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OSUR - Q1 2013 OraSure Technologies, Inc. Earnings Conference Call

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CORPORATE PARTICIPANTS

Doug Michels *OraSure Technologies Inc - President and CEO*

Ron Spair *OraSure Technologies Inc - COO and CFO*

Kathy Weber *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

CONFERENCE CALL PARTICIPANTS

Peter Lawson *Masuhome - Analyst*

Amit Bhalla *Citigroup - Analyst*

Jeff Frelick *Canaccord Genuity - Analyst*

Brandon Couillard *Jefferies & Co. - Analyst*

Shaun Rodriguez *Cowen and Company - Analyst*

Nicholas Jansen *Raymond James - Analyst*

Spencer Nam *Janney Capital Markets - Analyst*

PRESENTATION

Operator

Good afternoon, everyone, and welcome to OraSure Technologies' 2013 first quarter financial results conference call and simultaneous webcast. As a reminder, today's conference is being recorded. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer period.

(Operator Instructions)

To allow time for as many questions as possible, questioners are asked to limit themselves to only a single question with no more than one follow-up question related to the same topic. Once the follow-up is completed, a questioner can rejoin the queue for further questionings -- questions, sorry. OraSure Technologies issued a press release at approximately 4.00 pm eastern time today regarding our 2013 first quarter results and certain other matters. The press release is available to you on our website at www.OraSure.com or by calling 610- 882-1820. If you go to our website the press release can be found by opening the Investor Relations page and clicking on the link for Press Releases. This call is also available realtime on our website and will be archived there for seven days. Alternatively you can listen to an archive of this call until midnight May 15, 2013 by calling 855-859-2056 for domestic or 404-537-3406 for international. The access code is 42321505.

With us today are Doug Michels, President and Chief Executive Officer; Ron Spair, Chief Operating Officer and Chief Financial Officer; and Kathy Weber, Senior Vice President and General Manager, Consumer Products. Doug and Ron will begin with opening statements which will be followed with question-and-answer sessions. 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 and regulatory filings and approvals. 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, 2012, its quarterly reports on Form 10-Q and its other SEC filings. Although forward-looking statements help to provide complete information about future prospects, listeners should keep in mind that forward-looking statements may not be reliable. The Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call. With that, I would like to turn the call over to Doug Michels.



Doug Michels - *OraSure Technologies Inc - President and CEO*

Thanks, Judy. And good afternoon, everyone, and welcome to our call. I am pleased to report that 2013 is off to a good start. I will touch on some highlights from the quarter and then Ron will take you through the numbers. Our infectious disease business was up as the OraQuick In-Home HIV test generated additional revenues. We are encouraged by the growth in HIV OTC sales and continue to discover new ways to increase consumer awareness and use of this exciting new testing option. We are seeing strong year-over-year growth from our molecular collection systems business, DNA Genotek, and we were also pleased with a better than expected performance of our cryosurgical business, which was helped by international over-the-counter sales. We are encouraged by our Q1 results and we look forward to build on this momentum. The commercial launch of our OraQuick In-Home HIV test is in full swing and it is gratifying to know that we have helped more than 100,000 individuals learn their HIV status since launch. Our corporate goal is simple--help as many people as possible, answer questions about their health status, especially as it relates to serious illnesses such as HIV and HCV. We are fortunate to work in a field where we can combine what is good both for business and for public health. So with that as a brief introduction, let me now turn the call over to Ron Spair for a review of our first quarter financial results.

Ron Spair - *OraSure Technologies Inc - COO and CFO*

Thanks, Doug, and good afternoon, everyone. Our first quarter 2013 consolidated net revenues were \$21.2 million, compared to \$20.9 million reported in 2012. Our consolidated net product revenues increased 6% as result of higher sales of our molecular collection systems, infectious disease testing and substance abuse testing products. These increases were partially offset by lower sales of our cryosurgical systems and insurance risk assessment products. Our infectious disease testing revenues were \$10.7 million in the first quarter of 2013 compared to \$9.8 million in the first quarter of 2012. The overall 9% increase was primarily as a result of \$1.4 million in net sales of our OraQuick In-Home HIV test which we began selling in the fourth quarter of 2012. During the first quarter, gross sales of our OraQuick In-Home HIV test were \$1.5 million, which were offset by \$109,000 in customer allowances, including cooperative advertising, cash discounts and other allowances. Gross sales of this product increased sequentially from the 902,000 recorded in the fourth quarter of 2012. Although sales of the in-home test increased, we believe the rate of sales growth during Q1 was negatively impacted by certain retail execution issues, which Doug will discuss later in the call.

