ours as well.

Turning to our microbiome business. We recorded almost $800,000 in revenues in Q1, a 373% increase over the first quarter of last year. Important to note, we recorded approximately $1.1 million in microbiome revenues for the full year 2016, and we certainly expect to exceed that total by the end of Q2. The majority of our microbiome revenues continue to be derived from our Oragene GUT or fecal sample collection kits and related services. We acquired 135 new microbiome testers in the first quarter, a 65% increase over Q1 of 2016, with the majority of Q1 microbiome revenues coming from academic or research customers.

And not all of the new testers are new customers, as we're also seeing increased cross-selling of microbiome solutions to existing genomics customers who are expanding their research to include microbiome data. For example, during the quarter, we closed the sale for both GUT microbiome kits and our oral microbiome collection kits with a world-renowned research institute, which has been an Oragene customer for over 10 years. So we believe our ability to provide trusted solutions for both genomics and microbiome research is a meaningful differentiator for our business. And while GUT microbiome remains a primary area of interest in this market, we're starting to see more and more interest in other microbiomes, allowing us to deliver increasing value with our portfolio of microbiome collection devices and services.

And finally, in February, we announced the settlement of our litigation against Ancestry.com and its contract manufacturer. As part of the settlement, Ancestry paid us $12.5 million, and we granted Ancestry a royalty-bearing nonexclusive worldwide license to certain of our patents. This license is

specifically limited to the saliva DNA collection kits sold or used as part of Ancestry's genetic testing service offering and does not cover the sale or use of product outside of its business. And we're pleased with the terms of the settlement, and we're certainly happy to have this matter resolved.

And a final area, I want to update yet this afternoon is operations. The second automated OraQuick production line I mentioned on prior calls, has been installed and it's now validated and the related regulatory submissions have been made. We expect to begin producing products later in the second quarter on this equipment. And this will add additional capacity of up to 10.4 million devices per year, when this equipment becomes fully operational. And we also plan now to order a third automated line, and that's going to happen this quarter. We estimate this third line will become operational in the back half of 2018 and would add up to an additional 10.4 million devices of annual capacity.

At the same time, we're also expanding capacity at our OraQuick assembly contractor in Thailand. We use this firm to assemble and supply non-U. S. and non-CE mark OraQuick products, primarily in developing countries. We expect installation and validation of an additional semi-automated assembly line to be completed in 2017 with related regulatory approvals obtained in early 2018, and an additional line is also planned for 2018.

Certainly given the growth in our molecular business, we're also expanding production capacity there. 2 additional automated assembly lines have been ordered which will more than double our capacity. We expect the first line to become operational by the end of this year and the second in early 2018. These changes will help ensure that we have more than enough capacity to meet forecasted global demand for HIV, HCV and molecular products through at least 2019. And lastly, as noted on the prior call, we're currently working with a consulting firm to help us optimize the global footprint for the manufacturer of our products. We expect this engagement will conclude in the next several months.

So in summary, there is an awful lot for which to be excited. Our business has more opportunity than at any time since I've been with OraSure. That opportunity is translating into strong financial results as evidenced by our recent quarters. Our international HCV and HIV products and our molecular business continued to fuel strong growth, and we are taking the necessary steps to ensure we can meet future demand for our products on a worldwide basis. We believe the recent trends in our business will continue and certainly should make 2017 a very successful year for OraSure.

So with that, why don't we open the floor to your questions? Operator, if you'd please proceed.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Brandon Couillard from Jefferies.

Brandon Couillard

Doug, just a question on the DNA Genotek business. I mean should we look at this sequential growth in that segment is still being somewhat subdued in the sense that some of the new contracts, be it WeGene or Helix, are still not at full steady state yet early into their launches? And would you -- does the 23andMe preventive claim approval create any type of step-function change in their test volume growth trajectory in your view?

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

The first question with regard to WeGene and Helix, you're absolutely right. They're in the early stages of adoption, and we would certainly expect that portion of our business to expand and continue to grow. At least that's our projection. So we're pretty excited about that.

I don't want to -- I don't -- I want to make sure that you understand some of the comments I made in the prepared remarks. If you look at our top 20 customers, we saw growth in the first quarter pretty much across the board, 17 of our top 20 customers increased purchases quarter on quarter from Q1. Our top 5 customers in the molecular business were particularly strong. But we're seeing demand across the board. And then I mentioned

the great performance of our microbiome business. So we expect this business to continue to perform throughout the rest of 2017 and frankly, well into '18.

And then you have the exciting announcement that 23andMe put out about their FDA approvals. The impact of that, I think, is probably best directed to 23andMe, but it's certainly a positive. And as 23andMe business grows, so will ours. So I think we're just really well positioned across the whole genomics and microbiome business. Do you have anything to add, Ron?

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

I think to your point and question about sequential growth, I think we will see that in the DNA Genotek business and the molecular business throughout the rest of the year.

