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OSUR - Q4 2012 OraSure Technologies, Inc. Earnings Conference Call

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PRESENTATION

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

Good afternoon, everyone, and welcome to OraSure Technologies 2012 fourth 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)

OraSure Technologies issued a press release at approximately 4.00 pm Eastern time today regarding our 2012 fourth quarter and full-year financial 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 news 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, February 13, 2013, by calling 855-859-2056 for domestic or 404-537-3406 for international. The access code is 87367276.

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 this call may contain certain forward-look 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 statements, its annual report on Form 10-K for the year ended December 31, 2011, 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 under takes 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*

Thank you, Judy, and good afternoon, everyone. Welcome to our call. We finished 2012 on a positive note. Both company's revenues and net loss for Q4 came in above our guidance and our consolidated full-year revenues exceeded 2011. We also had some notable developments in 2012. As you know, last year, we achieved the most significant milestone in our history when we received FDA approval of our OraQuick In-Home HIV test and we began selling this exciting new product to consumers. As I will discuss later in the call, the commercial launch of this product is going well with weekly consumer purchases increasing in response to promotion.

As Judy mentioned, Kathy Weber, OraSure Senior Vice President and General Manager of Consumer Products is here with Ron and me this afternoon, and Kathy will be able to respond to any questions you may have about our over-the-counter efforts during the Q&A session. 2012 was also the first full year of contribution from our molecular collection system subsidiary DNA Genotek. DNA Genotek performed well in both the commercial market and the challenging research and academic market. We are excited about the future of molecular diagnostics and DNA Genotek is well positioned for growth in 2013 and beyond. So with that, as a brief introduction, let me now turn the call over to Ron for his financial review.

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

Okay, thanks, Doug, and good afternoon, everyone. Our fourth quarter 2012 consolidated revenues were \$22.1 million, compared to \$23.7 million reported in 2011. Our consolidated product revenues decreased 7% as a result of the lower sales of our substance abuse cyrosurgical systems and insurance risk assessment products. These decreases were partially offset by higher sales of our infectious disease products and higher molecular collection systems sales. Our infectious disease testing revenues were \$11.8 million in the fourth quarter of 2012, compared to \$11.6 million in the fourth quarter of 2011. The overall 2% increase was primarily a result of the inclusion of the first sales of our OraQuick In-Home HIV test and higher OraQuick HCV sales, partially offset by lower OraQuick HIV professional sales.

During the fourth quarter of 2012, gross sales of our OraQuick In-Home HIV test were \$902,000. Under applicable accounting rules, this amount was offset by trade spend, discounts, and returns and allowances, resulting in net revenues recorded of \$546,000. Fourth quarter domestic HIV revenues were down \$618,000 or 6% due to various factors including changes in public health testing programs and their timing of purchases, reductions in government funding, price competition, and a shift to automated laboratory-based blood tests by some customers. Our international HIV revenues increased \$52,000 to \$773,000 in the fourth quarter of 2012. Fourth quarter domestic HCV revenues increased \$421,000 or 99%, largely as a result of broader adoption of our product by domestic customers who are able to use a CLIA-waived product. Internationally HCV revenues for the fourth quarter remained approximately the same when compared to the fourth quarter of 2011.

Our molecular collection systems revenues primarily representing sales of the Oragene product line increased slightly to \$4.3 million in the fourth quarter of 2012 compared to \$4.2 million in 2011. Revenues for the prior year quarter included a \$1.5 million purchase by DNA Genotek's largest customer which did not repeat in Q4 2012. In substance abuse testing, our revenues decreased to \$2.1 million in the fourth quarter of 2012 from \$3.5 million in the fourth quarter of 2011. Primarily as a result of lower Intercept sales and lower sales of our QED point-of-care saliva alcohol test. Fourth quarter 2011 QED revenues were unusually high to our fulfillment of an order backlog resulting from production issues that were resolved in October of 2011. The decrease in Intercept sales was the result of lower purchases by our largest domestic laboratory distributor who began selling its own competitive oral fluid drug testing system at the end of 2011 and lower international sales due to a reduction in purchases by our UK laboratory distributor.

Fourth quarter 2012 cyrosurgical revenues decreased 14% compared to the fourth quarter of 2011 primarily as a result of lower over-the-counter sales and lower professional sales in the international marketplace, partially offset by an increase in professional sales in the domestic market. Our OTC cryo sales during the quarter decreased \$523,000 when compared to 2011, largely as a result of the timing of distributor purchases and the resolution of certain regulatory issues that increased sales in the prior year period. Overall, professional cryo sales increased by 4% to \$2.2 million due to distributor ordering patterns in both the domestic and international markets. Turning to our gross margin, our overall margin for Q4 of 2012 was 60%, compared to 62% reported for the fourth quarter of 2011.