The increase in net revenues of our OraQuick In-Home HIV test was partially offset by a decline in sales of our OraQuick HCV and HIV professional products. First quarter domestic HIV professional revenues were down \$476,000 or 6%. Roughly one-half of this reduction is due to a one time purchase in the hospital market during the year-ago period, with the remainder primarily caused by the timing of public health customer purchases. First quarter HCV revenues decreased 18%, largely as a result of the variability in the ordering patterns of our customers. Our molecular collection systems revenues, primarily representing sales of the Oragene product line increased to \$3.9 million in the first quarter of 2013 compare to \$3.3 million in 2012. Revenues for the current year's quarter included a first-time order placed by a new pain management customer as well as new orders received from an existing customer who did not purchase product in the same period of 2012. Sales to this existing customer are expected to continue through 2013. These increases were partially offset by a decline in sales in the academic research market due to continued constrained research funding, primarily in North America. In substance abuse testing, revenues increased to \$2.2 million in the first quarter of 2013 from \$2.1 million in the first quarter of 2012, primarily as a result of higher Intercept sales. The increase in Intercept sales was the result of higher purchases by our UK laboratory distributor.

First quarter 2013 cryosurgical revenues decreased 11% to \$3.1 million from \$3.5 million in the first quarter of 2012, primarily as a result of lower professional sales in the domestic marketplace. This reduction largely resulted from higher distributor purchases made in the fourth quarter of 2012 in anticipation of price increases implemented in early January 2013. Despite the lower revenues, our cryosurgery business performed better than expected, primarily because of higher international over-the-counter sales. Licensing and product development revenues were \$202,000 in the first quarter of 2013 compared to \$1.2 million in the first quarter of 2012. During the first quarter of 2012, we received a \$1 million milestone payment under our hepatitis C collaboration agreement with Merck. No similar payment was received in the 2013 quarter. Turning to gross margin, our overall margin for Q1 of 2013 was 57% compared to 66% reported for the first quarter of 2012. The lower 2013 margin was a result of a number of items which negatively impacted our OraSure segment including a change in product mix, the absence in the current quarter of the \$1 million milestone payment received in the first quarter of 2012, higher royalties paid on sales of our OraQuick products and an increase in scraps, spoilage and unabsorbed overhead costs as result of production issues that were identified and corrected in the current quarter. We expect our consolidated margin to remain in the high 50% range throughout the remainder of this year.



Turning to operating expenses, our consolidated operating expenses for the first quarter of 2013 increased \$5.2 million or 30% compared to the first quarter of 2012. This increase is largely due to higher spending associated with advertising and promotional activities for our OraQuick In-Home HIV test. Advertising and promotional costs for this product were \$6.9 million in the first quarter of 2013 compared to \$1 million spent on launch preparation costs in the first quarter of 2012. R&D expense for the first quarter remained flat at \$3.4 million and G&A expense declined to \$5.4 million from \$6.1 million in the first quarter of 2012 due to lower legal and consulting expenses. From a bottom line perspective, we reported a net loss of \$10.2 million or \$0.18 per share for the first quarter of 2013 compared to a net loss of \$3.3 million or \$0.07 per share for the same period of 2012. Turning briefly to our balance sheet and cash flow, our cash balance at March 31, 2013, was \$79.3 million compared to \$87.9 million at December 31, 2012. Cash used in operating activities in the first quarter of 2013 was \$7.7 million, which included the advertising and promotion spend on the OraQuick in-home test. This compares to \$1.4 million used in the first quarter of 2012. Moving to guidance for the second quarter of 2013, we are projecting consolidated net revenues of approximately \$23.5 to \$24 million and a consolidated net loss per share of approximately \$0.15 to \$0.16 for the quarter. Included in our Q2 guidance is approximately \$0.01 per share in severance cost related to certain operational efficiency improvements in Q2 which are expected to save up to \$2.8 million on an annualized basis. With that, I will now turn the call back over to Doug.

Doug Michels - OraSure Technologies Inc - President and CEO

Thanks a lot, Ron. A top priority for the Company continues to be the commercialization of our OraQuick In-Home HIV test. During the first few months of this year we've seen continued sales growth. Average weekly sales have increased from approximately 3,000 units in January to almost 5,000 units by late April. We believe this continued growth is positive and shows that consumers are responding to our awareness building and consumer activation efforts. Our experience to date also indicates that it takes time to drive broad awareness about a new product and motivate consumers to purchase the product. Essentially, we are asking customers -- consumers to do something they've never done before--test themselves for HIV in the privacy of their own homes. Our sales growth has largely been driven by three things--continued national advertising, continued national public relations, and the recent addition of regional and local marketing activities targeting communities at highest risk for HIV. Specifically, we continued our print, digital and television advertising throughout the first quarter, shifting from our 45-second launch TV spot to more efficient 30- and 15-second spots. This allowed us to generate a greater number of impressions against our target audiences.

