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OSUR - Q4 2011 ORASURE TECHNOLOGIES, INC. EARNINGS CONFERENCE CALL

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PRESENTATION

Operator

Good day, everyone, and welcome to OraSure Technologies 2011 Fourth Quarter and Full Year 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)

For opening remarks and introductions, I would now like to turn the call over to Judy Clarke at OraSure Technologies. Please go ahead.

Judy Clarke - *OraSure Technologies Inc - IR*

Thank you. Good afternoon, everyone, and thank you for joining us today. I would like to begin by telling you that OraSure Technologies issued a press release at approximately 4 pm Eastern time today regarding our 2011 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 15, 2012, by calling (855) 859-2056 for domestic or (404) 537-3406 for international. The access code is a 44923763.

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

Before I turn the call over to Doug, I must also remind you that this that call may contain certain forward-looking statements, including statements with respect to revenues, expenses, profitability, earnings 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 SEC filings of OraSure Technologies, including its registration statement, its annual report on Form 10-K for the year ended December 31, 2010, its quarterly reports on Form 10-Q, and its other SEC filings. Although forward-looking statements help to provide complete information about future prospects, listeners should keep in mind that forward-looking statements may not be reliable. The Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call. With that, I would like to turn the call over to Doug Michels.

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

Thank you Judy, and good afternoon everyone. I want to thank you for joining us on our call today. 2011 was a year filled with several milestone achievements, which should help pave the way for a very successful 2012. We made substantial progress on our two main clinical development programs involving our OraQuick HCV test and our OraQuick HIV over-the-counter test. In addition, we completed the acquisition of the DNA Genotek earlier in the year, with Q4 being the first full quarter of consolidated operations.

Our clinical programs are key to our growth strategy, and they have been the focus of the Company for the last several years. We are also happy that DNA Genotek is now part of OraSure, and we are excited about the potential of the molecular diagnostics market. We believe that OraSure is extremely well-positioned for growth that is diversified across multiple business lines.

Consolidated revenues for the fourth quarter were up 26% compared to the fourth quarter of 2010. The increase includes newly acquired revenue from the DNA Genotek acquisition. For today's call, Ron will provide a detailed review of our fourth-quarter financial results, and I will follow with some additional comments on our clinical programs and business, and then we will take your questions. Now, let me turn the call over to Ron.

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

Thanks Doug, and good afternoon everyone. Starting with revenues, our fourth-quarter 2011 revenues were a record $23.7 million, compared to $18.8 million reported in 2010. Revenues for the current quarter included $4.2 million from our DNA Genotek subsidiary. Included in that $4.2 million was $1.5 million of product shipped to DNA Genotek's largest customer. This customer makes bulk purchases generally once a year. Excluding DNA Genotek's results, our revenues increased 4%, as higher sales of our infectious disease, substance abuse testing, and cryosurgical systems products were partially offset by lower sales of our insurance risk assessment products, and lower licensing and product development revenue.

Infectious disease testing revenues were $11.6 million in the fourth quarter of 2011, compared to $11.4 million in the fourth quarter of 2010. Our fourth-quarter 2011 results included $813,000 in domestic and international OraQuick HCV revenues, compared to $107,000 in the fourth quarter of the prior year. In addition, our OraQuick HCV revenues increased sequentially from the third quarter by $388,000. The increases in HCV revenues were partially offset by a decrease in domestic and international HIV revenues of $363,000, largely due to changes in customer ordering patterns.

In substance abuse testing, revenues increased from $2.9 million in the fourth quarter of 2010 to $3.5 million in the comparable period of 2011, primarily as a result of increased intercept sales caused by the timing of orders placed by one of our laboratory customers. QED sales also increased, as we fulfilled an order backlog created by a disruption in production earlier in the year.

Fourth-quarter 2011 cryosurgical revenues increased 10% compared to the fourth quarter of 2010. Professional sales in the US increased 12%, while international professional sales decreased 21%. Over-the-counter sales were up 26%. The higher domestic professional sales reflect the continued efforts of our manufacturer sales representatives, improved focus by our distributors, and an increase in sales to governmental entities. International sales decreased in the current quarter due to customer ordering patterns. Our over-the-counter cryosurgical sales during the quarter increased $217,000 when compared to 2010, largely as a result of higher sales to our European distributor.

