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# EDITED TRANSCRIPT

OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

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MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

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**Max Masucci**

## PRESENTATION

### Joni Messenlehner

Good afternoon, everyone, and welcome to the OraSure Technologies 2018 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 p.m. Eastern time today regarding its 2018 first quarter financial results and certain other matters. The press release is available on our website at [www.orasure.com](http://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 Dr. Stephen Tang, President and Chief Executive Officer; and Ron Spair, our Chief Operating Officer and Chief Financial Officer. Dr. Tang and Ron will begin with opening statements, which will be followed with a question-and-answer session.

Before I turn the call over to Dr. Tang, you should note 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 ended December 31, 2017, 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 statement to reflect events or circumstances after this call.

With that, I would like to turn this call over to Dr. Stephen Tang.

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### **Stephen S. Tang** - *OraSure Technologies, Inc. - President, CEO & Director*

Thank you, Joni. Good afternoon, everyone, and welcome to our call. It's a pleasure to be hosting my first earnings call as CEO of OraSure Technologies. Later on in the call, I'll share with you my thoughts since becoming CEO and update you on my initial impressions. I would like to thank all of those on the OraSure team that have assisted with my transition and helped make my job a bit easier today as we had a very strong start to 2018.

As a result of years of planning, investment and execution, OraSure now operates 2 key businesses, molecular collections and infectious disease testing, that are driving solid results. Overall, our business is well positioned to continued future growth. Our path forward is clear. We see opportunities to expand through growth of our existing products and the deployment of our strong balance sheet to further maximize the value of our company.



## MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

Innovation is critical to the success of any company and is one of my top priorities. We all know that companies that do not innovate are destined to be left behind. Our ability to innovate has made us a leader in our field. We intend to foster our rich history of innovation to gain access to new opportunities and expand existing markets.

Our Q1 results were driven largely by our molecular collections and our human immunodeficiency virus, or HIV, self-test businesses. Consolidated net revenues for the quarter were \$42 million, a 29% increase from a year ago period. Product revenue growth for Q1 was 22%.

Our molecular business delivered revenues of \$18.4 million, which represents a 72% increase over Q1 of last year. Our international HIV sales grew 117% for the quarter, driven primarily by our HIV self-test business. This increase largely offset the decline in domestic HIV revenues and lower international hepatitis C virus, or HCV, test sales caused by the nonrenewal of the large government supply contract in support of a countrywide HCV eradication program.

Gross margins increased 344 basis points from Q4 2017. We reported a loss of \$2.1 million or \$0.03 per share. As Ron will explain in greater detail, this resulted from a \$0.10 per share nonrecurring charges associated with the previously announced management transition. We ended Q1 with nearly \$180 million in cash and cash equivalents on our balance sheet.

So with that, let me now turn the call over to Ron. After his detailed financial review, I will provide some business updates, and then we'll both take your questions.

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

Thanks, Steve, and good afternoon, everyone. 2018 is off to a great start. Our first quarter consolidated net revenues increased 29% to \$42 million compared to \$32.5 million reported in the first quarter of 2017. Our consolidated net product revenues rose 22% to \$38.3 million compared to the prior year period. Higher sales of our molecular collections products and the OraQuick HIV self-test were the main drivers of this performance. Our molecular revenues rose 72% to \$18.4 million in the first quarter of 2018 compared to \$10.7 million in the first quarter of 2017. Sales of our products to commercial customers increased 97% to \$14.3 million, largely due to our \$143 million agreement to supply Oragene devices to a leading consumer genomics customer, coupled with higher sales to other large customers.