We've also continued our national public relations efforts around key dates such as National Black HIV AIDS Awareness Day in February and Women and Girls HIV Awareness Day in March. And we are continuing our relationship with Ervin "Magic" Johnson who has assisted us in generating over 200 million media impressions for our brand since the start of the launch. In late March, we moved into a new phase of our marketing activities, layering in regional and local radio, outdoor advertising and event marketing, reaching consumers in bars, nightclub and community events. The local radio activity featured prominent celebrity DJs such as Tom Joiner and Elvis Duran. The goal of these activities was to provide more information about HIV and the impact it is having on various communities. We are also reinforcing the idea that it has never been easier to learn your HIV status with the OraQuick In-Home HIV test. The intent of these activities is to stimulate conversation about HIV and create buzz and support around the need for testing. Bundled together, we call this our Make Knowing Your Thing Today campaign.

We are carefully measuring and tracking the impact of all of our marketing activities to optimize our marketing plans for the back half of 2013. We have recently deployed our first post-launch awareness and tracking survey, which will tell us where our messages are taking root and where more work is needed. We are also analyzing store level point-of-sale data to understand by geography, and in some cases down to the zip code level, where our sales are strongest. And in addition, we are monitoring the social media space to understand the conversation about our product. We look at click-through rates and dot-com conversion. All of this learning is helping us focus our efforts and drive greater efficiency in our marketing spend. One area that we are monitoring quite closely is the retail environment. During the first quarter we completed several retail audits to help assess our sales execution. These audits involve a sampling of individual retail stores around the country to check on product availability and placement. As is typical with any OTC launch we found areas in need of improvement.

For example, we discovered that some retail stores in higher volume areas were not carrying enough shelf inventory to meet demand, resulting in out of stocks. In addition, given the high retail value of our product, some retailers, concerned about potential theft, elected to place the test either in a locked cabinet or behind the pharmacy counter for security purposes. We've made the results of our audits available to our key retail partners and are working with them to ensure adequate product supply is on shelf. In addition because confidentiality is important to consumers, we are encouraging retailers not to place product behind the counter or otherwise make a consumer request assistance from store personnel in order to complete a purchase. The retail community has been and remains highly supportive of the launch and has been responsive to the new

learnings that we have shared. As we continue to optimize our marketing and selling activities the product has steadily increased in standing within the retailer product categories and now holds top-ten positions among branded products in the sets of our leading retailers. Given our performance and learning, we are now actively seeking expanded distribution in both the e-commerce and brick and mortar space. In the weeks to come, we expect you will see the product become available on Walgreens.com, Rite-Aid.com and Drugstore.com.

While sales performance and the other items I have mentioned are important to consider in measuring how we were doing, they do not reflect the full impact of our product. As you know, our primary contact with end users is through our consumer support center. Since launching the product we've received over 10,000 calls to our support center. Calls have been received from all 50 states and the District of Columbia and the support center continues to exceed the performance goals we established prior to the commercial launch. Significantly, data from the support center indicate that we have received calls from nearly 100 individuals who said they had obtained a positive result after using our OraQuick In-Home HIV test. In all cases these individuals were either directly referred into care by our support center representatives or they told us they would seek out a health care professional directly for follow-up. While this does not represent a comprehensive view as to all positive test results obtained by consumers, we believe it is an important early example of the potential public health impact that our test can provide. In fact, our market research indicates that as few as 5% of individuals testing positive may contact the support center. And assuming this survey is at least directionally accurate, the potential number of positive results identified with our test is likely much higher, suggesting that the product is delivering the intended positive benefit in the fight against HIV and AIDS.

Turning briefly to our OraQuick HCV test, as Ron indicated, HCV sales were down for the quarter compared to Q1 in 2012. However, this decline does not tell the whole story as we in fact experienced growth in both the number of new customers purchasing our test and the average size of purchase orders received during the quarter. The lower Q1 revenues were largely due to the timing of orders by a few large customers, each of whom we expect to reorder later this year. While sales of our OraQuick HCV test continue to be impacted by economic and funding challenges, we remain confident and optimistic about the long-term prospects for this product and its potential public health benefits. As you may know, May is Hepatitis Awareness Month and the second annual National Hepatitis Testing Day is coming up on May 19. In recognition of this month and date, we are collaborating with numerous national and local public and private organizations across the country to raise awareness of hepatitis C as a public health issue and to educate the public about the importance of HCV testing. In particular, OraSure's OraQuick HCV Rapid test will be deployed at public testing events in Washington, D.C., LA, New York, Chicago, Pittsburgh and over 35 other locations around the country. And a final area I want to address is our molecular collection system business. DNA Genotek had a strong first quarter, with sales increasing almost 20% compared to the year-ago period. The primary growth driver was higher sales to commercial customers. The increase in commercial business was a blend of new customers ordering for the first time and existing customers growing their business.