Our insurance risk assessment sales decreased from $1.4 million in 2010 to $1.1 million in 2011. This was largely due to continued softness in insurance underwriting and the adoption by some underwriters of a simplified issues policy. This is a policy where lab-based testing is replaced by having insurance applicants respond to a questionnaire about their behaviors. We had two customers adopt this policy.

Turning to gross margin, our overall margin for Q4 of 2011 was 62%, compared to 64% reported for the fourth quarter of 2010. The decrease in gross margin in the quarter was largely due to an unfavorable change in product revenue mix. In addition, 2011 gross margin included $102,000 of increased cost of products sold, caused by the turnover of finished goods inventory subject to the stepped-up value adjustment recorded in connection with the DNA Genotek acquisition.

Turning to operating expenses, our total operating expenses for the fourth quarter increased $2 million compared to the fourth quarter of 2010. Fourth-quarter 2011 expenses included $3.1 million of DNA Genotek expenses. R&D expenses actually decreased by approximately $751,000, reflecting lower clinical trial costs associated with our OraQuick HCV program, which was partially offset by the inclusion of DNA Genotek expenses.

G&A expenses increased, primarily as a result of higher accounting and legal fees. Sales and marketing expenses increased for the quarter, primarily due to the inclusion of the DNA Genotek expenses. From a bottom-line perspective, we reported net income of $115,000, or zero cents per share for the fourth quarter of 2011. This compares to a net loss of $1 million, or $0.02 a share for the same period of 2010.

In the fourth quarter of 2011 we recorded an income tax benefit of $553,000 on a loss before taxes of $438,000. The income tax benefit is associated with the DNA Genotek loss before income taxes and certain Canadian R&D, as well as investment tax credits. Turning briefly to our balance sheet and cash flow, our cash balance at December 31, 2011, was $23.9 million. This was down from the $75.7 million on hand at December 31, 2010, as a result of the DNA Genotek acquisition and related expenses. During the fourth quarter we generated $1.1 million in cash from operations, compared to $3.6 million generated from operations in the fourth quarter of 2010.

Turning to guidance, for the first quarter of 2012, we are projecting consolidated revenues of approximately $20.5 million to $21 million, and a consolidated net loss per share of approximately $0.08 to $0.09 for the quarter. Expenses in Q1 of 2012 are expected to be higher than in Q4 of last year, as a result of approximately $1.7 million in pre-launch prep costs for our OraQuick HIV OTC test. Additionally, we are in the process of conducting a refresh of our overall corporate strategy, and this will run through mid-year. The costs associated with this activity will also impact Q1. Some of these costs were expected to be expended in Q4 of last year, but were deferred to 2012, which contributed to the over-performance last quarter. Now I'll turn it back to Doug.

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

Great, thanks Ron. During the fourth quarter, we achieved two significant milestones in our principal clinical programs. I'd like to briefly comment on these, as well as certain other developments in our business. The first milestone relates to our OraQuick HCV test. In November we announced the receipt of a CLIA waiver for this product. Our OraQuick HCV test is now FDA-approved and CLIA-waived for both Venus and Fingerstick whole-blood applications. This is the only FDA-approved rapid hepatitis C testing product available for sale in the United States.

Receipt of the CLIA waiver has always been an important strategic objective, as it substantially increases the potential market reach, and broadens the public health benefit of this new product. Our test can now be used by more than 180,000 sites in the United States, where previously the test could only be performed in laboratories certified under CLIA to perform moderately complex tests. With the waiver, our test can now be used in a variety of settings, including health clinics, community-based organizations, and physicians offices.

Not surprisingly, now that we've received the clear waiver, several sales and marketing initiatives can be implemented. For example, Merck can now begin detailing the product into the United States physicians office market under our HCV collaboration. These detailing activities have started, and will be ramping up during the first quarter. Additionally, we can now finalize and implement our distribution arrangements for physicians offices and federally funded community health centers through several large distributors, including McKesson, Henry Shein, and PSS. We will also be focusing our direct sales efforts on public health departments that already have the infrastructure in place to conduct rapid HIV testing, and we will continue to market this product directly to hospitals.

As discussed in prior calls, the difficult economic environment has created challenges for our business, and has adversely affected funding available for our OraQuick HIV product, particularly in the US public health market, and to some extent in hospitals. We expect those same headwinds to continue, and we expect that they will have a similar impact on the OraQuick HCV test.

