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# EDITED TRANSCRIPT

OSUR - Q3 2013 OraSure Technologies, Inc. Earnings Conference Call

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## PRESENTATION

### Operator

Good day, ladies and gentlemen, and welcome to the OraSure Technologies Inc. third-quarter 2013 earnings conference call.

(Operator Instructions)

As a reminder today's conference is being recorded for replay purposes. I would like to turn the conference over to your host for today, Ms. Judy. Ma'am, you may begin.

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### Judy Clarke - OraSure Technologies Inc - IR

Good afternoon, everyone, and welcome to OraSure Technologies' 2013 third-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. If you would like to ask a question during this time, simply press star then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key. To allow time for as many questions as possible questioners are asked to limit themselves to only a single question with no more than a follow-up question related to the same topic.

Once the follow-up is completed, a questioner can rejoin the queue for further questions. OraSure Technologies issued a press release at approximately 4.00 p.m. Eastern time regarding its 2013 third-quarter results and certain other matters. The press release is available to you 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. This call is also available real time on our website and will be archived there for seven days. Alternatively you can listen to an archive of this call until midnight November 13, 2013 by calling 8(855)859-2056 for domestic or (404)537-3406 for international. The access code is 87563319.

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 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 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 10K for the year ended December 31, 2012, its quarterly reports on form 10Q 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.

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

Okay. Thank you, Judy, and good afternoon, everyone, and welcome to our call. The Company delivered strong overall results for the third quarter. Consolidated net revenues reached a record high growing 12% over the third quarter of 2012. The principal drivers of this growth were a 48% increase in DNA Genotek revenues and a 20% increase in our infectious disease business. Our molecular collections systems continues to deliver record results driven by a higher sales to commercial customers. Our infectious disease revenue has also increased nicely, driven by sales of our OraQuick in-home HIV test and higher international sales of our OraQuick HCV test.

During the third quarter we also launched a new promotional campaign for our OraQuick in-home HIV test, and I will provide additional insight into how this campaign is progressing and certain other business items later in the call. With that let me turn the call over to Ron for a more detailed financial review.

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

Okay. Thanks, Doug, and good afternoon, everyone. Our third quarter 2013 consolidated revenues were \$24.7 million compared to \$22.1 million reported in 2012. Our consolidated product revenues increased 13% as a result of the record sales from our molecular collection systems segment and higher sales of our infectious disease testing products. These increases were partially offset by lower sales of our substance abuse testing, cryosurgical systems and insurance risk assessment products. Our molecular collection systems revenues, primarily representing sales of the Oragene product line, increased to \$5 million in the third quarter of 2013 compared to \$3.4 million in 2012. This 48% increase was the result of higher sales in the commercial marketplace.

Our infectious disease testing revenues were \$12.9 million in the third quarter of 2013 compared to \$10.7 million in the third quarter of 2012. The overall 20% increase was primarily a result of \$1.8 million in net sales of our OraQuick in-home HIV test, which we began selling in the fourth quarter of 2012. Q3 sales of our professional HIV and HCV tests in the international markets also increased. During the current quarter, gross sales of our OraQuick in-home HIV test were \$1.9 million, which were offset by \$172,000 and customer allowances including cooperative advertising, cash discounts and other allowances. Net sales of this product included approximately \$217,000 of direct sales of our OraQuick in-home HIV test to public health customers.

In addition to the increase in net revenues from our OraQuick in-home HIV test, sales of our OraQuick HIV and HCV professional products in the international market increased 31% and 283% respectively. International sales of our professional HIV test in the third quarter of 2013 increased to \$1.2 million from \$884,000 in the same period of last year primarily due to sales in support of a significant testing program in Africa. International sales of our HCV test in Q3 increased to \$924,000 from \$241,000 in the prior year due to the first installment of products shipped under an order from a multinational humanitarian organization. These sales increases in the international market were partially offset by a decline in domestic HIV revenues which were down \$434,000 or 5% due to competition from other rapid and automated laboratory-based HIV tests, reductions in government funding and the timing of customer purchases.