Brandon Couillard

Just to clarify, last year you absorbed headwinds from 2 customers that went bankrupt in that business -- to make sure I would understand, have you fully anniversaried those already? And was there 1 customer of the 2 that actually came back online in the different form and began reordering in the first quarter?

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

Yes, and yes. So we have completely anniversaried them and one of them did come back and began ordering minor amounts in Q1 of 2017.

Brandon Couillard

And then last one on Zika, need more clarity you can give us in terms of the time line for EUA approval. And has there been some type of delay in advancing the product to a commercial stage? And do you think you'll be able to make it out in time some point over the summer?

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

Yes, so in the last call we said, we expected to submit for EUA approval perhaps as early as Q2. It still may happen right towards the end of Q2, likely flip over into Q3. That's why we revised our commentary on that, but we still believe we've got a really effective assay. And certainly, continue to be very bullish on the market opportunity. Obviously, we've got to get EUA approval to get it out there in the hands of clinicians and public health officials, so they can begin using it.

Operator

Our next question comes from the line of Nicholas Jansen from Raymond James.

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

Two questions for me. The first one, I just wanted to get a little bit more details if you can provide any, on the large contract to supply more than $20 million of DNA collection devices. Is that a customer that's new to the organization? Is that one of your existing customers making a much bigger commitment to you guys, if you think about the next couple of years? Just trying to flesh out a little bit more details on that supply arrangement.

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

It is a current customer. We signed the agreement this past month, and we've begun to deliver against that contract. I can't really provide a lot more detail beyond that, but we're certainly very excited about it. I think it represents, as we mentioned the largest contract in our molecular business ever, and really speaks to the sustainability of our business and growth in that business. And we're very appreciative of receiving orders like that. We're going to fulfill them and try to fulfill them as quickly as we can, so we can get some more like that.

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

And then secondly, just looking at the comments that you made, Doug, about your production line expansion. It seems like you're basically tripling the amount of capacity for OraQuick and doubling on DNA Genotek. So certainly that's a pretty sizable and lengthy investment. And I just want to kind of get a better sense of your level of visibility of why you would need to move that quickly.

Certainly, I would hope that some of this is relating to some larger momentum in the business you're seeing right now. But just trying to get a better sense of, should we think about your revenue growth potential aligning with this level of capacity expansion?

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

Well, that's what it's designed to satisfy, right? Certainly with any equipment of the magnitude of the OraQuick assembly equipment or even the automated equipment up in Canada, there is a lead time. We've got pretty good visibility on the magnitude of possibilities in our HIV self-tests and our hepatitis C eradication programs, the molecular business as it's ramping.

So we put together forecast out through 2020, and they're pretty exciting. And the last thing we want to do is get caught short from a product supply perspective. I'm highly confident that we won't do that, assuming we execute on bringing this equipment in and getting it online and validated. There's regulatory approval times with some of this as well. So we're just -- this is all part of production planning.

Don't forget also on the OraQuick business, we also have the ability to ramp manual assembly now that most of that manual assembly is going on in Thailand where we speak to it as semi-automated. So we can ramp that pretty quickly as well, as well as here in Bethlehem. So you're right. I mean, that kind of capacity increases is a good sign for the business and our expectations.

Operator

Our next question comes from the line of Mark Massaro from Canaccord Genuity.

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

The first question is on the strong growth in international HCV. I'll be curious if you could quantify how much revenue you might have recognized from the large country elimination program. I think the number was about $1.9 million in Q1. So I'm guessing it might have stepped up this quarter. And then, any color you could provide on how we should expect that large contract, I think, it's $16.6 million of revenue to be realized in '17 -- how might that flow across quarters?

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

Right. So on the last call, we indicated that we expected approximately $2.9 million of combined HIV, HCV revenues from that large contract in Q1 of 2017. As it turns out we shipped approximately $3.1 million of combined HIV and HCV revenues to that country in Q1. And in Q2, we expect that to step up a bit to the high $3 millions, so approximately $3.9 million for both HIV and HCV with most of it going to HCV. And then of course, we have the balance of the year to play out and to work with that country to schedule the shipments to meet their demands appropriately.

And so I would anticipate that from a modeling perspective, you would see a larger bolus of revenues in Q3 than you would in Q4 as the contract would wind down the initial year 1 commitment. And then of course, the discussions, as Doug indicated, are beginning now for the renewal phase and assuming that, that goes as we expect, we should see a potential contribution from that in the fourth quarter of 2017 and then through '18.

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

That's very helpful. Regarding the large contract signed this past month, can you speak whether or not this is a commercial customer or an academic customer?

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

That's a commercial customer.

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

Okay, great. And you may have addressed this, but can you speak to the impact we might expect from the various manufacturing operations you have expected in towards the back half of this year and then into '18? Just how should we be thinking about incremental spend and investment in the business and how it may flow down the income statement?