The lower margin in 2012 was the result of an unfavorable change in product mix and a decline in the absorption of labor and overhead cost related somewhat to the impact of Hurricane Sandy. Our consolidated operating expenses for the fourth quarter increased \$4.5 million or 30% compared

to the fourth quarter of 2011. R&D expenses decreased from \$3.3 million to \$2.9 million for the quarter due to lower clinical trial costs associated with our OraQuick In-Home HIV test and lower international product registration costs. Sales and marketing expenses were \$11.6 million for the fourth quarter, an increase of \$5.2 million over 2011 due to the inclusion of \$5.2 million of costs related to the commercialization of our OraQuick In-Home HIV test. G&A expenses decreased from \$5.2 million to \$4.9 million due to lower legal, accounting, and consulting fees. So from a bottom line perspective, we reported a net loss of \$5.9 million or \$0.11 per share for the fourth quarter of 2012. Compared to net income of \$115,000 or \$0.00 per share for the same period of 2011.

Turning briefly to our balance sheet and cash flow, our cash balance at December 31, 2012, was \$87.9 million compared to \$23.9 million at December 31, 2011. We completed a secondary stock offering in Q3 of 2012, which increased our cash balance by approximately \$70 million. Cash used in operating activities in the fourth quarter of 2012 was \$1.4 million compared to \$1.1 million of cash generated from operating activities in the fourth quarter of 2011. Turning to our guidance for the first quarter of 2013, we are projecting consolidated revenues of approximately \$20 million to \$21 million and a consolidated net loss per share of approximately \$0.18 to \$0.19 for a quarter. Revenues projected for Q1 of 2013 are sequentially down from our performance in Q4 of 2012, primarily as a result of lower infectious disease product revenues, partially offset by higher HIV-OTC sales.

Q1 has historically been the softest quarter of the year for our base infectious disease business while Q4 has been the strongest. Additionally, we did see a somewhat higher than expected Q4 2012 buy-in from our domestic professional cryo distributors in advance of a price increase that took effect in early January 2013. From a profitability perspective, the medical device excise tax and higher royalties under the terms of our settlement agreement reached with Alere in 2009 are included in the cost of goods sold for the affected products. We believe that our ongoing gross margins should be in the upper 50% range. We will also be investing \$7.3 million in Q1, 2013, to support our direct-to-consumer advertising campaign for the OraQuick In-Home HIV test. And with that, I will now turn the call back over to Doug.

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

Thanks, Ron. You know, much of our recent focus has been on commercializing our OraQuick In-Home HIV test. We are very pleased with the progress to date. Consumer purchases are responding to our national PR and advertising campaigns with sales increasing on a weekly basis. As you may recall, we initiated our national TV advertising in December and as a result, weekly consumer sales during December grew 30% over the comparable levels in November. In January, we increased the frequency of our TV spots and consumer sales were up 40% over December. Consumers are now purchasing about 4,000 units per week compared to about 2,000 units per week in November of last year and we are seeing similar growth in internet sales through our website.

TV promotion is an effective tool to generate broad awareness to a large population such as sexually-active adults. It is clear from our results to date that our advertising is working. This week, we are taking steps to make our TV promotion more efficient by introducing shorter-duration advertisements, for example, 15- to 30-second spots versus 45 seconds into the mix. This allows us to increase both the reach and frequency of our advertising at the same cost. And we also continue to supplement our TV advertising with digital and print media, which are an efficient and effective way to communicate with our target customers. In addition to national TV advertising, our promotional campaign will soon incorporate more locally based on-the-ground tactical marketing. Examples include promotion at music festivals and gay pride events and the use of local radio ads and increased local signage and banners.

Initially, these local activities will occur primarily in 6 to 10 urban areas that have the largest populations of our target consumers. We will also continue working with Magic Johnson to supplement our awareness efforts during 2013. In evaluating our progress, one thing to keep in mind is the expected purchase cycle for our tests. Based on market research, we believe there is generally a lag between when many customers first become aware of the product and when they decide to purchase. In some cases, this lag can be several months and this obviously impacts our sales growth rate and is a major reason why our advertising is focused on building broad consumer awareness. This also highlights the importance of continuing to keep the brand message in front of the consumer.