Third quarter 2013 cryo revenues decreased 13% to \$3.6 million from \$4.2 million in the third quarter of 2012 primarily as a result of lower professional sales in the domestic marketplace and lower OTC sales. Professional, domestic cryo of sales decreased 11% compared to the third quarter of 2012 due to variability in distributor order patterns. OTC sales decreased 18% to \$1.4 million in the third quarter of 2013 from \$1.7 million in the third quarter of 2012. This decrease was primarily the result of the timing of orders placed by our Latin American distributor as well as a net decrease in sales to our European distributor. Our substance abuse testing revenues decreased to \$2.1 million in the third quarter of 2013, from \$2.3 million



in the third quarter of 2012 primarily as a result of lower Intercept sales. This decrease resulted primarily from reductions in purchases by our UK distributor who began selling its own competing oral specimen collection device.

Turning to our gross margin, our overall margin for Q3 was 61% compared to 63% reported for the third quarter of 2012. The lower 2013 margin was primarily a result of higher royalties paid on sales of our OraQuick products and an unfavorable change in product mix partially offset by an improvement in overhead absorption and a decline in scrap and spoilage costs. Our consolidated operating expenses for the third quarter of 2013 remained relatively flat at \$17 million compared to \$16.8 million in the third quarter of 2012. Increases in sales and marketing expenses and G&A expenses were partially offset by lower R&D expenses. Sales and marketing expense increased \$379,000 largely due to higher staffing costs, partially offset by lower trade show expenses. Spending associated with advertising and promotional activity for our OraQuick in-home HIV test increased slightly to \$1.9 million in the third quarter of 2013 compared to \$1.8 million spent in the third quarter of 2012.

G&A expenses increased \$122,000 due to an increase in staffing related expenses partially offset by lower spending on legal and professional services. R&D expenses for the third quarter declined \$324,000 due to lower staffing and supply costs. From a bottom line perspective, we reported a net loss of \$1.9 million or \$0.03 per share for the third quarter of 2013 compared to a net loss of \$2.4 million or \$0.04 per share for the same period of 2012. So turning briefly to our balance sheet and cash flow, our cash balance at September 30, 2013 was \$82.6 million compared to \$87.9 million at September 31, 2012. Cash provided by operating activities in the third quarter of 2013 was \$6.1 million compared to \$1.7 million used in operating activities in the third quarter of 2012. Looking forward, we expect to spend \$5.6 million on advertising and promotion activities in Q4 related to our OraQuick in-home HIV product. A significant portion of this represents a shift in spending from the third quarter of 2013 to the fourth quarter and is one of the primary reasons why we exceeded our Q3 guidance for the bottom line.

As we have discussed in prior calls, our current revenue recognition practices for the OraQuick in-home HIV product have us deferring revenue recognition from the time of shipment to the retailer or distributor until the consummation of a sale by the retailer or distributor either in a store or over the Internet. Under US generally accepted accounting principles, product revenue cannot be recognized unless the amount of future returns can be reasonably estimated. Since the launch of the product in September of 2012, we have continued gathering information regarding retailer industry leader inventory levels and return practices. We expect to change to a more traditional revenue recognition policy under which revenue is recognized upon shipment to the retailers or distributors once we believe we have a sufficient amount of this data to develop a reasonable estimate of the level of expected returns.

We anticipate that this change in accounting policy may occur in the fourth quarter of 2013 and, assuming it does, could positively impact our revenues by approximately \$2 million. We have included these additional revenues and corresponding gross margin contribution in our guidance for Q4 2013. In light of the foregoing, we are now projecting consolidated net revenues of approximately \$27.5 million to \$28 million and a consolidated net loss per share of approximately \$0.07 to \$0.08 for the fourth quarter of 2013. As we look out to the first quarter of 2014, we will likely be recognizing revenues for our HIV OTC product based on shipments to the distribution channel, and, of course, we would not have a similar revenue recognition adjustment. Additionally, I would like to take this opportunity to remind everyone that the first quarter has historically been our weakest quarter for both our infectious disease and cryosurgery business. Therefore, we do anticipate a sequential decline in revenues from Q4 2013 to Q1 2014.