Microbiome sales continued to gain traction and increased to 66% to \$1.3 million in the first quarter of 2018 as compared to the first quarter of 2017. International HIV sales increased 117% to \$5.7 million from \$2.6 million in the first quarter of 2017 due to higher sales of our OraQuick HIV self-test into Africa and higher sales of our professional product in parts of Asia and Europe, partially offset by a decline in sales to the Middle East. The test shift into Africa during the quarter were subject to the support payments under our charitable support agreement with the Bill & Melinda Gates Foundation, or the Gates Foundation, and included countries outside of the UNITAID/Population Services International, or PSI, Self-Testing Africa program, or the STAR initiative. Product revenues during the first quarter of 2018 included approximately \$985,000 of support payments associated with this agreement. Domestic professional HIV sales continued to decline and decreased 12% to \$3.3 million in the first quarter of 2018 compared to \$3.8 million in the first quarter of 2017 due to previously discussed market factors. Our international HCV sales in the first quarter of 2018 decreased 85% to \$665,000 from \$4.4 million in the same period last year, primarily due to the nonrenewal of a foreign government supply contract in support of a countrywide HCV eradication program. Also contributing to this decline was a larger onetime order which occurred in the first quarter of 2017 but did not reoccur in the first quarter of 2018.

Domestic HCV sales decreased 5% in the first quarter of 2018 to \$1.6 million from \$1.7 million in the prior year period, primarily due to the impact of grant funding delays that negatively affected our hospital customers and the fact that a large NGO discontinued its testing program.

Sales of our cryosurgical systems product decreased 9% in the first quarter of 2018 to \$2.8 million compared to \$3.1 million in the first quarter of 2017. Sales of our domestic Histofreezer products sold to physician offices decreased 42% to \$875,000, primarily due to the timing of orders placed by our distributors as well as competitive losses. Sales of our international over-the-counter cryosurgical product increased 28% to \$1.5 million in the first quarter of 2018 compared to \$1.2 million in the first quarter of 2017 due to higher sales in Latin America.



## MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

Other revenues were \$3.7 million in the current quarter, representing \$1.6 million of royalty income associated with a litigation settlement agreement; \$1.5 million of funding from the Biomedical Advanced Research and Development Authority, or BARDA, for our Ebola and Zika products; and \$529,000 of cost reimbursement under our charitable support agreement with the Gates Foundation.

Turning to gross margin. Our gross margin for the first quarter of 2018 was 58% compared to 62% reported for the first quarter of 2017. Margin for the current quarter decreased primarily due to an increase in lower margin product sales and a decrease in the absorption of fixed costs as a result of lower production levels in the first quarter of 2018 compared to last year, which benefited from the large foreign government HCV eradication program. These declines in gross margin were partially offset by the increase in other revenues and a reduction in scrap and spoilage costs.

As we look forward, we currently expect gross margins for Q2 to approximate those of Q1. During the second half of the year, we expect gross margins to increase somewhat based on the projected sales mix and certain assumptions regarding foreign currency exchange rates and projected scrap and spoilage.

Turning to operating expenses. Our consolidated operating expenses for the first quarter of 2018 were \$25 million compared to \$4.4 million in the comparable period of 2017. This increase was largely due to the inclusion in Q1 2018 of \$6.4 million worth of transition costs associated with Doug Michels and my retirements and the related cost of hiring Steve Tang and my CFO successor. In addition, the first quarter of 2017 included the gain from our litigation settlement of \$12.5 million, which was recorded as an expense reduction. We had no similar gain in the first quarter of 2018. Lastly, Q1 2018 includes higher spending on our Ebola and Zika products and higher staffing and consulting costs, partially offset by a reduction in legal expenses.

Income tax expense was \$2 million in the first quarter of 2018 compared to \$3.9 million in the same period last year and consists entirely of Canadian taxes due. Income tax for -- expense for Q1 '17 included the additional taxes due as a result of the \$12.5 million litigation settlement gain.

From a bottom line perspective, we reported a net loss of \$2.1 million or \$0.03 per share for the first quarter of 2018 compared to net income of \$12.4 million or \$0.21 per share for Q1 of 2017. The transition costs previously discussed approximated \$0.10 per share in the first quarter of 2018, while the litigation settlement gain last year approximated \$0.16 per share on an after-tax basis. I should note that the \$6.4 million in management transition costs primarily reflect noncash stock compensation charges.