As a result, and in an effort to mitigate the impact of the tight funding environment, our sales and marketing teams have sought to assist customers in identifying funding for HCV testing efforts, and we are already starting to see some good results. We worked with Advocate Trinity Hospital in Chicago, where we were able to help locate grant money for hepatitis C testing, and this hospital is now the first in the nation to conduct rapid hepatitis C testing using our OraQuick product in its emergency room. This would not have been possible without the CLIA waiver and the experience of our sales team.

For the full year 2011, we generated $1.6 million in revenue from domestic and international sales of our OraQuick HCV tests. Although predicting future HCV revenues is somewhat difficult given that we are now just developing the market for a rapid test, we do expect to see growth in sales during 2012 compared to last year, because of the CLIA waiver and the heightened profile HCV is receiving.

With the advent of new drug therapies for HCV, major pharmaceutical companies are eager to raise awareness of this condition. Furthermore, we believe HCV screening and treatment is likely to attract more significant attention in the future, due in part to the efforts of government agencies. As you may recall, the Department of Health and Human Services issued its viral hepatitis action plan last year, which lays out a strategy for expanding awareness, prevention, care, and treatment of viral hepatitis, including HCV. This is a multi-year plan that includes revising the CDC's guidelines for hepatitis C testing and linkage to care.

In furtherance of this plan, the CDC is considering a new strategy for hepatitis screening that's broader in scope than the current screening approach. In particular, the CDC is now evaluating the use of a strategy expanded to include persons born from 1945 to 1965 in the definition of those at risk who should be screened for hepatitis C. This age range includes tens of millions of people, actually it's as many as 70 million people, and it is our expectation that revised CDC guidelines will be issued later this year.

There have also been studies and support demonstrated by the community for the implementation of a broader testing strategy. According to a study published online this past November in the Annals of Internal Medicine, birth cohort screening for hepatitis C is cost effective in primary care settings, and such a proactive screening strategy could identify over 800,000 currently unidentified cases, which could save many thousands of lives each year. Similarly, the chronic liver disease foundation and organization, which is comprised of our nation's leading hepatologists and gastroenterologists, earlier this year issues a position paper in support of broader hepatitis C testing, and recognizing the benefits associated with rapid hepatitis C testing.

The viral hepatitis action plan also indicates that hepatitis will continue to be the nationally recognized through the designation of World Hepatitis Day on July 28, and the promotion of the month of May as Hepatitis Awareness Month. Additionally, beginning in 2012, this year the plan provides for the designation of May 19 as Hepatitis Testing Day in the United States. This national designation is obviously important to our business, and we've been invited to open the NASDAQ stock market on Friday, May 18, to help recognize this date. We believe these activities will continue to focus attention on the need for greater levels of hepatitis C testing, and the benefits and use of our OraQuick HCV rapid testing product.

Turning to our HIV over-the-counter clinical program, as previously announced at the end of 2011, we submitted the third and final module to our application for FDA approval of an OraQuick rapid HIV test for home use. This module contained the findings from the final phase of clinical testing, which involved the use of an investigational version of our product by subjects in an unobserved setting. Approximately 5,800 individuals were enrolled and tested in this phase across 20 sites nationwide. This work resulted in the identification of more than 100 previously undiagnosed HIV-infected individuals.

Our submission is currently under active review by the FDA, and we hope to participate in an FDA blood product advisory committee, or BPAC, meeting later this year. According to the FDA website, BPAC meetings are scheduled for May, July, and December of 2012, and obviously our hope is to be scheduled as soon as possible. As you know, HIV/AIDS continues to be a major health issue, both domestically and around the world.

The CDC estimates there are approximately 1.2 million people in the United States infected with HIV and that approximately 240,000 or so are unaware of their status. Unfortunately, this is occurring despite the widespread availability of both laboratory-based and rapid point of care HIV testing options. According to the CDC, individuals who do not know their status are unknowingly responsible for up to 70% of the approximately 50,000 new infections that occur each year.

We believe that these data are compelling, and we believe that these data clearly demonstrate that the current state of HIV testing is inadequate. Additional options are urgently needed for identifying undiagnosed individuals, and this is a major reason why we've invested so much time and resource into our over-the-counter clinical program. We believe that our rapid HIV in-home test, if approved by the FDA, will be a significant step forward for HIV testing, and a powerful addition to the HIV testing options that are currently available. This view is not only supported by our market research and our experience in the professional market, but also by other parties.