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

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**Judy Clarke** - OraSure Technologies Inc - IR

Okay. Thanks, Ron. As mentioned on our last call, we intentionally reduced our marketing activities related to the OraQuick in-home HIV test during the third quarter as we prepared for and ultimately launched our new promotional campaign. Consequently, third quarter sales of this product declined about 12% compared to the second quarter. During the third quarter our OTC marketing team assessed what practices and strategies proved to be most effective during the first nine months of the launch and developed new marketing activities based on that analysis. This retooled campaign has already launched, and elements will continue to be added through the first quarter of next year. Importantly, our OraQuick in-home HIV test maintains a strong ranking at major retailers. For example, the product holds top 10 positions in the categories in which it is merchandised at both Walgreens and CVS.



In addition, Internet or .com sales now represent 8% of total brand retail sales and grew 1% from the second quarter. Interest from public health customers and advocacy groups also remain strong with sales of the product to these entities approximating \$200,000 in Q3. Our new marketing campaign entitled, Life As We Know It, was officially launched in late September in conjunction with Gay Men's HIV Awareness Day. As previously communicated, this new campaign is designed to address several key elements of our analysis from the first nine months of product availability. Of most significance was the need to significantly increase brand awareness among key consumer target groups such as MSM, or men who have sex with men, and African-American women. Our new campaign focuses on the importance of urban high prevalence markets and incorporates influential and trusted spokespeople from within the target communities we serve.

The campaign also addresses some of the sensitivities involved with starting a conversation with consumers about HIV. Initially the campaign will be reaching out to two groups among those at highest risk for HIV, gay men and African-American women. Our activities include programs with national reach such as television and a number of more focused efforts in critical local markets. Today, 15 markets account for nearly half of our sales, and we are planning local efforts in all of these markets. Importantly, nine of these markets are additions to our earlier local marketing efforts which we piloted in the second quarter. As part of the campaign, we have teamed up with powerful and influential voices in these communities to reach consumers through testimonials, through interactive panel discussions, through shareable discussion guides and informative videos.

In addition to Magic Johnson, we have engaged television host and best-selling author, Ross Mathews; actor Darryl Stephens; television host Dr Rachael Ross; author, blogger and life coach Demetria Lucas; journalist Jacque Reid; and drag queen star Jinkx Monsoon. The campaign also uses leading media properties to communicate with these target communities including Logo TV and its online properties for the gay community, a network that reaches into over 52 million homes; and BET, Essence and Interactive One, all top-rated media brands for African-Americans. The campaign also includes high-profile consumer events as well as targeted broadcast, outdoor digital and print advertising. Although the campaign officially began on September 27, many of the campaign elements are planned to launch at various times during the fourth quarter. For example, our press tour was Ross Mathews and our TV partnership with Logo launched in September, but additional elements followed in Q4.

Similarly, radio, targeting African-American women, launched in mid-October, and the majority of our out of home and print advertising intended to reach the MSM community launched during the last week of October. For the month of October we placed about 13% of the total campaign impressions expected in the fourth quarter with the balance expected to hit in November and December. We will continue to add new elements through the first quarter of next year with the most notable first-quarter addition being our TV partnership with BET, a television network with strong delivery to the African-American community. We estimate that by the end of this year, when multiple elements are up and running, our program will have reached over 60% of the MSM community and over 40% of African American women. As we have introduced various elements of the campaign, we have started to see some positive signs.

We are driving highly interested consumers to our website, with 64% of MSM consumers visiting the site since the September 2013 campaign launch stating that they intend to purchase. This is versus 45% of our Q3 visitors and 50% of female visitors indicating an intent to purchase versus 30% of Q3 visitors. Social media mentions of OraQuick are also up and have more than doubled since the launch of the new campaign. Although our success will ultimately be measured by sales, these early signs indicate that our programs are reaching and are connecting with our targeted consumers. As discussed on prior calls, the retail environment remains challenging, but here again, I am pleased to report that we are making progress. We continue to improve store inventory levels with out of stocks known running below 5% even in our highest volume stores. This is a substantial improvement from earlier in the year.

However, significant barriers to consumer access at retail particularly in high prevalence markets continue to impact sales. An audit conducted in the first quarter of this year revealed that 23% of stores nationally and 56% of stores in high prevalence areas have some type of barrier to access at retail. These include placement of the product in locked cases or behind the counter and other that prevention devices. We place high priority on addressing these issues at retail and recently completed a substantial retail project with representatives personally calling on over 5000 stores to assess and improve retail conditions. The results from this project are still being tabulated, but we believe we have been able to improve retail placement and over 30% of the stores visited in one large retail pharmacy chain alone.