Turning to our balance sheet and cash flow. We continue to maintain a solid cash and liquidity position. Our cash and investments balance at March 31, 2018, was \$178.4 million compared to \$176.6 million at December 31, 2017. Cash generated by operating activities during the first quarter of 2018 was \$7.6 million compared to \$12.6 million in the same period last year, which included the \$12.5 million litigation settlement.

Turning to guidance for the second quarter of 2018. We're projecting revenues to range between \$42 million and \$42.5 million and consolidated net income of approximately \$0.03 per share. These results reflect the final management transition costs of approximately \$1.7 million.

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

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**Stephen S. Tang** - OraSure Technologies, Inc. - President, CEO & Director

Thanks, Ron. So as you've heard, our molecular business performed well in Q1, with revenues up 72% from the prior year period. Coincidentally, we acquired 72 customers during the quarter in this business segment. It's important to note that we're announcing for the first time 2 of our top 20 customers purchasing both genomics and microbiome products as research continues to show the utility of combining these 2 fields of study. We believe this type of synergy between our product lines is a very encouraging trend and will continue.

In our genomics business, sales to commercial customers were the primary growth driver, with revenue increasing 97%. We won 10 new commercial accounts in Q1, of which 5 are consumer genomics companies. Large epidemiological studies continue to represent an attractive opportunity for the business.



## MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

In Q1, the Simons Foundation renewed its supply agreement for 125,000 of our FDA-cleared Oragene DX saliva collection kits along with fulfillment services to meet their recruitment goals. The Scripps Research Institute and the Mayo Clinic also selected Oragene DX and our fulfillment services for a pilot of 13,000 individuals for the improvement of rural and underserved populations in the All Of Us program. As reported in the New York Times yesterday, this program is a historic effort to gather data from of 1 million or more people living in the United States to accelerate research and improve health through precision medicine.

On the academic side, we reported modest revenue growth compared to the prior quarter -- prior year quarter. However, we posted 66% sequential growth from fourth quarter of last year. Our microbiome business also continued to grow, with sales for the quarter were up 66% compared to the prior year period and up 15% sequentially over Q4 of last year. We expect microbiome sales to become an increasingly important part of our business. As previously mentioned, 2 microbiome purchasers have moved into the top 20 molecular accounts. Of our top 20 microbiome customers purchasing in Q1, 17 are repeat purchasers, having made multiple purchases over the last 12 months, and 12 are commercial customers.

Our service business posted a solid quarter in Q1. (inaudible) include a venture-backed biopharma customer with multiple Phase II programs underway to develop microbial therapeutics to treat gastrointestinal infections and inflammatory diseases. This customer uses our kits to collect standardized stool microbiome samples for multiple clinical and academic sites across North America and the European Union. They also sent biopsy specimens and biological material from animal models to our services facilities for processing and analysis.

We also closed a deal in Scandinavia where there is a history of large cohort studies with the University of Turku, purchasing 10,000 OMNigene GUT kits. This group investigates the clinical role of gut microbiota in certain clinical conditions by studying both the composition and the metabolic capabilities of the gut bacteria.

Finally, in the very near future, we expect to start shipping product to fulfill our supply agreement with the Harvard T.T. Chan School of Public Health (sic) [Harvard T.H. Chan School of Public Health]. We announced this agreement last quarter for the supply of kits for a microbial-specific recollection of the Nurses' Health Study 2 cohort.

As stated in prior calls, we see a similarity between the early days of research activity with microbiome testing in the initial development of human genomics testing. That similarity gives us good reason to believe that we may see the same robust growth trajectory in the microbiome market that we've experienced genomics. In fact, given the repeat testing requirements in the microbiome market, this could very well become an even larger opportunity than genomics.