On the sales side, each of our major retailers such as CVS, Rite-Aid, Wal-Mart, and Walgreens remain highly supportive and are pleased to see that sales are increasing in response to our promotional efforts. With respect to internet activity as of mid-January, we had almost 500,000 unique visitors to our OraQuick.com website. We estimate about 50% of this traffic comes through mobile devices such as smart phones and tablets. We



believe this reflects the effectiveness of our ad campaign and in particular, the use of various types of digital media. In the near future, we expect to launch an app for mobile devices which will allow consumers to find a local retailer carrying our product to watch a demonstration video, a product demonstration video, or to visit our website to make a purchase.

A final area I want to address is our consumer support center which is functioning well and is exceeding our performance goals. Approximately 85% of calls are received between the hours of 7.00 am and 10.00 pm and our average response time is about 5.8 seconds. The types of calls received have shifted from asking about price and product availability to usage of the test and interpreting results. Importantly, we have received a minimal number of product complaints and this suggests that consumers are able to use the product properly. Additionally, consumers testing positive with our product are using the medical provider referral services offered by our call center.

So in summary, our efforts to commercialize the OraQuick In-Home HIV test are progressing quite well. Our awareness and consumer activation efforts through TV and other promotional activities are proving effective as they stimulate sales growth and we expect this trend to continue as we execute against our strategies throughout 2013. With respect to our OraQuick HCV test, we are encouraged by the substantial growth we experienced during 2012. Revenues for this product were up 44% for the year compared to 2011. However, we still have higher expectations for this product and our sales and marketing group will continue to focus on market development, especially in the public health, hospital, and physician office markets. During the fourth quarter, we were pleased to see that several major organizations including the American Association For the Study of Liver Disease, the Infectious Disease Society of America, and the National Viral Hepatitis Roundtable announced their support for the CDC's new guidelines recommending that all baby-boomers receive a one-time test for HCV.

In addition, the United States Preventive Services Task Force, USPSTF, issued new draft recommendations for HCV testing during the quarter. In these draft recommendations, the USPSTF gave a B grade to HCV testing for persons who inject drugs or are otherwise identified with risks for infection. This is significant in that at-risk HCV testing previously had a C grade and a B grade or better is generally needed from the USPSTF before physicians will offer the service consistently. So this change should result in greater HCV testing, particularly among individuals at risk for the disease. Moving from our newer products, I want to briefly comment on our professional HIV and our substance abuse testing products. As noted in prior calls, our professional OraQuick HIV business has been impacted by reduced government funding and increased competition. This is likely to continue. The availability of government funding is particularly important in the public health market and may come under even greater pressure if the mandatory cost reductions occur under federal sequestration.

In substance abuse was discussed on prior calls, we have experienced delays in our development efforts for high through-put assays primarily because Roche has been unable to obtain FDA clearance of an assay for THC or marijuana. We are in discussions with Roche about this development effort and the future of our collaboration. Finally, turning briefly to our molecular collection system business, DNA Genotek had a strong fourth quarter and year 2012. New orders were higher than in 2011 and the company continued to deliver product to large commercial customers whose test offerings are seeing increased adoption in the genetic testing market. In addition, the academic research market, which has long been a core area for DNA Genotek, has continued to deliver solid revenues despite a less-than-optimal funding environment. DNA Genotek had a particularly strong quarter in the European research market during Q4. We remain enthusiastic and confident in the growth prospects for DNA Genotek. The company's largest customer recently confirmed that it will make a substantial purchase during 2013 and another long-standing customer in the UK recently signed a multi-year supply agreement.

These activities, when combined with the increase in new customer orders during 2012 and some new products under development, have set the stage for what we believe will be a strong 2013 from DNA Genotek. So in conclusion, now that 2012 is complete, our focus for the new year is on execution. We will continue to devote significant time and resources to making our OraQuick In-Home HIV test a commercial success and we will also focus on expanding sales of our OraQuick HCV product and improving the performance of our professional HIV and substance abuse businesses. We look forward to discussing our results on future calls. And with that, I'll now open the floor to your questions. So, operator, proceed.



QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Amit Bhalla, Citi.

Amit Bhalla - Citigroup - Analyst

The first question on OTC-HIV. You talked about 4,000 units per week that you're selling in the first month of the year. Can you talk about the mix between online versus retail and give us any color you can on how you're thinking about the product for the first quarter of the year in the context of your guidance.