We will continue to work with the retail community at the headquarters level as well as at the store level to ensure that all consumers have easy access to our product. And finally, we continue to advance our international activities, and we are encouraged by positive signals from health authorities, advocacy organizations and retailers in key markets. I hope to have more to report on this in the near future. Turning next to our



OraQuick HCV test, total HCV sales increased 72% for the current quarter compared to last year and were up sequentially over the second quarter. As Ron mentioned, a major contributor to this growth was a significant international NGO which placed large orders for both the third and fourth quarters. There have also been positive developments on the hepatitis front since our last call.

As previously discussed, the New York State legislature passed a law early this year that would require New York health care providers to offer hepatitis C testing as a routine part of healthcare provided to baby boomers. I am happy to report this law has been signed by the Governor of New York and will take effect on January 1, 2014. We believe this law will be a model for other states and should help expand HCV testing in the future. As indicated previously, we believe the expected approval of new and more effective therapeutic treatments for hepatitis C will not only provide a significant benefits for patients suffering with the disease but will also positively impact the amount of testing for hepatitis C. As you may know, there has been some recent developments in this area as well. Earlier this month the antiviral drugs advisory committee to the FDA voted unanimously that available data supports approval of the use of Gilead Sciences sofosbuvir in combination with ribavirin for the treatment of hepatitis C in adults with genotype 2 and genotype 3 infections.

The committee also unanimously supported approval of sofosbuvir in combination with pegylated interferon and ribavirin for treatment of hepatitis C and treatment in adult patients with genotype 1 and genotype 4 infections. The committee also recommended approval of simeprevir, which is made by a Johnson & Johnson affiliate for use in combination with pegylated interferon and ribavirin for the treatment of hepatitis c genotype 1 in adults with compensated liver disease. And a final development was the FDA's recent decision to grant what is known as break through therapy designation for an oral combination drug regimen being developed by Merck for the treatment of HCV genotype 1 infected patients. This designation is significant in that it is used by the FDA to help expedite drug development for the treatment of a serious disease when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies.

And finally, the National Medical Association or NMA has just officially released a consensus panel about hepatitis C in the African-American community. As you probably know, the NMA is the largest and oldest association representing the interests of over 50,000 African American physicians. Among other things this paper recommends the broader use of rapid HCV testing to better serve the African-American community primarily because rapid testing greatly increases the probability that positive test results are actually received by the affected patient. So in view of the strong growth in our HCV sales coupled with the many continuing positive developments in this area, we believe there is much to be optimistic about for our OraQuick HCV test. And the last area I want to address is our molecular collections system business.

The third quarter was another record quarter by DNA Genotek. The company continued its strong growth trend by generating a 48% revenue increase over the same quarter in 2012. Large repeat customers in the commercial market were key to driving this growth. Although sales to academic customers worldwide were also up over Q3 of 2012. In addition to servicing the growing needs of its commercial customers in the US market, the customer also signed on new commercial customers outside of the United States, and we expect to see continued revenue growth by DNA Genotek in Q4 of this year as well as into 2014. To meet this expected growth, DNA Genotek began a manufacturing capacity expansion in the middle of 2013. This expansion which is expected to triple the company's current production capacity is well underway and projected to be fully operational in the first quarter of next year.

So as we finish the year, I believe there is much to build upon and much to be very excited about. Our new marketing campaign for the OraQuick in-home HIV test is moving into full swing and should begin contributing to higher revenues. There continues to be many positive developments that we believe will help expand our rapid HCV testing business, and we are also very pleased that DNA Genotek continues to deliver against the high expectations we set when we first acquired that business. We look forward to a strong finish in 2013, and we also look forward to updating you on our progress in future calls.

So with that, I will now open the floor to your questions. Operator, you may proceed.



## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions)

Jeff Frelick, Canaccord.