Turning to infectious disease. The trends we've been seeing in the recent periods continue to impact this part of our business. Once again, the highlight of the quarter is our international HIV business. As discussed in prior calls, Population Service International, PSI, has initiated phase II of the Self-Test Africa, or STAR, project, which is expected to deploy 4 million HIV self-tests into an expanded list of African countries, with the largest being South Africa. During the quarter, we filled orders for our OraQuick HIV self-test under phase II as well as from a growing number of countries outside of the STAR program as they begin to scale their testing activities. These other countries are using United States Agencies for International Development, USAID, and the President's Emergency Plan For AIDS Relief, or PEPFAR, funding to purchase our product. An important growth driver for HIV self-test is the charitable support agreement with the Gates Foundation. The more favorable pricing we can offer as a result of this agreement is stimulating additional demand in a growing number of countries in Africa and elsewhere.

During Q1, we shipped approximately \$1.3 million HIV self-tests to both STAR and non-STAR countries, which represents a 30% increase over the number of units shipped in fourth quarter of last year. In the second quarter this year, we expect to ship more self-tests than we shipped in the first quarter. To date, based on initial expressions of interest, ongoing pilot studies and scale-up of efforts, we are selling or promoting our self-test to approximately 40 countries in sub-Saharan Africa, West Africa, Asia, Central Asia and Latin America. One of the larger efforts is underway in securing in-country registration for our product in the growing number of countries we intend to serve. Our opportunity to register our HIV self-test in countries covered by the GATES agreement are largely on track as we have prioritized competing -- completing regulatory work in the countries most likely to implement HIV self-testing on a broad basis.



## MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

As I mentioned on the last call -- as we mentioned on the last call, another promising opportunity in many countries is the pharmacy market, even though the market is not covered by the Gates agreement. We continue to support pharmacy pilot programs initiated by PSI, primarily in sub-Saharan Africa, and continue to believe the pharmacy channel will eventually be important to self-testing business.

We are also continuing our work with the Gates Foundation and other large global funding organizations to promote our charitable support agreement and the value of HIV self-test thing. We remain optimistic about HIV self-testing and believe this will continue to be an important source of future growth for our infectious disease business.

As Ron noted, domestic HIV businesses continue to decline, and this was more than offset by the growth in international HIV sales. Although we have secured some fairly sizable customer wins on the domestic front recently, largely due to product performance and the strength of our product portfolio, we expect the same domestic trends will impact future periods. These negative trends are largely the result of reduced U.S.-based budgets, continued competition and pressure to move the fourth-generation automatic laboratory testing solutions.

As you've heard, our total HCV revenues for Q1 decline from the prior quarter, primarily as a result of the nonrenewable large foreign government product supply. Our domestic business was also down slightly compared to last year, primarily due to grant funding delays and a large nongovernment organization discontinuing its HCV screening efforts. Nevertheless, we do remain confident in our overall HCV business and believe it will continue to be a source of growth for our company.

Domestically, we expect to see more investment in HCV screening as government and state organizations allocate resources to deal with the opioid crisis and resulting HCV infections. We also continue to see customers here in the U.S. shipping as much money and resources as possible to support HCV testing and treatment programs despite the overall funding challenges.

On a global basis, the interest in HCV testing and treatment continues to expand as the cost of HCV therapies is now reaching extremely low levels globally. We recently attended the International Liver Meeting in Paris where the World Health Organization continues to execute against its strategy to eliminate HCV and hepatitis B by the year 2030. Many of the sessions at the meeting focused on the elimination of HCV and have us start test and treatment programs at the local level. As a result of these market conditions, we continue to believe high prevalence countries will eventually take on large-scale screening. Despite these helpful market conditions, some significant logistical and funding issues still need to be addressed and resolved for many of these programs. And for this reason, we have not included any major new elimination programs in our current revenue forecast and will treat them as pure upside for the remainder of the year.

Turning to operations. Our capacity balancing efforts have continued. With -- our work with Thailand contractor has started in -- to add additional manufacturing and packaging rooms to be used for the supply of non-U. S. and non-CE-marked OraQuick product. This contractor is negotiating a lease for an additional space needed and plan to install equipment to increase capacity by 50% by the end of 2018.

A fourth automated assembly line for Oragene collection kits has been built and delivered and is now being validated in our contract manufacturer in Canada. A fifth automated assembly line has been ordered, with delivering and installation plan for late 2018.