Highlights include one new significant customer engaged in pharmacogenomic testing related to drug metabolism and a significant new order by one of DNA Genotek's existing commercial customers. As further prospective, approximately 45 % of DNA Genotek's revenues during the first quarter came from commercial customers while the remaining approximately 55% came from academic and research institutions. You will recall that this represents a bit of a change in product sales mixes. DNA Genotek's revenues have historically been derived mostly from the academic research market. And this is not to say that academic research customers will not remain an important customer base. Despite ongoing funding challenges and in particular uncertainly related to the ultimate impact of federal sequestration, DNA Genotek continues to bring in new customers and increase its business with existing customers in this market. DNA Genotek is also expanding its international network of distributors. DNA Genotek is off to great start and we expect to see this performance continue throughout the remainder of 2013. So in summary, we're off to a solid start in 2013. We're excited to see increasing sales of our OraQuick In-Home HIV test and we continue to gain insight and experience on how best to market this product. We expect the application of that knowledge to be reflected in our future results. And with that, I will now open the floor to your questions. Operator, if you'd please proceed.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)



Peter Lawson from [Masuhome].

Peter Lawson - *Masuhome - Analyst*

Ron, just looking at the gross margins, what was the biggest driver of the weakness in the quarter? And what was the impact of medical device [acting]?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

In the gross margins, we listed a number of different impacts that we felt in that quarter and the largest one was more to do with the product mix. We had a substantial amount of HIV -- excuse me, of the OTC products and the cryo area that were sold both to [Henoma] and to [Reckit van Kaiser]. And then we also had a bit of an impact from the \$1 million missing that was pure gross margin in the 2012 quarter. That was out of this quarter; that was the milestone. And then we had the royalty that kicked in to Alere which we spoke about that we did not have in Q4 of 2012 and now we have that applied to our HIV and HCV products. And then lastly we had a production issue that caused us some margin impact that we don't expect to have an effect in the second quarter here. So it was in that order, Peter, of how the impacts were felt.

Peter Lawson - *Masuhome - Analyst*

And then the operational improvements, what was that and which business does that affect?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

It was an across-the-board review of all of our operations to determine how we could streamline and perform more effectively and efficiently with the people that we have on board based on the business outlooks that we have in the various business segments. And so all areas were impacted.

Operator

Amit Bhalla from Citi.

Amit Bhalla - *Citigroup - Analyst*

Doug, can you talk about what you assess the dollar impact of the stock outs to be and talk to us about how you're ensuring it won't happen again for the remainder of the year. And then secondly, we agree with you on the April trends being positive, but May looks like it had started to slow again. Can you talk to us about what you are assuming for 2Q performance overall?

Doug Michels - *OraSure Technologies Inc - President and CEO*

Yes. Let me -- I will talk a little bit about the stock outs and the less than one piece per shelf as best I can. Very difficult to estimate. And obviously when we saw that trend in some of the higher prevalence markets where we expect to see the disproportionately higher proportion of sales, something we obviously acted upon immediately. And the good news is is the retailers have been very responsive. Within a couple of weeks of us getting that data out to the retailers, they responded by pushing product out of their central distribution locations and to the stores and talking with the store managers to get it on shelf. Very hard to estimate what the impact of that was. But we are pretty confident it had an impact and you saw that somewhat of a slowdown in growth rates in the February and March area. And we think that the improvement in April was partly due to better availability at shelf as well as some of the impact from these local market activation activities. We are into the first week of May and obviously there is fluctuation that we see week on week. Kathy is here on the call to take any additional OTC questions. So I can ask her if she has comment relative to that. We expect -- just so that you are aware, to see continuing month on month growth throughout 2013 and beyond.



Kathy Weber - *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

I think that's the key point is that we have seen month on month growth and, on any OTC launch, you are going to see fluctuations week by week and they can be driven by pay cycles of consumers, the timing of events and activities in the marketplace, the level of retail inventory because, to Doug's point, the retailers have been very responsive and we've -- they've worked with us to push more product out to the appropriate stores. But that process is an optimization process also as we learn more and more about where the product is selling, how much inventory they need to carry, where the best location is in store that we will continue to see those fluctuations. But I think the important thing to remember is that consistently from launch month over month we have seen increases.

Amit Bhalla - *Citigroup - Analyst*

And just a follow-up on HCV, I hear what you are saying about just timing of orders, but do you feel like you are losing any shared automated molecular HCV testing at all on your HCV business?

Doug Michels - *OraSure Technologies Inc - President and CEO*

No, I don't think that there is any indication that we are losing to molecular testing whatsoever. We are continuing to see new opportunities open up in HCV. We are encouraged by the fact that the different governmental agencies, in this case SAMSA, Substance Abuse and Mental Health Services Agency, led a \$1 million RFA specifically for rapid testing. The responses to that RFA closed out on April 5 and we expect to see a benefit from that in the back half of the year. We were pleased to see the CDC issue two MMWRs -- actually, I think they were published -- they are dated May 7, so they made available in the last several days, one of which was the update of guidance for clinicians and laboratorians for HCV testing. This is a long-awaited new guideline which in essence streamlines the whole process for testing patients for HCV antibody and moving immediately to viral load testing, which is very logical. And the recommendation specifically highlights the availability of the OraQuick Rapid Hepatitis C test. So we are encouraged by what is going on, by the dialogue in the marketplace around HCV. Everybody is excited about the new therapies that are in development and we expect that we are going to be in a wonderful position to capitalize on the growth and testing with our technology.