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

Sure. This is Kathy. I'll take that call. On the first part of your question on e-commerce, we have a very healthy e-commerce business. It is running at a rate that's higher than what I've seen in other OTC healthcare categories and I think that makes sense given the concerns around privacy and the emphasis we've put on digital advertising and online support so we're seeing a very strong correlation between our digital activity and our online sales. So it is running at a higher rate than our -- than I've seen in the past. In terms of expectations for the quarter, I'd characterize sales as building as expected. And I think you have to think about what we're really doing here with this launch. We're building a new brand. We're building a new category, and we're building a behavior that consumers have never taken on before in terms of testing for HIV and, you know, in their own home. And that will take some time and some investment but when you do it right, when you build a brand like that, you're creating an annuity that will deliver in the short term and deliver in the long term.

I've had the privilege of working on brands that are 20, 30, even 100 years old, delivering profit and revenue growth even at that point in their career. But I think the key is doing it right from the beginning, and I do believe that we're doing this right. I think that when I look at what has been done here, we have a very large pool of potential consumers and that's one of the first criteria to see, you know, are your sales going to build? Do you have consumers? We also have a product that has such a clear and differentiated benefit and that's another, you know, key criteria for a successful launch. We have a very solid and stable distribution network.

Doug talked about the relationship with our retail community and they are very, very supportive of this and they are watching the product move up the rankers in terms of the SKUs that fit in the different sets at retail. They're seeing it move up the rankers and we have resources to invest in the launch. Ron talked about the first-quarter investment. So long answer to your question, the sales are building as expected and I expect them to continue to build behind this support we're putting out there and this support structure, this infrastructure, that we've built to drive this brand.

Amit Bhalla - Citigroup - Analyst

And then a follow-up for Ron. Ron, on the gross margin, in the current quarter, it definitely look like a mix played a role, the cryo business compared to last quarter was a much smaller portion of total revenues in the quarter. When we look to first quarter, you did say you're look for upper 50s% in gross margin. That's lower than we would be expecting for the first quarter of the year. Talk us through what is happening in your business to lead to the first quarter margin guidance.

Ron Spair - OraSure Technologies, Inc. - COO and CFO

Sure, so we have to focus on a couple of different areas. One of them is the imposition of the medical device excise tax, which of course was not in play for Q4 of 2012. And then other contributing part is the imposition of a higher royalty rate pursuant to the agreement that we entered into



with Alere on -- back in 2009 which kicks up that rate and that, combined with the medical device excise tax, has drawn our gross margins down accordingly.

Amit Bhalla - Citigroup - Analyst

What can you quantify those? Those are two discrete items so ex those, what would be your margin?

Ron Spair - OraSure Technologies, Inc. - COO and CFO

We would be back up into the same neighborhood, margin-wise, as we were previously so they are probably looking at something on the order of, depending upon mix, obviously, somewhere in the 400 basis points of margin degradation across those two items.

Amit Bhalla - Citigroup - Analyst

Okay, thanks, Ron.

Operator

Jeff Frelick, Canaccord.

Jeff Frelick - Canaccord Genuity - Analyst

Could you give us say maybe a little bit more color just around HCV sales, given the -- we saw a nice pick up there in the US, but just some color around the characteristics of using it, are you seeing repeat orders in the same practices, are they you know, directing the testing towards baby boomer populations? Anything along those lines would be helpful.

Doug Michels - OraSure Technologies, Inc. - President and CEO

No problem, Jeff. We did see an increase both domestically and international in the fourth quarter, and the largest percentage of revenues in the US market really came out of the public health market. So that's where we're seeing the growth in the business at least for the time being. Physician office revenues were relatively flat. We are servicing right now an excess of 200 customers on a quarterly basis and a large percentage of those are repeat purchases. So we continue to see, you know, extreme, extremely high level of interest in testing, as I mentioned before. Obviously, it's not a question of the will to test or the desire in the public health market for sure. It's really the issue of funding, which we're also working on both at the, you know, legislative level, as well as working with the different jurisdictions to try to see if we can't free up some moneys and other budgets to help fund increased testing.

Jeff Frelick - Canaccord Genuity - Analyst

Okay, and just in keeping with Judy's wishes, one follow-up, can you just give us an update on the physician office distributor training? Where you are with training all your partners there?

Doug Michels - OraSure Technologies, Inc. - President and CEO

Good question and very timely. We were just -- just this last week out with one of our major distributors, you know, conducting refresher training. We had done all the physician office training -- distributor training mid-year 2012, but obviously, you know, they've got a big bag of tricks and so



they're very committed to this product and had our whole team out at one of our largest distributor partners just this last week and we'll be following up with the rest as they conduct their annual meetings and regional training meetings throughout the year.