Work is also underway for a new automated assembly line for our OMNIgene GUT product. The goal is to complete construction, installation and validation of equipment by year-end. The automated line will provide capacity for sales growth and support for upcoming clinical work involving OMNIgene -- the OMNIgene product.

Lastly, the contraction of our newly leased warehouse here in Bethlehem, Pennsylvania, has been completed and the certificate of occupancy was recently received. Environmental qualification and equipment validation is underway, and regulatory submissions will follow.

The final area I want to address is the recent management changes here at OraSure. As for my transition, things are proceeding smoothly in large part because of my 7 years of prior service on OraSure's Board of Directors and because I had the opportunity to work closely with Doug Michels before his departure at the end of March. The executive team has done a wonderful job in assisting in this transition. Since my April 1 start date as CEO, I've been actively learning more about our business, shareholders, customers and stakeholders as well as getting to know our management team and employees a bit better. One of my primary focus areas has been the ongoing examination of our long-term business strategy. That



## MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

exercise is progressing on schedule, and we expect it to be completed and reviewed with the board sometime during the summer. For obvious competitive reasons, we will not be able to foreshadow the specific goals and objectives we have developed in the strategy work, but we'll share with you some initial elements for our plan at the higher level, when appropriate. New initiatives will be more evident as we begin to implement our strategy. We will update you on those initiatives as they occur in future periods. So more to come on that front.

A key part of our updated strategy is the identification of business development opportunities. So I'm very pleased that we are able to bring David Rappaport onboard as our new Senior Vice President, Business Development. Most recently, David served as Senior Vice President, Healthcare Investment Banking, at Raymond James & Associates, where he provided investment banking services to the firm's life science practice. He also has prior experience in healthcare investment banking at several other firms. David is highly qualified, and I look forward to the positive impact that his new energy and ideas will bring to the business development function here at the company.

As you know, the other big change that's coming is the appointment of a new Chief Financial Officer, who'll be replacing Ron when he retires. That effort has also been progressing and is near completion. We expect to have something to announce on that front in the very near future. In the meantime, I would like to thank Ron for his tireless 16 years of service to OraSure as CFO and COO. He is a remarkable senior executive, who has led us well to our current success and has helped position us for further success.

So in conclusion, we have a lot to be excited about at OraSure. Our business is strong and driving consistently solid results. We have many growth opportunities that are still in their early stages of potential. The day has never -- the company has never been on a more sound financial footing, with nearly \$180 million in cash and no debt. We are close to completing our strategic development work, and our manufacturing capacity is now aligned with the expected future demand for our products.

As I said in my opening remarks, innovation is crucial for ongoing market leadership. Fostering a culture of innovation is paramount to me and OraSure and has and will be the fuel for our continued growth. I am highly confident that our future holds great promise because of what I've learned in the past 7 years about our business, our people and the opportunities before us.

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

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

Operator, could you open the Q&A session.

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## QUESTIONS AND ANSWERS

### Operator

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

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

Ron, I understand -- and this will be your last conference call, just want to say it's been a pleasure working with you over the many, many years, and wish you all the best in the next stages of your life.

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

Thank you, Brandon.

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## MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

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

Steven, just to kick off, understanding many elements of the strategic evaluation are still forthcoming, would be curious at a high level, what areas of the business you see opportunities to sort of reallocate resources? Other areas that you want to make incremental investments versus perhaps some that you might want to deemphasize? And with respect to the balance sheet and M&A opportunities, curious what your view would be of the types of assets that would be most appealing?

**Stephen S. Tang** - *OraSure Technologies, Inc. - President, CEO & Director*

Yes, thanks for the question, Brandon. We're not at a point where we can talk about resource allocation yet. But I think as you can tell from our performance, our growth prospects, organically, are aligned well behind our HIV self-test international as well as our human genomics and microbiome products. So I think you can anticipate continued growth from those segments and continued investments for our annual operating planning budget as well as investments in growth opportunities inorganically through our balance sheet through business development opportunities.