Operator

Jeff Frelick from Canaccord.

Jeff Frelick - *Canaccord Genuity - Analyst*

Doug, just to follow-up on the mix with respect to HCV. You had mentioned you added some new customers. I think you were hovering around couple hundred public health customers previously using HCV. Where does your customer base shake out now exiting the quarter?

Doug Michels - *OraSure Technologies Inc - President and CEO*

We had well over 100 customers ordering in the quarter. And we talked about 200 customers, over 200 customers. That was the last call. That was total for 2012. You can see that we are seeing some momentum. We had about 42 new customers order in the first quarter. And so we expect that is going to continue.

Jeff Frelick - *Canaccord Genuity - Analyst*

And then with respect to getting some traction on the position off the side, I think the last quarter you said you were going through the physician office distributors and doing some training at their national meetings. Has all the training been completed? Where are you with that initiative?



Doug Michels - *OraSure Technologies Inc - President and CEO*

That has been completed and happy to say that for the major physician office distributors, the hepatitis C test remains an emphasis product for them in the first quarter as well as in Q2 here.

Jeff Frelick - *Canaccord Genuity - Analyst*

And then with respect to funding at the state level, are you guys noticing any pick up there as budgets are a bit more, I would say, controlled. Just what you are seeing at the state level, both funding for HCV and HIV?

Doug Michels - *OraSure Technologies Inc - President and CEO*

Obviously, it's highly dependent on the state, given their economic situation, but we are starting -- I think we are starting to see some stability. Obviously, where those dollars get spent is critically important. The US PSTF recommendation for HIV, the fact now that that has come out with a A grade rating is very encouraging. The public health jurisdictions, as I think you know, Jeff, are -- there is an incentive for them to maintain the level or increase the level of their testing programs because their future grants from the CDC are generally funded based on not only the number of HIV tests that are performed but the yield that they get from those tests that are deployed. And generally the CDC likes to see a yield of at least a 1% positivity rate of new infections diagnosed because that's really how we can drive down incidents. So if jurisdictions are faced with budget challenges or budget cuts, one of the last things they want to do is reduce their testing volume if at all possible. We are starting to see some stability. Obviously, there continues to be challenges. But we believe that 2013 is going to be a -- certainly a much better year than 2012 as it relates to that.

Jeff Frelick - *Canaccord Genuity - Analyst*

Thank you for commenting on that. And then maybe just my last question for Kathy. The -- can you maybe share the impact of the shorter, more frequent ad spots how that resulted in any more hits on your website customer visits versus the prior quarter?

Kathy Weber - *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

We definitely saw -- as we said, our sales have continued to grow month over month. So through the beginning of April, the growth was largely driven by TV. So the shift to the 30s and 15s increased the impressions and was really the only driver of the increase of sales up through that first quarter. What's driven the next sort of level of growth that we have seen has been the layering in of the local and regional activity. And that activity has increased web traffic both at a local level, at a national level. We are seeing -- we made some other shifts in our media, not just the shift to 30s and 15s but our digital strategy has evolved with learning where we moved away from some banner ads that were less effective and moved more into paid search and we've seen dramatic increases in our digital conversion rate literally in the past month from making that change. I think the point is as we shift we try to become more efficient. We're measuring any -- in any way that we can, whether it's sales, website traffic, conversion rates. We have some surveys, awareness and tracking surveys, zip code analysis to measure where we are having impact and what we can do differently and more smartly.

Doug Michels - *OraSure Technologies Inc - President and CEO*

We are also -- Jeff, we're also going to be rolling out a new mobile app to make ordering easier for consumers. Interesting, as we look at visits to our website, we see that 62% of visits have been from mobile devices, yet only 33% of on-line orders come from mobile devices. And then conversely, 38% of visits from consumers come from a desktop but 67% of transactions are coming from the desktop. So why the disconnect? Why aren't consumers ordering from their mobile phone or tablet, and that's because we think that there is an app we can deploy that is going to make it easier for consumers to place the order directly from their mobile device. Really a lot of learning as we generate this data now and, as Kathy said, we've got have half a dozen or more different studies going on where we're looking at demographic analysis of our buyers at retail demographic

of our purchasers on e-commerce. We are doing a website survey to look at consumers' on-line experience. We are serving consumers who participated in some of these regional events to understand what their impressions are and whether they purchased the product post participation. So lots going on. A lot of learning. And obviously we're going to translate all that learning into our future programs in the back half of the year and beyond.

Jeff Frelick - *Canaccord Genuity - Analyst*

You just spurred a question. One more for Blackberry Guy. I have been fighting the iPhone. Will customers be able to order on their iPhone at a local pharmacy and walk by there in a short time frame and pick it up at the counter and have the product waiting for them as opposed to cruising the aisles and looking for the product.