Jeff Frelick - *Canaccord Genuity - Analyst*

Great, thanks.

Operator

Peter Lawson, Mizuho Securities.

Peter Lawson - *Mizuho Securities - Analyst*

Just getting back to the question around the OTC-HIV business, is it possible to get a break out how much came from traditional brick-and-mortar versus the online channel?

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

You know, we -- Kathy?

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

Yes. I can show the number. It's double-digit percent coming from the online channel and that includes our own online channel, as well as retailers' online channel.

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

Obviously, Peter, that's continued to come down since the beginning of the launch when the product was only available online and as unit volume has continued to grow at retail, the percentage, being serviced through OraQuick.com or CVS.com, which are the two main channels right now, has continued to decrease. At this point in time, it's in the low double digits. Whether it goes down into single digits, I think remains to be seen. I would say it probably will as we continue to, you know, grow our sales in the retail channel.

When we began this effort, we talked to the retailers and they indicated that they had very few SKUs that generated more than 2% to 3% from online sales. But this product being a little bit different than most consumer health care products than consumers with wanting confidentiality and discretion in purchase, we anticipated percentage of revenues coming online would be higher than the norm. And obviously we're seeing that right now. Where it ultimately settles out, I think that's TBD. It will probably be up in the mid-to-high single digits as a percentage of total revenues but we'll try to give you some color on that as things progress.

Peter Lawson - *Mizuho Securities - Analyst*

Got you. How do you think that business performs in 1Q the entire OTC-HIV business? Do you think it grows from 4Q or was there kind of a stocking or bonus of orders in 4Q that wouldn't repeat?



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

So, Peter, as far as the revenue recognition that we employed for the fourth quarter, it's all about the sell-through so we actually recognize revenue when it's consumed at retail or sold over the internet as opposed to stocking orders, which might be the traditional consumer products methodology of revenue recognition, and so consequently as Kathy indicated, our expectations are that consumption at retail and over the internet will continue to increase as we progress throughout the year and so it is absolutely our expectation that the first quarter revenues recorded by OraSure are going to be, you know, well north of where we were in Q4 of 2012.

Peter Lawson - *Mizuho Securities - Analyst*

Got you. Do you know any feeling of seasonality in that business?

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

What we've learned that the -- it doesn't appear to have seasonality. Just look at the category, doesn't appear to be seasonality. The biggest driver of the business is the promotional support, and that makes sense because the challenge here, what we need to do is build awareness. We need to get the message out there to the consumers, and we have found that the product is tremendously sensitive to our promotional efforts and as Doug mentioned, we're expanding our advertising program in the first quarter. We'll be moving to 30 and 15 second television spots, which allows us to get that message out there to literally hundreds of millions of people. And that is the biggest driver of the, you know, the rate of sales and what we've seen. So long answer, no seasonality that we've seen, more promotionally sensitive.

Peter Lawson - *Mizuho Securities - Analyst*

Great, thanks very much.

Operator

Shaun Rodriguez, Cowan and Company.

Shaun Rodriguez - *Cowan and Company - Analyst*

On the HIV professional business, you noted funding and algorithm changes that impacted the business in 2012 and although it looks like Q4 recovered a bit on a sequential basis, looking forward, maybe Doug, I'm wondering if you should share your thoughts specifically on the potential impact of the recently PMA approved DTP product that look likes it could get a CLIA waiver in the coming months and I guess specially the impact on share and pricing as you look at the outlook there.

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

Yes, you know, it's always very difficult to predict the impact of new product entrance. This product, in particular, received approval for an oral indication. It is not yet CLIA waived. I don't expect it will be CLIA waived until later in 2013, if at all. There's very little information in the marketplace about the product other than approved performance claims for professional use, which are actually inferior to the OraQuick HIV test. You know, the OraQuick HIV test has been the standard in the industry for years and continues to be, despite significant competition.

There's at least half a dozen other rapid blood tests that have been approved for some time. They're CLIA waived. Generally, they're being sold at lower price and despite that, the customers have chosen our technology over significant number of other competitors. We believe that understanding how this new test is performed. It has multiple steps. Obviously I mentioned its sensitivity and specificity profile is not as robust as our product and



it's not CLIA waived so at this point in time, I don't expect a significant impact from it. We'll see as the year progresses what develops, but our customers are very satisfied with our product and continue to support the technology.