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### Jeff Frelick - Canaccord Genuity - Analyst

Could you give us a sense of maybe. Doug, just your expectations for HCV testing in New York State following the recent requirement law that was passed as we move into 2014? Does that start impacting -- does that show up kind of early 2014 or (technical difficulty)?

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

You know it is difficult to project how quickly that is going to build. You know, the law that was passed recommends one-time testing for baby boomers which there is estimated to be approximately 5.1 million in New York State alone. Census data shows New York state is the third largest baby boomer population in the country, and obviously we are working on multiple fronts to drive education of healthcare workers on the value of rapid testing. We are going to certainly average our strong position in public health, and obviously we have got to influence physician behavior. So, that is all a process.

But we are very excited about this, and we are hearing from other states and jurisdictions that they are interested in possibly considering the same kind of legislation. So we can use the HIV model going back several years when that law was first passed, and we did see a gradual uptake of that law in the state of New York in the first year. We saw overall HIV testing increase about 10%. That included both rapid and laboratory-based testing.

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### Jeff Frelick - Canaccord Genuity - Analyst

Okay. Just my follow-up, maybe for Ron, you talked about the change in revenue recognition. At the retail level are inventories is getting low, and we should we expect to see some replenishment of inventory there in the fourth quarter?

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

So Jeff, we are -- we have been replenishing inventory all along here. What we are seeing is that the replenishments are now approximating the consumption, although there are some retailers that have pockets of inventory that may be a little bit higher than ideal. And that may affect some of the purchasing, particularly in the early part of 2014 as we move to this sell in model. So I think again, I think that is another excellent point that we should all keep in mind is when we're thinking about revenues for early 2014.

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### Jeff Frelick - Canaccord Genuity - Analyst

Okay. Thanks. I will jump back in queue.

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

Thanks Jeff.

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**Operator**

Amit Bhalla, Citi.

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**Unidentified Participant - - Analyst**

Hi, good afternoon, this is [Nick Nolan] in for Amit today. Maybe first off we can talk about the fourth quarter guidance. Just to clarify, you did mention that this new accounting changes could potentially add up to \$2 million in revenue. Is that revenue number that you gave, it is probably about -- a little over \$2.5 million higher than [work] consensus or where we thought it would be. Is that all due to this accounting change or is there some acceleration in the HCV front and also in the DNA Genotek that is also in that assumption?

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

You know Nick, there is definitely, the major part is related to the revenue recognition change. And so, if you go back and you think about where consensus estimates are going into the call, in and around the \$25.3 million mark, you are talking about here now an increase of \$2 million approximately or so for the revenue recognition change which brings you up to the lower end of our guidance number. That said there are some movements around within the other parts of the business. As Doug indicated, we are expecting DNA Genotek to have sequentially up revenues. We are again expecting HCV to be up. So there is some movement around and in the various other components which get you to the guidance range of \$27.5 million to \$28 million. But to your point a large chunk of that is related to the revenue recognition change.

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**Unidentified Participant - - Analyst**

Okay. One more on the HIV front and the advertising spend there. It seems like the third quarter spend was a little less than our expectations coming in. What was your assumption of why to make the HIV spend more fourth quarter back loaded? Or what were some of the initial over the last three months, what were some of the things that came about that you thought it would be best to push that back order to the fourth quarter?

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

I'm going to defer to Kathy on that.

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

Hi, Nick. Really it was the readiness of the whole campaign. As you have probably seen and heard us talk about, there are multiple elements to the campaign. There are celebrity endorses. There is digital programming. There is radio. And it is very much a content driven strategy where we are capturing content that is really relevant and shareable by consumers. And to get that all launched in an organized fashion, we decided really the best strategy was to launch at the very end of the month, of September, the very end of the quarter, around national HIV Gay Men's Awareness Day. We picked that because we know that anchoring our launches and our programs to these key dates around HIV and AIDS really works well for us. So that was the decision to make sure everything was ready, that creative was ready. We had a good approach to roll out the different elements, and we could anchor it on that date. So we took some of the media that we originally planned for September and moved it into the fourth quarter.

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**Unidentified Participant - - Analyst**

Okay. Great. I will jump back in the queue.

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**Operator**

Shaun Rodriguez, Cowen and Company.