Kathy Weber - *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

That's an interesting idea. It's not something that, to be honest, we had considered but I think that that's an interesting idea. Because anything we can do, and this is another area we are spending a lot of time -- anything we can do to make it easier for people and to have the fewest interactions with another person in terms of getting the product. It's not currently in plan but I think it's a great idea.

Doug Michels - *OraSure Technologies Inc - President and CEO*

And Jeff we will give you the specific number that you can do so you can order as many kits as you possibly can.

Jeff Frelick - *Canaccord Genuity - Analyst*

Thanks. (laughter)

Operator

Brandon Couillard from Jefferies.

Brandon Couillard - *Jefferies & Co. - Analyst*

Ron, could you give us a sense of the anticipated marketing spend for the HIV OTC product in the second quarter and in the second half of the year. Is your full year outlook of I believe it was \$16 million to \$17 million still in the ballpark?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

We actually were representing that our expectations for the full year are in the high teens of millions of spend on the HIV OTC product for 2013. And if you look at our anticipated spend as we sit here today for Q2, we are looking more at a low \$6 million number for spending in the second quarter here, Brandon.

Brandon Couillard - *Jefferies & Co. - Analyst*

Any chance you could give us the mix between internet and retail in the first quarter?



Ron Spair - *OraSure Technologies Inc - COO and CFO*

The --

Kathy Weber - *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

The sales?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

Are you talking --

Brandon Couillard - *Jefferies & Co. - Analyst*

Yes, for the OTC product.

Ron Spair - *OraSure Technologies Inc - COO and CFO*

Let me look into what I have on --

Kathy Weber - *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

Our internet sales are just roughly under 10%, just under 10% of total retail sales.

Brandon Couillard - *Jefferies & Co. - Analyst*

And then one more for Ron. When should we expect the savings from the ops review to begin kicking in?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

I would suggest that after we get through the charge here in the second quarter that we will begin to see that in the third quarter here free and clear of any severance-related charges. But the action was implemented recently and so we will have some contribution to offset the severance charge in the second quarter but the full benefit will accrue to us beginning in Q3.

Brandon Couillard - *Jefferies & Co. - Analyst*

And then one last one for Doug. Could you give us just an update I guess qualitatively on your thoughts around a new HCV partnership. Would you characterize that as near-term priority or a second-half goal? What is your view on that dynamic?

Doug Michels - *OraSure Technologies Inc - President and CEO*

Well, obviously, there is a lot of dynamic in the therapeutic space. We benefited I think greatly from our relationship with Merck over the last several years, not just in the development of the HCV test but also as they contributed milestone payments. Obviously, we all know how the race between Merck and Vertex turned out. As part of that Merck agreement there were restrictions in our ability to work with other players in the pharmaceutical space. We don't want to get into a restrictive agreement like that again. And at the same time we realized the importance of working collaboratively with the different pharma companies. And we have ongoing dialogue with them. You should know that. I mentioned that in our last call. And since



that last call we continue to meet with and actually talk about how we can work together. I think it's clear that the therapy providers know the importance of diagnosing more chronically infected individuals and doing that in relatively short order. With the new therapies, there is going to be shorter treatment regimen, fewer side effects. It's going to encourage more treaters to get into the game. And hopefully we will begin to work through that backlog of warehoused chronically infected patients sooner, which then again highlights the need to diagnose more of the individuals who are chronically infected. Discussions continue and, as I've mentioned before, when we have something substantive to say about that, we will obviously let you know what is going on.

Operator

Shaun Rodriguez from Cowen.

Shaun Rodriguez - *Cowen and Company - Analyst*

On the HIV professional business, can you just talk about your confidence in your guidance for this to be about flat for the year? I know you called out comps and timing as drivers for the decline in the quarters. I'm trying to understand if we should expect a significant bounce back here.

Doug Michels - *OraSure Technologies Inc - President and CEO*

Well, we are relatively confident in that. Obviously, we are predicting the future. We see continued -- slight softness continuing in the funding area but we also see hopefully a positive lift from the new task force recommendations and increased HIV testing. And so those two things together continuing with our strong market position, we expect to have a pretty solid year.

Shaun Rodriguez - *Cowen and Company - Analyst*

And then a couple on the OTC. So first I'm just curious about the data that you have on who is buying the test. I'm really trying to understand how who is buying the test is matching up with who you are targeting in your marketing and just really curious about the sorts of data you are privy to.