Shaun Rodriguez - *Cowen and Company - Analyst*

Okay, great. That is very helpful. And then maybe jumping to HCV, although it was an up grade from the USPSTF, it does appear some in the community were disappointed that the task force wasn't as aggressive as CDC in recommending universal screening so I guess another one for Doug. Could you just share your thoughts on this, whether you think the task force might change their rating following the comment period and I guess most importantly, your views on the impact on this just slight discrepancy between the agencies and the impact it might have on uptake.

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

Once again, you know, the community was pretty vocal in encouraging the task force to reevaluate their rating on the birth cohort testing recommendation and at the same very encouraged that finally encouraged the USPSTF upgraded their what had been a C rating for individuals at risk to a B. The almost coincident with this rating change that the same task force finally aligned their recommendation on HIV to recommend routine screening for individuals ages 15 to 65 with the CDC HIV recommendation for routine screening, which goes back to 2006.

It seems like, unfortunately, this task force is a step behind our nation's preventive services agency in terms of staying on top of state-of-the-art health care recommendations. I think the positive development here is that it's on the task force's radar. We now have a positive recommendation for individuals at risk. I'm highly confident some time -- I don't know how. I can't speculate how quickly, but they will upgrade their recommendation for birth cohort testing and all that is going to benefit us both in the near term and longer term, and clearly the community is behind trying to get this recommendation changed, as are we and other folks that are operating in the space including the therapeutic providers.

Shaun Rodriguez - *Cowen and Company - Analyst*

Thanks very much

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

You bet.

Operator

Jon Wood, Jefferies.

Brandon Couillard - *Jefferies & Co. - Analyst*

Hey, good afternoon. It's Brandon Couillard in for Jon. Ron, in terms of the OTC-HIV, I guess, contra revenue effects in the fourth quarter, can you give us a breakdown between the trade spend, the discounts, and then the returns/allowances?

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

Sure. Trade span was approximately \$250,000. Cash discounts were approximately \$90,000. And returns and allowances were about \$15,000. And I would like to just point out that the cash discounts represented the cash discounts that were attributed to the sell-in of the total pipeline fill so that is not going to be a recurring charge in Q1 and will start up again when we begin heavier shipments of product back into the trade once

they've exhausted their inventories. Similarly, trade spend is a function of the amount of product acquired by the retail trade and again was based on an allowance keyed off of the total product shipped in.

And according to our calculations, the trade spend in Q4 pretty much was exhausted against the allowance that was calculated on the amount they purchased so again, we don't see or anticipate that -- anywhere near that level of trade spend being deducted from revenues in the first quarter of 2013 here. So the gap between gross revenues and net revenues will be much closer in Q1 and going forward than it was in Q4. This is really a by-product of some of the accounting anomalies for our company versus a standard consumer products company.

Brandon Couillard - *Jefferies & Co. - Analyst*

All right, thanks. That's helpful. And then Doug or Ron, I mean, could you give us an update on where you stand with your efforts to replace Merck as a marketing party for the HCV product in the US?

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

Yes, absolutely, and I think, you know, we have said in previous calls and I know that one-on-one that we discontinued the Merck relationship primarily because it had some restrictions that kept us from working with other pharmaceutical companies in the HCV space. You know, that market continues to be pretty dynamic, and one of the things that we want to avoid is tying ourselves to one drug supplier and restricting our ability to work with others. That being said, we're engaged right now in active dialogue with all of the, you know, normal suspects, including Gilliad and BMS and J&J and others. We're having productive discussions, and as we have more to share about any one or more of those, we'll certainly share it as appropriate.

Brandon Couillard - *Jefferies & Co. - Analyst*

Thanks. And then, Ron, in terms of the first-quarter revenue outlook, I mean, could you carve out where you see the biggest swing factors that we should be aware of, whether it's on the HIV-OTC professional side or the cryo or the Intercept business, I guess the largest deltas on a sequential basis.

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

Right. I think what you'll see is that the infectious disease business, like we spoke of in the script itself, will be softer than Q4, Q4 being our strongest business for -- the strongest quarter, excuse me, for infectious disease. We'll see a downdraft in revenues from that core area of our business, offset by a nice uptick in our HIV-OTC revenues in the first quarter versus the 546 we reported net in Q4 of 2012. Our substance abuse business again down slightly in Q1, as well as cryo again, more of a seasonal impact as far as that business, which typically starts to ramp back up as you move into the warmer months of the year. So I would say that that's generally some color commentary on the moving parts although we don't give specific guidance on from a revenue perspective by business segment.