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**Shaun Rodriguez** - *Cowen and Company - Analyst*

OUS HCV was much bigger than we expected, and we already expected a pretty big sequential jump there because of the NGO that you called out. So is the degree -- because the degree of the sequential was more than I thought would be coming from that NGO at least initially, did they end up doing more than expected right out of the gates, or is the delta just reflecting more of a broad based demand there?

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

No, the delivery in Q3 was consistent with our expectations. I think we will see that modulate a little bit in Q4, and we expect substantial growth in the domestic number in Q4. If you kind of look year-to-date, even though Q3 was skewed more towards international as a result of this contribution from the NGO, actually year-to-date most of our revenues continue to be driven of the domestic market, about the 55% versus 45% international. So we expect good performance out of the domestic business, and we expect a good portion of that international business to repeat in Q4 as well.

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**Shaun Rodriguez** - *Cowen and Company - Analyst*

Okay. And actually related to that last point, OUS HIV was I think a bigger quarter then -- probably the biggest quarter you have had in several years. So I think you have related it to some African program. Is there any relation between that program and the international NGO that has been supporting on the HCV side, or is this completely independent?

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

No, it is completely independent. And to your point, our HIV international business through the first nine months is up approximately 7.3%. Domestic is down approximately 5%. Overall total consolidated at least on the OraQuick front is down a little shy of 4%, consistent with how we thought about the business coming into 2013 that it would be relatively flattish, up or down in the low single digit percentage range. We are pleased with the performance, really across each one of the different segments based on our original projections for the year.

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**Shaun Rodriguez** - *Cowen and Company - Analyst*

One last one before I jump in the queue. Can you just provide an update on business development discussions with potential HCV therapeutics partners.

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

I appreciate you asking the question. It's been asked on numerous calls, obviously, and we continue to be engaged with potential partners. Obviously, it is clear to us and I believe clear to the likes of the Gilead's and the J&J's and the AbbVie's that there is potential benefit in working together to expand diagnoses and the benefits of a rapid test to enable patients to receive their result and enables physicians to direct them to the next level of care as quickly as possible. So those discussions continue. I don't have anything formal to announce at this point in time, but we will continue to engage with those potential partners, and at some such time that we have more to say about it you can be sure we will.

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**Operator**

Branding Couillard, Jefferies.

**Brandon Couillard** - *Jefferies & Co. - Analyst*

Good evening. Doug, the October data out of Nielsen's suggested a modest decline in the OTC HIV sell through in October. Could you remind us what the typical lag time is between awareness and users actually pulling the trigger to buy the tests? And then secondly, I know it may be early, but a preliminary view on how we should expect the OTC HIV marketing budget to trend next year would be helpful.

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

Yes, I will put the majority of this over to Kathy, but I do want to reemphasize that this campaign kicked off in late September and October, and elements of the campaign continue to deploy. And actually they are going to continue to deploy through the fourth quarter and into the first quarter of 2014. We believe the new campaign will have a significant impact and of course we are going to continue to monitor every component of that and everything that we possibly can to evaluate effectiveness. But like I said, I will flip that to Kathy to talk about her views on the timing of impact and how these things rollout.

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

Yes, Brandon, it really depends on the consumer. We have done a lot of work understanding when you make someone aware, when they decide to purchase the product. It is different. The MSM consumer is much more aware of HIV testing, comfortable with testing behavior and our product is really a supplement largely to a behavior that already exist. So the MSM consumer we expect, once we make them aware, they will purchase in relatively short term with the one exception is if they have just tested, then they will wait a few months for the next test. Just tying to what Doug was saying, most of the impressions against the MSM target really started to hit at the end of October. We have a very focused out of home plan. We have a print advertising plan. We have a public relations plan really targeting the MSM consumer, and a lot of that, really the bulk of it hit very, very late in October and then will roll out in November and December.

So we should see that awareness build and then the pick up from the MSM consumer start. The African American consumer is a little bit different. There is less acceptance of the behavior. There is more stigma in the community and reluctance to talk about it. So our marketing approach is very different, and we actually just launched -- if you go to our website today, you will see some of the new campaign materials targeting the African American consumer. But we expect there will be a little bit more of a lag there. When we reach her with our messaging we need to talk to her a few times to get her to adopt the product. So that will also, as those elements of the campaign roll out, ultimately result in purchase, but it will take a little bit longer for her.