Kathy Weber - *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

Yes, Shaun. It's Kathy. I will answer it two different ways. The real answer on who is buying, the definitive answer will come from some of these analyses that Doug talked about. We have the tracking study in market. We will understand by target, by the MSM community, the Latino community, the African-American community who -- what the awareness levels are and who's been buying the product, detailed information on that. And then we will do the -- we'll get a good sense from the demographic analysis where we will actually go in and look at store level sales. This is getting down to the store and matching that up with zip code data about demographics so we'll know the type of neighborhoods. And you can -- there are companies we are working with, SPECTRA is one of them, where you can really get a good sense of your -- the profile of your consumer by looking at that demographic analysis. And we will have that in a few weeks. What we know so far is that -- or we believe that not surprisingly the MSM community is showing the highest interest in our product and when we look at the data we have, dot-com conversion rates, the appeal of our banner ads and how that is linking back to sale on-line, it's highest with that community and that's not surprising. We knew that their purchase interest was higher, their purchase cycle is shorter. So we suspect that we are getting some volume from the MSM community.

Doug Michels - *OraSure Technologies Inc - President and CEO*

MSM is men that have sex with men.



Kathy Weber - *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

Yes. Thank you. And then some of the other communities we expect will take a little bit more time to get to purchase. That's very consistent with the pre-launch market research learning. But the real answer to your question will come in a few weeks as we look at this -- these various studies.

Shaun Rodriguez - *Cowen and Company - Analyst*

And then just a last quick one. Your net to gross revenues for the OTC product were I think in the mid-90s. Is this ratio expected to remain around these levels for the balance of the year?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

I would say that that is what our expectations are and probably more in the low 90s though, Shaun, to be honest.

Operator

Nicholas Jansen from Raymond James.

Nicholas Jansen - *Raymond James - Analyst*

Just trying to think about the components of growth for your 2Q guidance. Anything you want to specifically to call out in terms of product areas that you expect to have difficult comps year-over-year or things that we should think about in terms of modeling the appropriate businesses correctly?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

Right. So our expectations are that the HIV OTC product will experience sequential growth in Q2 over what we had recorded in Q1 here obviously. We are also expecting that our Q2 cryosurgery business will be up substantially as a result of us moving now more into the seasonably impacted summer season where cryo has always historically done its best, along with continued purchasing in the HIV OTC area. So that will be another growth area. And of course DNA Genotek will again post growth sequentially and certainly from a comparability standpoint versus the year-ago quarter.

Nicholas Jansen - *Raymond James - Analyst*

And then maybe thinking about the DNA Genotek, you obviously are having some good success with some new customers. Maybe you can talk about 23andMe and some of your larger customers. How are their purchasing orders trended over the last couple quarters and what should we anticipate for the back half of the year there?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

We haven't given that level of granularity by customer. But suffice it to say, we expect to see continued purchases from 23andMe in 2013. And some of the new customers that were referenced in our prepared remarks are exciting and we believe are going to put continued orders -- continued demand on the Company. So really DNA Genotek's business is clicking on a number of different cylinders. It's one of the key reasons why we bought the company 18 months ago and we look forward to a good year from our molecular collections business.

Nicholas Jansen - *Raymond James - Analyst*

And then lastly, looking at the balance sheet, you have about \$80 million of cash on the balance sheet. You're in good position there. What should we think about in terms of M&A. Any thoughts on perhaps a buy back given where the stock is today. Just your thoughts on capital deployment.

Ron Spair - *OraSure Technologies Inc - COO and CFO*

So you are right. We do have a substantial amount of cash on board and we do have, as we have talked about previously, an active business development program, so we are always out looking for opportunities, whether they be products, technologies, bolt-ons. So we do focus a lot of our efforts in that area and we will continue to do that. So not that there is anything that we are prepared to talk about. But certainly it's an active area of activity for us.

Operator

Spencer Nam from Janney Capital.

Spencer Nam - *Janney Capital Markets - Analyst*

I have just a couple of quick questions. So this stock out issue with the over-the-counter HIV, the -- I'm imagining that when you guys analyze the situation there is somewhat of a gap between the moment that you recognized that a particular store is out of the stock and then you try to replenish it and it takes time for that to happen and so forth. And that I would assume that that event gets repeated across several stores across the country. I don't know whether you -- today versus say a month ago, whether you've been able to shrink that gap of time between stock being out of a particular store versus you guys are replenishing the stock from those places. Has that -- (unintelligible) addressed to the point where the gap has -- is closing?

Kathy Weber - *OraSure Technologies Inc - SVP and General Manager, Consumer Products*

Yes. Spencer, I will answer that--I guess in two ways. In general, when a retailer sells a product, they replenish their store level inventory weekly. So if a retailer is out of inventory -- and that's a generalization but most of them get -- will get shipments in once a week at the store level. So if you are out, you can potentially be out for a week. So what we've tried to do with the retailer -- and that is very difficult to influence. That cycle is -- the retailer's infrastructure and their systems and that's difficult to influence. What we have been trying to influence is the amount of pieces of product that the retailers will carry on their shelf to reduce the chance that there will be an out of stock, that there will be a situation where there is one or less than one, zero pieces, of product on the shelf. And that we have been able to influence. CVS and Walgreens have both agreed, particularly in the stores that are demonstrating that they're higher volume stores, they've increased the level of inventory on shelves. So we -- the chances that a store will have no inventory is lower.