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

Okay. And then a couple for you, Ron. If we're looking at the 2Q revenue guidance, typically, we see a bigger quarter-to-quarter sequential step-up in the revenues going from 1Q to 2Q. The guidance for 2Q implies flat to up modestly. What are the puts and takes, plus and minuses that we should think about, especially considering that the molecular business typically sees a bigger quarter-over-quarter jump?

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

Yes. No, thank you, Brandon. It's basically -- when we look at the revenue contributors across all the different business segments, we really factor in all the puts and takes, as you say, as far as what's -- whether it has an opportunity to contribute perhaps a little bit more in the quarter versus those that are impacted by some seasonality, if you will, or some vagaries regarding distributors. And so we don't get down to the level of guiding on the individual products, but it's really just a summation of our best guess is to what we believe will be the total overall revenues from the business in the second quarter of 2018. And I suspect that granularity to the constituent parts of that really won't be available until we go public in August with our second quarter results.

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

Fair enough. And if I could sneak one more in on the international HIV business. Any chance you could give us a sense of the relative growth contribution from -- between the STAR pilot program and then those other countries to whom you're shipping tests. And then I think you mentioned 40 of those countries, which seems like a much bigger number than, I guess, I would've expected at this point. How would you describe your visibility and your view around the funnel of how that's developing?

**Stephen S. Tang** - *OraSure Technologies, Inc. - President, CEO & Director*

The STAR Phase II program calls for formulating the units, Brandon. We are well on our way as to fulfilling that requirement. And so I think what is exciting for us is that significant amount of the countries that we're serving are or will be buying outside of the STAR program. So that gives us a great leverage, I think, in further sales. So we're pleased with how STAR Phase II has been progressing, and I think we expect to see further growth outside of STAR.

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

So just to add to that, Brandon. We do have 6 countries that are participating in the STAR program. And the 40 countries that we spoke of in the call script actually are those that we're selling to or promoting our self-test to. So we're not necessarily selling to all 40 of them currently, so just to



## MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

make that small point of clarification. There's plenty of opportunity ahead as we actually do start selling to them and translate that promotional effort to an actual sale. So I think as Steve pointed out, there's a lot of positive momentum building in that the self-test program.

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**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, again, to Ron on the retirement. So just I wanted to ask on the DNA Genotek business, you have lot of consumer genomic companies and you've had them for a while. So just on a math front, can you kind of -- would you be able to maybe describe what we should anticipate in terms of percent of revenue in each turn of quarter? I mean, we now know that this is kind of a backdated thing, with Christmas being the strongest time of the year. Just kind of -- can you help us with the magnitude in terms of Q1, Q2, Q3, Q4? Just on the consumer genomics kind of ordering patterns, if you are willing to share that.

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

Well, Dave, I think we're learning right along with you here as we progress throughout the various seasons. And so we had a -- we had certainly an experience in the fourth quarter that indicates to us that there was a strong seasonal impact from Black Friday, Cyber Monday and the Christmas holidays. And now as we move through the balance of the year, I would expect that we'll learn some more about the impact of Amazon Prime Day in 2018 and Cyber Monday and Black Friday and the Christmas holidays and 11/11 and any of the other more impactful spiky-type of revenue events that occur throughout the year. So I don't know that we can, with any level of accuracy, predict what the aggregation of all of our consumer genomics customers as well as the royalty payments might amount to from an intra-year distribution. But it certainly is a promising fact set that we have to work with.

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

All right. Got it. All right, so just in terms of -- you called out the 13,000 patients in the recent funding of \$1.45 billion into collecting 1 million patient samples. So what's the potential to turn that 1,300 into a bigger percent of that million patients? And kind of as a follow-on to that, why -- what is your potential in all these different kinds of research projects here? It just seems to me a no-brainer to not use blood when you're collecting samples from healthy patients who you want to volunteer.