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

And, Brandon, I think you asked about spend levels. What I will say to that is obviously we are committed to supporting the campaign at the level that Ron described in the fourth quarter. And future spending decisions will obviously depend on how the campaign is going and what kind of results are being realized. Based on that, you can be sure that we are going to make adjustments as appropriate. So I don't want to make a commitment now to what those future spending levels are going to be. We are very enthusiastic about this campaign. We are eager to see its impact, and we will be monitoring those results very, very carefully.

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**Brandon Couillard** - *Jefferies & Co. - Analyst*

Then a quick two-part follow-up for Ron. What drove the positive operating cash flow experience in the third quarter? And then just to make sure I understand this correctly, revenue recognition changed for OTC HIV is effectively a one time catch up in nature? Is that how should think about?

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

Certainly -- let's do the latter one first. Certainly think about the revenue recognition change as a one timer, and we are expecting that to positively contribute to total revenues of somewhere in the neighborhood of \$2 million, plus, minus. And obviously the gross margin effect and the operating income effect from that. And then we will move over to the sell in model, which I think folks are more familiar with for a consumer products-based initiative. And, as I mentioned earlier to a previous question, we will see some volatility there in the early part of the year as a result of moving to this methodology which could affect our revenues because of the fact that there are pockets of inventory in some of the distribution centers, in some of the retailers that will need to be worked through before consumption mirrors sell in perfectly.

But we expect to get there. It just may be a little bit of a less predictable start than what we see now with the precise consumption data that is being tracked. Now with respect to your earlier part question, with the first part on driving positive cash flow, clearly the DNA Genotek contributed a significant portion, proportionally anyway to the operating income driving about that \$2.7 million or so of positive cash flow from operations, and OraSure Technologies drove the rest of it. We saw good performance on receivables as well as slight reduction in inventory. So just a good performance across the board.

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**Brandon Couillard** - *Jefferies & Co. - Analyst*

Thank you.

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**Operator**

(Operator Instructions)

Peter Lawson, Mizuho Securities.

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**Peter Lawson** - *Mizuho Securities - Analyst*

Just before the build out in the DNA Genotek business, what was the capacity utilization?

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

I missed the first part of that question, Peter I'm sorry.

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**Peter Lawson** - *Mizuho Securities - Analyst*

Just the capacity utilization in the DNA Genotek business, what was th pre-build out?

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

Well, the actual build out, if I am interpreting your question correctly, will not -- that additional capacity won't be available until the early part of 2014 here, coming up. So that is the additional manufacturing equipment which is going to effectively triple our existing capacity. Right now I can assure you that we have sufficient capacity to meet all of the demands that are being placed on us, both commercially and academically at DNA Genotek. We just want to certainly anticipate the future growth and provide for that.

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**Brandon Couillard** - *Jefferies & Co. - Analyst*

So you are below the 50% utilization of?



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

Of the existing? No, we are north of that. We are well north of that.

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**Peter Lawson** - *Mizuho Securities - Analyst*

Got you. And then just if you give an update around the DNA Genotek business, have new customers signed up and how the 23 and Me, Ancestry customers' doing.

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

Actually, our commercial customers including 23 and Me and Ancestry were strong contributors to third-quarter revenues as well as, just look at our top 25 customers, they represented in excess of 50% of total revenue contribution. But as we mentioned, we are capturing new customers in the commercial space on the international front, and we remain very enthusiastic about the opportunities in the academic research space despite the challenges in funding on a global level. We have seen nice growth actually in some of our rest of world activities on the academic research -- in the academic research space. And we are eagerly looking to get the product licensed or approved for sale in some additional geographies like Russia which we believe represents a significant opportunity for the Company. So, really across all segments the business is performing quite well.

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**Peter Lawson** - *Mizuho Securities - Analyst*

Great. Thanks much.

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

Thanks, Peter.

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**Operator**

Nicholas Jansen, Raymond James.