Brandon Couillard - *Jefferies & Co. - Analyst*

Lastly, the large DNA Genotek order you called out that you anticipate in 2013, any comment around either the magnitude of that anticipated order or the timing?

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

The order is in hand and we would anticipate that we would deliver that over the course of 2012 or 2013, consistent with our customer's demands, which they have the right to alter based on some of their -- the uptake of their end-user requirements. So we've not disclosed the magnitude of



the order size, but it is a very nice chunk of business from our largest customer, and, you know, reaffirms the continuing relationship that we have with them and the value of our product to the organization.

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

I also want to highlight and expand a little bit on some of my comments about DNA Genotek. They had a very strong year in 2012 on the commercial side of the business, and I think most of us are aware that the academic research market for the last couple of years has been, you know, challenged with some of the same funding issues that governments have and that we're seeing over on our professional side of our business. Despite that, the company performed well on the academic research space and actually, if we look at the number of new customers and their order intake in 2012 versus 2011, it was actually up in double digits on a percentage basis.

What we did experience were smaller order sizes from that increased customer, that larger customer base on the academic research side of the business primarily because, obviously, funding was reduced so the institutions had to conduct smaller studies. But there's still a strong demand for DNA Genotek's technology, and it's on the basis of a growing customer base both in academic research, as well as the good progress that they made on the commercial front that we anticipate seeing very strong growth from DNA Genotek in 2013. Consistent with our expectations when we made the acquisition a year and a half ago, but real pleased with how things are moving along there and expect a good year from them.

Brandon Couillard - *Jefferies & Co. - Analyst*

Great, thank you.

Operator

(Operator Instructions)

Nicholas Jansen, Raymond James.

Nicholas Jansen - *Raymond James - Analyst*

Hey, guys, a quick question on the core professional HIV business. You know, it was down about 12% in 2012. Certainly there's a sequestration that's looming and we're not sure if that's going to be overturned or not. What do you think about a reasonable expectations for us to kind of think about in terms of the magnitude of the revenue decline in that business in '13?

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

Yes, so obviously I think you have to look at it two ways. Let's just talk briefly about sequestration. I think that nobody knows whether sequestration is going to become a reality. You know there are a lot of models out there right now. The assumption is if sequestration were to occur in March, you know, everybody's modeling things off on 8.2% impact in terms of funding levels and that's against -- generally against the 2012 funding levels. You know, there was a continuing resolution passed in September of 2012. As that trickles down through the different agencies, to HHS, that gets whacked up between the different agencies funded within HHS, CDC being one of them, and obviously then you get down to the CDC prevention program.

If you look at total spending by the CDC for HIV prevention, it's in the \$800 million range. Those dollars go to a broad range of different activities including education, research, evaluation, and how those cuts get divided between those different programs is a TBD. You know, I couldn't even speculate on it. I was looking at minutes from the end of October advisory committee to the director and even Tom Frieden, when asked directly about sequestration, he said in the event of these cuts, each division and branch in CDC will determine how to preserve its essential function with minimal damage.



You know, he's not even out there giving any kind of guidance on how the CDC's going to whack up any kind of budget cuts so for me to make any projections, sorry. You know, I can only tell you what -- what's going on a high level that you're probably well aware of. Our projections for the HIV professional business in 2013 is that it's going to be relatively flattish from where we were in 2012.

Nicholas Jansen - *Raymond James - Analyst*

That's helpful. And then briefly on HIV-OTC, I think last quarter you talked about \$16 million to \$17 million of kind of spend to really build awareness. I was wanting to make sure that number still applies. Seems like the \$7.3 million for the first quarter is high but I know you guys were talking about kind of front-end loading it so maybe just talk about the cadence of spending on HIV-OTC? Thanks.

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

That's a great question, Nick. Thank you. It's consistent. The disclosures we made in Q4 are consistent with where we are today. I think we're looking at spending in, you know, upper teens of millions as we talked about last time with the front-end loading of that expenditure in the first half of 2013 here.

Nicholas Jansen - *Raymond James - Analyst*

Thanks much.

Operator

Jeff Frelick, Canaccord.

Jeff Frelick - *Canaccord Genuity - Analyst*

Oh, yes, thanks, just a quick follow up. Ron, you talked about the lower expectations for gross margin going forward. I wanted to -- royalty payments to Alere-- I assume those will -- that's around a lateral flow pattern which expires in 2015 so should we expect gross margins to them not creep back up into the low 60s?

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

Yes, Jeff.