For example, a new study conducted by researchers at the HIV Center at Columbia University Psychiatry and the New York State Psychiatric Institute was recently published in the Journal of Sex Research. This study asked a group of gay men who habitually engage in risky sexual practices whether they would be willing to use a rapid HIV in-home test such as our OraQuick oral test to screen their sexual partners. The study found that the vast majority of those individuals questioned would likely ask their partners to take the test and might engage in safer sexual practices if their partner's response raised doubts about his HIV status. We believe this study provides another piece of evidence supporting the benefits of an HIV over-the-counter test.

As indicated in prior calls, we're focused on planning for the commercial launch of our OraQuick HIV test, and we've made good progress during the fourth quarter. We've now engaged advertising and public relations firms and have selected a firm to act as our sales representative to the retail trade and to provide logistics in order to cache services for our product. We've also created an integrated project plan and we formed a cross-functional team to ensure that we're prepared to launch this product as quickly as possible, once we receive FDA approval.

In substance abuse, I'm happy to report the launch of the high-throughput oral fluid drug assay program with Roche Diagnostics. We're pleased to add this new product line, and we expect these products to contribute to our overall growth. To date, assays for PCP, cocaine, opiates, methamphetamine and amphetamine have been FDA 510(k)-cleared for use with our intercept oral fluid collection device, and to round out a complete NIDA-5 panel we still need clearance for a THC assay for marijuana. The final clinical studies are continuing, and we expect Roche to submit this assay for 510(k) clearance later this year.

Turning now to our newest business line DNA Genotek, as previously noted the fourth quarter of 2011 was the first for which we've reported consolidated results, and the business progressed largely as expected. DNA Genotek contributed over $4 million in revenues, which was consistent with our expectations. The integration process has also gone very smoothly, and this is a credit to the DNA Genotek team. DNA Genotek's senior management is continuing to build the business, and we're highly confident in their future success.

A final point I want to mention is the appointment during the fourth quarter of Mr. Gerald Ostrov as a member of the Company's Board of Directors, which we had previously announced. On numerous occasions over the past several years, our Board has discussed the value of adding a Director with strong experience and expertise in consumer products, especially as the clinical program for our HIV over-the-counter test has continued to progress. Jerry's addition to the Board fills this very important need, and comes at a very opportune time. Jerry has much to offer from his extensive consumer experience at Bausch & Lomb, at Johnson & Johnson, and at Ciba-Geigy, and he is already providing wise counsel and important contributions to our efforts.

In summary, 2011 was a very successful year for OraSure, as we made great strides on our clinical programs and added exciting new offerings to our product portfolio. This success has provided us the opportunity to transform the OraSure business in 2012 and beyond. I want to thank all of our employees for their efforts and dedication toward the development of products that are critical tools in the battle against the spread of infectious diseases and substance abuse.

We've already had several of these important products approved, and we will not rest until the job is complete. We are working very hard to maximize the HCV opportunity in the near-term, and we remain very excited and optimistic about the prospects for offering the first ever rapid HIV test into the US retail marketplace. With the progress of our clinical programs, the potential of new product offerings and entry into new markets, and the addition of DNA Genotek, we believe OraSure has never been better positioned for the future. With that, let me open the floor to your questions. Operator, please proceed.

QUESTIONS AND ANSWERS

Operator

Thank you, sir.

(Operator Instructions)

Scott Gleason, Stevens.

Scott Gleason - *Stephens Inc. - Analyst*

Thanks for taking our questions. I guess just to start off, when we start thinking about the HCV piece in the public health setting, could you guys maybe give us a little bit of an idea of maybe what your assessment is of what percent of public health clinics currently have funding in place for hepatitis testing? Is there a good percentage that do outsource lab-based testing today that you guys could kind of roll in, and I guess replace that with point-of-care testing?

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

Yes. A number of the public health jurisdictions currently either provide some form of hepatitis C testing. It's obviously up to this time, it's been laboratory-based testing, or they send it out. It's been an area that's been grossly under-funded, given the prevalence of the disease here in the United States. Our hope is that we can affect a change in that. I would say on a percentage basis of public health jurisdictions that provide some level of hepatitis C testing, it's probably less than 50% today. But obviously we certainly would expect that that will change significantly now with the addition of a rapid test in the product offering.