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**Nicholas Jansen** - *Raymond James - Analyst*

I think, Doug, you maybe mentioned on your discussions about HCV domestically perhaps bouncing back in the fourth quarter nicely. Just wanted to get your feedback on why that is the case. You've seen the last couple quarters be a little bit more choppy on that and. Maybe how much visibility do have in terms of a bounce back in the fourth quarter? And secondly, on the international HCV front, how sustainable do you think -- you have one NGO buying now, but what does your pipeline look like for others to think about the contribution for next year on the international front?

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

Right. So on the domestic front we see a number of drivers to increased revenues. Certainly, the fact that the birth cohort screening opportunities we believe are going to be realized. Those recommendations take effect in January. But we believe different providers, both physicians as well as on the public health front are beginning to prepare for that. We are very focused on integration opportunities with our HIV leadership position. SAMSA grantees, substance abuse and mental health services grantees awards for their HCV screening programs were made in September. And all of those awards were for rapid hepatitis C testing, and the CDC grants for this year are expected to be made in the fourth quarter. Take all of



those things together, and you can see why we are bullish on our domestic business in the fourth quarter and into 2014. And we have pretty good visibility on those opportunities and their contribution to the fourth quarter.

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**Nicholas Jansen** - *Raymond James - Analyst*

Then just on the international front, the pipeline with the other NGOs?

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

Yes, so, on the international front obviously this NGO that we captured this year, we expect is going to continue -- going to continue to be a customer. We are seeing increased interest in hepatitis C testing driven largely by the enthusiasm over the new therapies around the world, and we are pursuing a number of opportunities across multiple geographies.

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**Nicholas Jansen** - *Raymond James - Analyst*

And then, Ron, maybe regarding your comments with regards to the first quarter 2014. I acknowledge the Q4 revenue guidance includes kind of let's say a \$2 million one-timer, and then historically, Q1 declined by \$1 million to \$2 million sequentially. Anything else we should be thinking about there in terms of maybe framing the magnitude of the sequential decline that you might be trying to get out to the street?

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

I think you touched on the relevant points. One is that the one-time nature of the adjustment that we put through for the revenue recognition change. So if you start with the basis of the \$25.3 million you had for consensus is estimates for the fourth quarter, and then you look at a sequential decline as you move into the first quarter of 2014 which we have seen historically be in the range of a couple of million dollars or so. You start to get into what might be a reasonable neighborhood for revenues for the first quarter of 2014, particularly when we still have to gain some visibility as to exactly how that recognition policy change is going to affect the first quarter as we spoke about. So that is pretty much the color would share with you here at this point in time, Nick.

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

I think you go back and look at the quarterly splits and the revenue make up going back to 2012 and the early part of this year. And you can see primarily in the infectious disease and cryo space, like Ron talked about previously, that those businesses tend to be lower in the first quarter, and that would be our expectation for Q1 of 2014.

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**Nicholas Jansen** - *Raymond James - Analyst*

Okay. Maybe if I can squeeze one more in on gross margins, I think they were a little bit better than what we were anticipating and certainly a good performance relative to the year-to-date trends. Remind us how we should be thinking about that going forward and maybe just the opportunities, longer-term with HCV growth and with the earlier royalties going away in 2015.

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

Yes, that is a big one, the latter one that you mentioned, Nick. That obviously will roll off in February of 2015, and we certainly are looking forward to that. I do believe that continued growth in DNA Genotek as well as continued uptake in HCV will be positive contributors to our gross margin as well as more efficient and effective manufacturing operations and reduced scrap and spoilage which we have been enjoying as of late, so all



positive contributors to our margin. That said, obviously the mix issue continues to be there and to be present, particularly as you sell more of our cryo OTC products. That definitely has a deductive effect on gross margins in the quarter in which we load that up.

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**Nicholas Jansen** - *Raymond James - Analyst*

Thanks guys. Nice quarter.

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

Thank you.

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

Thanks, Nick.

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**Operator**

Thank you. There being no further questions, I will turn the conference back to Mr. Doug Michaels for closing remarks.

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

Okay. Once again I want to thank everyone for being on the call is afternoon. Look forward to a strong finish to 2013 and look forward to speaking to you again next quarter. Have a good afternoon and evening, everybody.

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**Operator**

Ladies and gentlemen, thank you for your participation in today's conference. This does include the program, and you may all disconnect at this time.

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

Thank you.

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