Jeff Frelick - *Canaccord Genuity - Analyst*

Okay. And then maybe just one follow-up for Kathy. Maybe just speak to the trends you are seeing in the first quarter roll out with the OraQuick home test, maybe relate that to your professional experiences around any other consumer product that may look similar to this. I know it's unique but anything you can tie to a product that you've seen in your history. Thanks.

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

Yes. I would say -- we talked a little bit about the trend we're seeing in accelerating growth rate. So 30% December over November. 40% January over December. And that's, you know, that's largely driven by an increase in spending, an increase in messaging out to the consumer. And I think that's the piece that, you know, based on my experience, when you're trying to build something new, and again, as I mentioned before, we're



building a whole new behavior. It's a whole new brand for the consumer space. It's a whole new behavior, getting that awareness message out there is key. And we have a pretty broad group that we're targeting to get the awareness message out there.

The one learning, and Doug alluded to it in his opening comments a little bit, is that we have done a fair amount of research with our target consumers and we've learned that there is a lag for certain groups. There's a lag between when they become aware of the product and when they say they'll go and purchase it. You know, not surprisingly among different targets, so the MSM population, they have a certain awareness already of this product and of testing behavior and so they may purchase on a different cycle. An African-American who is less aware of this may have some cultural -- there may be some cultural stigma. Needs a little more time to work through that cycle. It may be a month. It may be six months between when they find out about the product being aware and they're positively predisposed to the product but when they actually purchase.

What I can say just based on seeing that information, knowing what I know about building awareness with consumers, I think we're going to see the sales rate continue to accelerate as we get the awareness out there to a larger population of people and then people start moving through that purchase cycle. Doug talked a little bit about, you know, the next layering of consumer activity and that's another key in my experience. The more you can layer and integrate your activity, the more successful you will be. We are now moving from the first layer, with which was national PR, national advertising, into these local market activation efforts. That's what I call them. The purpose of those is to move people through that purchase cycle to, you know, they become aware of the product and then you get almost in a conversation with them.

You use tools like, you know, local DJs. DJs that they are familiar with. You go into the community, into events that they may be frequenting whether it's a gay pride event or a music festival, but places where these communities are and you talk to them in a very conversational way, for lack of a better word, and that's what we're moving into as well in our market plan. And so again, building the awareness, getting these local activation efforts in place, and moving people through that purchase cycle. I think that's what's going to drive success. That's our plan and, you know, now it's a matter of just executing it.

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

And I think it's important, Jeff, to you know, to be reminded that that's exactly what we have been executing against since the beginning. We started with PR because we had to get the word out, you know, very broadly. PR is a little bit less specific. We wanted to make sure that we were in distribution, that we were solidly available, consumers had access. That was in place and then Kathy came on and evaluated everything and you recall, we were going to go out with TV in January. And she came in and said, hey look, we're ready to go. Products available, the message is working, and if we can just bump up the exposure, we're going to go into -- we're going to finish 2012 in a good position and have wind in our sails going into 2013.

We turned on the advertising in December. She talked about the great response we had from that. And then we bumped it up even more in January and we got another corresponding response and now, and now we're going to get more reach and frequency by shifting some of our advertising dollars from 45 second spots to 30 and 15, which gives us more exposure to more consumers and supplement that with the end-market activation activities. That's why we believe, we're highly confident. I don't want to speak for you, Kathy, but you have done this a million times. We're going to see this kind of growth through the first quarter and really through 2013.

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

Yes. And I do -- I do believe, I am very confident in this. It is based on seeing a lot of launches go successfully and fail. And I talked about it a little bit at the beginning, but we have such a good target, a good pool of consumers. We have a unique product, and it really is ground breaking in terms of the benefit it brings to the marketplace, and I wouldn't underestimate how stable and solid the distribution network is. I've been working with CVS, Wal-Mart, Rite-Aid, Walgreens for years and the levels of distribution we have and their willingness to partner with us and find ways, creative ways to give the product visibility in store and participate in these local activities. They want to participate as well. And then the investment. I mean, those are the criteria for a successful launch and I think we have them all. It's just a matter of executing and getting it out in the marketplace.



Jeff Frelick - *Canaccord Genuity - Analyst*

Thank you.

Operator

That brings an end to the Q&A session for 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 with us this afternoon and this evening. We look forward to catching up with you again at the end of our first quarter results and talking about how the first quarter went in a few months. Have a great night, everybody.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This concludes today's program. You may all disconnect. Everyone, have a great day.

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