Scott Gleason - *Stephens Inc. - Analyst*

Great. Just looking at the guidance, we're trying to reconcile the numbers for the first quarter. Is the right way to think about the sequential decrease that you guys got the $1.5-million bulk order benefit from DNA Genotek, and that's going away when we look at the first quarter. Is that the main disparity there?

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

I think that's part of it, Scott. Traditionally, Q1 has been probably our weakest quarter on the infectious disease side. We're also expecting substance abuse to be sequentially down as well.

Scott Gleason - *Stephens Inc. - Analyst*

Okay, great. Then I guess just last, Doug and Ron, can you guys talk a little bit about the flu test with Princeton Biomeditech? Did you guys have any meaningful sales this quarter, as we've kind of gotten into the flu season here, and I guess what's maybe the expectation for the first quarter here? Obviously it's been a week flu season in the US.

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

We did not have meaningful revenues in the fourth quarter. It's been a light season. I mentioned during our previous call that we had signed one GPO agreement. We are working to still have our product offered on a couple of others, two of the other largest agreements. Right now, it's under review by their new technology committee. Our reps are still out promoting the product, and obviously we want to see some improvement in the revenues. It's a good thing and a bad thing that we've had a light flu season, good for the American public health, not so good if you're selling flu tests. We'll give you an update on the next call and give you an idea as to whether we've see some improvement in the business, whether it contributed meaningful revenues here in Q1.

Scott Gleason - *Stephens Inc. - Analyst*

All right. Thanks for taking my questions, guys.

Operator

Caroline Corner, MLV.

Caroline Corner - *McNicoll, Lewis & Vlak - Analyst*

Hi guys, thanks for all of the updates. Just real quick with regard to the hepatitis C product, what are your plans there for an oral fluid label for that?

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

As we've discussed, Caroline, our first objective was to get the CLIA waiver, which is now in place. We plan to meet with the FDA on our oral fluid submission. That meeting is not yet scheduled, but we anticipate it will occur in the next couple to several months. We'll update you on that as it progresses.

Caroline Corner - *McNicoll, Lewis & Vlak - Analyst*

Okay, thanks. With regard to the OTC HIV product, you said that you have been interacting with distribution partners. Can you talk a little bit about which channels you want to sell the product through first, just your general broad-term marketing plans for the product?

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

Absolutely. We have a very large and very well-orchestrated and integrated plan that we're executing right now, as we prepare for commercial availability. If you think about that plan, you should think about it really in three major buckets. One is our efforts around the clinical regulatory activities that need to be executed, and that has to do with preparing for an ultimate advisory committee review, as well as any ongoing interactions that we have with the FDA. Given that we made our final submission here at the end of 2011, those interactions are ongoing. They've been very positive and collaborative.

The second major bucket of work, if you will, is on the commercial front. That involves, to your point, beginning to interact with those sales channels, those retailers that we anticipate will carry the product, and in that regard, we're talking about the retail pharmacies here in the United States, mass retailers, some large food suppliers, as well as we're going to have a significant online presence. I mentioned that we've contracted with a sales agent, an organization that's helping us in managing those calls and those relationships, and will continue to work with us once the product is ultimately available.

But while all that's going on we also have work that we're doing on the advertising front, as well as with public relations. There's stakeholder and advocacy work that we're involved in right now. We've got focus groups that we've met with numerous times, and that we're going to continue to meet with as we prepare for launch, and that even post-launch. While all this is going on, we also have to ensure that our call center is ready to go once the product is ultimately approved.

The third major bucket of work is on the operational front, and that has to do with making sure that we've got product that's available when we are ultimately approved, so that includes making sure we've got a robust production plan, we've got the supply chain ready to ensure availability, as well as working with our third-party logistics provider and make sure that all those activities are integrated with the call center, with the website, so that we can fulfill orders, and receive payment for those orders.

That's kind of a high-level overview of the whole integrated plan. Obviously, I gave you where we intend to sell the product. All those activities are ongoing, and as Ron mentioned, we're going to see some incremental expenses associated with those activities as we move out now into the first quarter and in through the first half of 2012.

Caroline Corner - *McNicoll, Lewis & Vlak - Analyst*

Okay, very good, thank you. With regard to the size of the market opportunity for the OTC product, I know you've done a lot of market research internally, but could you just walk us through your expectations of who this product is specifically targeted at within that quote-unquote worried-well population?