Spencer Nam - *Janney Capital Markets - Analyst*

And then in terms of the capacity -- I don't know whether you covered this. I may have missed this during your prepared remarks. But in terms of your capacity -- inventory at your level, how much of a cushion do you have here? Let's say there was a huge surge, have you guys done the stress test, if you will, that you could -- you would [nobble] them out of your inventory in case there is a ridiculous demand in the next, say, six months or something like that?



Ron Spair - *OraSure Technologies Inc - COO and CFO*

We are prepared for that. We have inventory staged and ready to go. And also if we can -- as you know, we manufacture the product right here and we maintain a sufficient stock of professional products so we can switch right over to making more of our over-the-counter product. So no issues on inventory whatsoever. Don't worry about that.

Spencer Nam - *Janney Capital Markets - Analyst*

And then on the DNA Genotek, clearly a pleasant surprise this quarter with additional customers, increasing demand. When we look forward, I think you alluded to the fact the second quarter also seems to be more positive in terms of the growth, that how much reliability we can put on some of this new customers that are coming in or the existing big customers increasing their order sizes? Is this something that we could look beyond, say, this year for example and say these guys are going to continue to build this demand in the -- across several quarters or across two or three years here?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

So Spencer, you have to think about the business now in two components, right--the academic research and the commercial segment. From academic research, generally these are contracts that have to be renewed each year or you have got to go replenish your academic research studies on an annual basis. So to the extent that we see a revenue shift to more of a commercial mix, that is good from a predictability perspective. And obviously that's what we are seeing right now. We measure back log of orders as we enter into the subsequent quarter and I can tell you that the backlog for DNA Genotek's business continues to grow, which is a good thing. What it means is that we are entering the second quarter with a higher level of sales already booked that have yet to ship in the quarter. Obviously we have to continue to generate new business in the second quarter to achieve our objectives, but we are going into the second quarter with a higher percentage of revenues already booked and we expect that that is going to continue throughout the rest of this year at least. Some positive trends going on in that business and those are some of the metrics that we use to measure performance.

Spencer Nam - *Janney Capital Markets - Analyst*

Final question. HCV rapid test, you indicated that discussions are ongoing right now between OraSure and drug companies. And you may not be able to answer this with any specificity, but I'm just curious if you look at the balance of interest, if you will, which side is more interested in this discussion? Is it drug companies or you guys? How should we think about that -- the balance?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

I think you can think about the balance as we are all interested. We all understand that there is a tremendous need for more diagnoses. We all understand that new therapies are going to soon be available that are going to promise nearly 100% cure rate. The federal government has already gone on record saying that they are keenly interested in reducing the morbidity and mortality associated with chronic HCV infection within the birth cohort of Americans born between 1945 and 1965. There is 80 million Americans with a believed to be 3.25% prevalence rate of chronic hepatitis C infection. Most of those are undiagnosed. Everybody knows that we could diagnose more patients. If we do that, we are going to get those patients into care. We're going to treat them and we are going to cure them. And that's going to be great for public health and it's going to be great for the economy as well. So we are all aligned on that. I think there is a uniform interest in seeing how we can deploy our respective assets most efficiently and effectively.

Spencer Nam - *Janney Capital Markets - Analyst*

So then would you characterize the situation as progressing in terms of your discussions or is it too early to tell?



Ron Spair - *OraSure Technologies Inc - COO and CFO*

More on that to come.

Operator

(Operator Instructions)

We will take another question from Amit Bhalla from Citi.

Amit Bhalla - *Citigroup - Analyst*

Just a couple of clean ups for Ron. Ron, I think the device tax, can you tell us what that was in the quarter and, second, on gross margin, as you look at gross margin for 2Q compared to 1Q, are you looking at flat, up or down?

Ron Spair - *OraSure Technologies Inc - COO and CFO*

We are expecting the Q2 gross margin to trend up based on the product mix that we are looking at for Q2 with a higher proportion of professional cryo sales than we had in the mix for Q1, which is our highest margin product. And then as far as the medical device excise tax, we haven't given visibility to that number for our Q1 performance, and it's not significant, Amit.

Amit Bhalla - *Citigroup - Analyst*

You're not -- I'm just confused why you're not giving that number for device tax.

Ron Spair - *OraSure Technologies Inc - COO and CFO*

Just because we haven't given that level of granularity into that part of the business.

Amit Bhalla - *Citigroup - Analyst*

We can talk about it off-line. Thanks.

Operator

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

Doug Michels - *OraSure Technologies Inc - President and CEO*

Okay, I just want to thank everybody for being on the call this afternoon and evening and we look forward to updating you in a few months on our 2Q results. Thanks again. Bye-bye.

Operator

Ladies and gentlemen, this does conclude your conference. You may now disconnect, and have a great day.



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