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

Yes. So with respect to the build-out, we have already paid for the automated line that we are validating currently and would expect to be turning on within the next month or so. And so that's behind us. It's part of our capital equipment, as will be the other investments that we're making in the automated manufacturing equipment that would come online later next year, as Doug spoke of here in the Bethlehem facility as well as the automated lines that are being installed up in the contract manufacturers up in Canada.

I would guess -- excuse me, guesstimate that all in from a CapEx perspective, we're talking somewhere in the neighborhood of $3 million to $4 million worth of investment that we would be making and very little of that would hit the P&L until we begin depreciating that equipment when we put it in service. The one piece that we put in service will start in the latter part of Q2 here, and then what we will have is some gap before we start looking at the other pieces that come on close to the end of this year or early next in Canada and then the latter part of 2018 here in the U.S., but we generally will take them out over 10 years. So the P&L impact is not going to be, I would say, it's probably not even going to be noticeable.

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

I mean -- and that's on the CapEx front, right? But as we get this equipment installed, we're seeing a substantial productivity enhancement in terms of throughput. We'll be able to report on that in future periods once that equipment is burned in, and we're actually operating it at full capacity. But we're going to see some cost improvements, I believe, once that equipment is online and producing at full capacity.

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

That's right. That is our expectation beginning with the equipment that we'll commission for production -- commercial production purposes in the second quarter here.

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

Great. And if I can sneak one last one in. You mentioned in your prepared remarks you saw over 100% growth from China. Can you speak to maybe how many new accounts you signed in Q1 and what your funnel might look like? I know, in the context of the Chinese precision medicine initiative, it seems like funding is coming from all over the place in the Chinese government. Can you -- so if you could just provide any clarity as to some of the new folks coming in, whether it's commercial, academic? Is it largely tied to the PMI funding or are you seeing pockets of growth elsewhere?

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

So it's primarily commercial revenues that are driving that growth, although we are seeing some improvement in the academic business there as well. But it's several new customers that are driving that kind of revenue growth, and we continue to capture additional ones. So we'll continue to update on that and as the business expands, we'll give a little bit more granularity as to how it's ramping.

Operator

(Operator Instructions) Our next question comes from the line of David Westenberg from CL King.

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

So can you guys parse out -- really the question, can you parse out what EPS would have been net of Ancestry?

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

Yes. So if you look at the tax effect of the Ancestry settlement, that -- there is about $3.25 million worth of income tax accrued as a result of that. And so the net after tax would be $9.25 million, which equates to approximately $0.16. And so adjusting diluted EPS to 21 will get you to 5.

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

And then can -- you talked about your new $20 million deal in collection -- molecular collection is being over 12 months. Is it a little bit over 12 months or is a lot over 12 months?

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

In our discussions with that customer, we wanted to keep the verbiage at 12-plus months. So I'm just going to leave it with that.

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

Got you. All right. And then are you seeing any additional competitors in the molecular collections front? Actually, I don't see many or any, but is there any of them that are really out there that have found a way to get around your IP? Or just any that you've seen that may be not as competitive, but are out there?

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

I think we're always competing against blood. We're always competing to some extent depending on the application with buccal swabs. And there are some others that have attempted to deliver larger volumes saliva collection stabilization products. But none have the IP portfolio that we have. And obviously, we've been successful in asserting and defending our IP when people have introduced infringing, what we believe are infringing

devices. And nobody has a body of data on the effectiveness of their collection and stabilization technologies nor the FDA approvals for use of those devices like we have.

And so I think it's the combination of all those factors that have really positioned us so well in the marketplace. And it's not just -- it's not just in the U.S. or in the academic market. We're selling into China at very attractive prices and continue to capture the marquee accounts that are beginning to do business in this space, and we expect that's going to continue. So we're very happy with our portfolio position as well as now the expanded opportunity that we're seeing with the microbiome.

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

Great. And then your submission on Zika that you expect out later this year. That one is first a blood submission, right? Correct?

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

Yes.

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

Okay. And how much further along might we see an oral testing product for Zika?

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

That's another development program that's funded by BARDA. And so I can't give you an exact timing on that right now because we're focused on getting this first product out, but as we begin work on that and have something substantive to say, obviously, we'll update you on that.

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

Perfect. And I'm just going to squeak one last one in. Some of the other companies that are seeing a lot of benefits from the accounting changes in stock-based comp and your stock has obviously done fairly well. So are you anticipating any impact from that in the back half of the year? I understand you guys have NOLs. So it's purely, probably something a little more cosmetic. But just curious if you're anticipating any of that?

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

No, we're not. We're not a tax-accruing entity at the moment. And so we have our DTA fully reserved and it really is not going to affect us.

Operator

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

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

Okay. I just want to thank everybody for being on the call this afternoon. And thanks for your continued interest and support of the company. We look forward to updating you after what we believe is going to be another great quarter in Q2. So talk to you soon.

Operator

Ladies and gentlemen, Thank you for your participation in today's conference. This does conclude the program, and you may now disconnect. Everyone, have a great day.