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

The primary age group that we believe product purchases are going to derive from are individuals between the ages of 18 and 45. But that doesn't mean that individuals younger than 18 or older than 45 won't be interested and won't be purchasing the product. But that's where we anticipate having the highest level of purchase intent. The original market research that we did several years ago suggested that this was a market opportunity at retail in excess of $500 million. Now we'll be selling into retail at some discount to that, which would reflect the retailers margin. We're actually refreshing that data right now.

Most importantly, what we're trying to refine as precisely as we can is where that demand, what channel that demand is likely to come from. How much of it would we expect to realize through retail pharmacies, mass retailers, and I think most importantly, online. Over the last three to five years we've seen -- we all know there's been a significant increase in online purchases and consumers' access to the Internet and to the web, and we anticipate that's going to highlight a significant difference from the work we did three years ago. We'll see a higher level of purchase intent online.

Caroline Corner - *McNicoll, Lewis & Vlak - Analyst*

Okay. Thank you very much for taking my call.

Operator

(Operator Instructions)

Jeff Frelick, Canaccord.

Jeff Frelick - *Canaccord Genuity - Analyst*

Doug, with respect to the early revenues on the HCV product, can you give us a sense where the majority of those sales are occurring? Is it public health, physician office, pharma? Any color there would be great?

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

Absolutely. We're real pleased with the revenues we saw in the fourth quarter, a little over $800,000. That was sequentially up from about $425,000 in Q3. That was about evenly split 50/50 or so, domestic versus international. We had some -- a couple of nice orders come out of the international space. Unlikely that those are going to repeat on a quarter-by-quarter basis, but I think that's a good sign. Most of the revenues that we realized domestically came out of the public health market. Obviously, we only received the CLIA waiver at the end of November. We actually didn't start shipping CLIA-waived product until the second or third week of December.

The big push now is to maximize the benefits of the CLIA waiver, and obviously we're counting on our relationship with Merck to help increase our presence in the physicians office market. On that note, all the trainings are complete. They have begun detailing in January, and actually the

detailing is taking place both with their direct sales force that's out calling on gastroenterologists and hepatologists and infectious disease specialists, but also through their national business group, which is their in-house telesales group.

They're very targeted effort to the referring primary care physicians, and we're refining right now how we make sure that those leads that are generated there make their way into our manufacturers rep organization, and into the physician office distribution chain. We're meeting on a monthly basis, evaluating, tracking performance, and we'll continue to do that. I don't think we will have real good data on this probably for sure through -- until we're through the first quarter, and probably some time into Q2. But I can assure you people are charged up and moving hard.

Jeff Frelick - *Canaccord Genuity - Analyst*

On the sales process, Doug, maybe just another clarifying question. Do you foresee most of the sales calls into the -- let's call it the primary care docs, via your reps cold-calling, your reps kind of going in hand-in-hand with your physician office distributors, are more or less lead referrals coming from Merck's inside sales department?

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

I think it's a multi-tier approach. In addition to the work that we've done with Merck, we also trained our 50-plus manufacturers' reps at the end of January at their meeting. They're now out promoting the product, in concert with the physician office distributors, the Sheins, the PSSs and the McKessons. Shein's sales force is completely trained. We've deployed collateral. Their call center's actually going to be trained in the next couple of weeks. We're working on a couple of contractual issues, just technical issues, nothing on the terms with PSS and McKesson. Those issues should be resolved within the next week or two. Then the same activities are going to start with their sales organization. This is all happening real-time as we speak.

Jeff Frelick - *Canaccord Genuity - Analyst*

Okay. Maybe a question for Ron. What was the change in product mix, Ron, that had some impact on gross margin in the quarter?

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

One of the big ones, Jeff, was actually the inclusion of the DNA Genotek revenue stream in with OraSure for Q4. That obviously had an impact on the overall gross margin. Additionally, there were lower levels of OraSure collection devices that were sold in Q4, which had a little bit of an impact from a margin perspective as well.

Jeff Frelick - *Canaccord Genuity - Analyst*

Okay. Then the strength in substance abuse testing in the quarter, was that lower comps, or is something else going on there?