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**Stephen S. Tang** - *OraSure Technologies, Inc. - President, CEO & Director*

You should be a medical advisor, I think. We agree. I think, overall, epidemiological studies are a key part of our business for both the microbiome and for human genomics. For the specific case you're talking about, the All Of US program, which NIH launched. It was covered by New York Times yesterday. The reason that they are sampling blood is that they're doing more than genomic analysis. They're doing other blood work to get a baseline for their patients. It doesn't take too much imagination to know that to reach 1 million patients, you're going to have to find an easier way to collect a sample. And the easiest way to collect samples is through saliva, that's why we have a strong business segment in that area. So I think over time that there will be the opportunity. But certainly, this entry point of 13,000 samples is a good one, and we'll continue to work with the program.

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

And then I'm going to ask a little bit more of touchy one in terms of HCV. So you -- even when you kind of strip out the project that you -- the countrywide elimination effort, you guys kind of -- you missed me by kind of a lot in terms of revenue estimates. So can you talk about who the



MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

customers are in the HCV international right now? What the composition of that kind of customer looks like versus what the composition of customer looked like maybe last year or the year before that x the 1 country doing the HIV -- HCV elimination effort?

**Stephen S. Tang** - *OraSure Technologies, Inc. - President, CEO & Director*

Well, we're exploring country by country eradication programs for HCV. We see parallels in the way that governments have viewed HIV eradication to calling their attention to HCV. Beyond that, I can't really share any more than that, David. I think that we continue to explore those market opportunities. Clearly, the types of funding sources for HCV elimination are lagging behind the global funding sources for HIV. So we continue to promote our product as easy to use for that purpose, and we hope to have more to report in the coming quarters.

**Operator**

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

**Max Masucci**

This is Max Masucci on for Mark. Steve, congratulations on the new role as CEO, and Doug and Ron, it's been a pleasure.

So you hired David Rappaport too as VP of Biz Dev, which is an encouraging hire. Other than finding a successor to Ron, are there any other areas at the VP level or above where you're looking to add? Are you contemplating adding a COO since Ron has been wearing both hats?

**Stephen S. Tang** - *OraSure Technologies, Inc. - President, CEO & Director*

Yes, thanks, Max. We are not currently contemplating the COO role. Things could change over time. But for now, I think we're comfortable with the organizational configuration. We don't have anything to share right now about hiring anybody else at the officer level. I have observed for the last 7 years, and -- as a board member, and the last month as CEO, that we have a very strong management team globally. And we've taken steps over the past few years of creating global functions and a global matrix organization. And so very pleased with how we're executing right now. And obviously, once we've formulated our strategy, operations of organizational alignment will come from there. So stay tuned.

**Max Masucci**

Great. And regarding DTC consumer testing and DNA Genotek. You're ramping your manufacturing lines, are you able to meet demand currently? Could you speak to any inflection you might have seen in recent weeks post 23andMe's BRCA FDA approval or from any of their other marketing initiatives, say, their DNA Day that they had in late April?

**Stephen S. Tang** - *OraSure Technologies, Inc. - President, CEO & Director*

Yes, on the manufacturing side, I think we're comfortable when we've balance demand -- supply and demand, and have the flexibility to ramp up. So no concerns there about capacity. I think we've made the correct investments without overinvesting in the infrastructure

And just regarding, I think, the progress, and not to comment on any specific customers' programs, but I think that as the health indicators and the biomarkers increase the need for an FDA-cleared device to go with an FDA protocol for these companies, it's going to tilt strongly in favor of our products. So if that market factor increases and there are more biomarkers to be analyzed, that will bode well for our business.



## MAY 02, 2018 / 9:00PM, OSUR - Q1 2018 OraSure Technologies Inc Earnings Call

**Operator**

That brings the end to our question-and-answer session for today's call. I will now turn the call back over to Dr. Tang for closing remarks.

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**Stephen S. Tang** - *OraSure Technologies, Inc. - President, CEO & Director*

We want to thank everybody for participating on the call today and for your continued interest in OraSure, and we wish you a happy afternoon and evening, and look forward to our next call.

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**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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