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

We had some additional -- well we had the one issue with QED that was resolved, which is our oral fluid alcohol test that we have some production issues with in Q3, and so experienced lower revenues in Q3. That issue was resolved, and the entire backlog was taken out in Q4. We're in a fine position with respect to that. That did, though, represent an additional incremental revenue bolus for us in the fourth quarter. Beyond that, we had some additional purchases of Intercept collector devices and assays from one of our laboratory partners at a rate higher than what we had anticipated and had seen in the prior year's quarter.

Jeff Frelick - *Canaccord Genuity - Analyst*

Great, thanks guys.

Operator

Spencer Nam, ThinkEquity.

Spencer Nam - *ThinkEquity - Analyst*

Thanks for taking my questions. I have just a couple of questions here. First question is, I just wanted to ask a little more of a hypothetical but potentially relevant question on the HIV OTC. I know that you guys have done everything that the panel -- the FDA has asked for in terms of both qualitative and quantitative aspects of the test. I know there's a lot of support around this, but the test does raise a social -- potential social issue, if you will -- particularly with the emotional challenges associated with someone finding out that he or she is HIV-positive, and the fact that the test is not a -- it's an antibody test which requires -- needs several weeks before the antibodies form.

I was curious whether you guys have thoughts that -- or that you get any sense from the FDA side that they may be -- that there is lingering concern in terms of how to manage these fairly serious issues once it goes OTC with this particular test, and why you guys believe that the other sentiment would overrule all that?

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

I think that's a great question, Spencer. The answer to it, I think, is also quite straightforward and clear. These issues and these questions were discussed and debated significantly all the way back to 2005 when the FDA asked the advisory committee in November of 2005 whether, considering all these issues and others, whether it was time to make a self-test for HIV available over the counter.

It was a result of testimony from healthcare professionals, doctors, psychologists, psychiatrists, public health experts, and the like, where they debated these questions, and ultimately came down on the side that indeed, given the advances in therapy, given the increased awareness about HIV and that it's a manageable chronic disease, that it's time to bring a test to market. So the advisory committee, after discussing all this, made a unanimous recommendation that the FDA should work with sponsor companies like OraSure to bring a product to market.

Now at the same time, the FDA has been very diligent in the clinical studies that we've been asked to perform, and have tested pretty thoroughly the call center that's been live 24/7, which supports the consumer through the testing process, which provides referral to appropriate professional services for individuals who need that, who are testing themselves. I think it's been well-discussed. I don't think that there's -- anyone's overly concerned about this right now. I think actually they're quite confident that the consumer who makes the decision to go down to their local drugstore or buy a test online is informed, that the packaging explains clearly what the test can do and what it can't do. That it also clearly identifies how they can get assistance if they need it, and all that's been part of the validation of our clinical studies.

Spencer Nam - *ThinkEquity - Analyst*

Appreciate that answer, that's helpful. Then, final question I have is -- so I looked at your guidance, and I held everything else essentially flat, almost, from kind of the mean value of last year's numbers, and I'm still over your range. I was curious where you guys, in terms of your revenue guidance, where you guys have the -- for the first quarter -- where you guys feel like you have the -- you need to exercise substantial conservatism?

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

Well, the revenue guidance for the first quarter was built up based on our current assessment of high probability of achievement of a revenue goal for the combined entities. As we had talked about a little bit on the call itself, DNA Genotek had a customer order of some size in Q4, which is more of a lumpy type of customer as far as repeat business, and not necessarily distributed evenly and rateably over the year itself. Although stripping that out and going with that number wouldn't be representative of what our expectations are for DNA Genotek in the quarter, we do see some additional growth coming out of that business. There was one large order in Q4 which we wanted to bring to everyone's attention.

Additionally, as I had talked about a little earlier on the call, infectious disease has historically been a lower-revenue-generating category in the first quarter of each fiscal year. Beyond that, substance abuse is down sequentially, based on customer orders and some loss of customers in the substance-abuse area.

Spencer Nam - *ThinkEquity - Analyst*

Great, that's helpful. Thanks very much guys.

Operator

This does conclude our time for questions. Thank you for your questions today. I would now like to turn the call back over to Doug Michels for any closing remarks.

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

I just want to thank everybody again for coming on the call this afternoon. We look forward to delivering a solid first quarter and an exciting 2012, and look forward to talking to you again on our next call, and continuing to provide you updates on our business. Have a great afternoon and evening everyone, bye-bye.

Operator

Thank you, sir. Ladies and gentlemen, this does conclude today's call. Thank you for your participation and have a wonderful day. Attendees, you may disconnect at this time.
