FINAL TRANSCRIPT

Thomson StreetEvents℠

OSUR - Q3 2011 Orasure Technologies Inc Earnings Conference Call

Event Date/Time: Nov. 02. 2011 / 9:00PM GMT

THOMSON REUTERS

CORPORATE PARTICIPANTS

Judy Clarke
OraSure Technologies, Inc. - IR

Doug Michels
Orasure Technologies, Inc, - President, CEO

Ron Spair
Orasure Technologies, Inc. - COO, CFO

CONFERENCE CALL PARTICIPANTS

Sameer Harish
ThinkEquity - Analyst

Jeff Frelick
Canaccord - Analyst

Caroline Corner
McNicoll, Lewis & Vlak - Analyst

Charley Jones
Barrington Research - Analyst

PRESENTATION

Operator

Good day, everyone, and welcome to Orasure Technologies' 2011 Third Quarter Financial Results Conference Call and simultaneous webcast. As a result, today's conference is being recorded. (Operator Instructions) For opening remarks and introductions, I would now like to turn the call over to Judy Clarke at Orasure Technologies.

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

Thanks, Tyrone. 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 p.m. Eastern Time today regarding our 2011 third quarter 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 November 9, 2011, by calling 855-859-2056 for domestic or 404-537-3406 for international. The access code is 18091365.

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 session.

Before I turn the call over to Doug, I must also remind you that this 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. Certain 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.

Also please note that today's results will include a discussion of certain non-GAAP financial measures. Non-GAAP reporting is provided to help you better understand our business in certain items, which impacted our results. However, non-GAAP financial results are not meant to be considered as a stand-alone measurement of performance or as a substitute or as superior to GAAP results. You should be aware that non-GAAP measures have inherent limitations and should be used only in conjunction with Orasure's consolidated financial statements prepared in accordance with GAAP. Our press release includes a table detailing the non-GAAP measures together with the corresponding GAAP results and a reconciliation to GAAP. We encourage listeners to review these items.

With that, I would like to turn the call over to Doug Michels.

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

Thank you, Judy. And good afternoon, everyone. We are very pleased with the Company's third quarter financial performance and the considerable progress we've made toward our strategic initiatives as we lay the groundwork for future growth.

Today we will cover several positive clinical developments that occurred during the quarter, the exceptional performance of our HCV device, our progress on readying the over-the-counter HIV product for commercialization, and the impending initial launch of our drugs of abuse high throughput oral fluid assays.

Another significant development in the quarter was the completion of the DNA Genotek acquisition in mid-August for just over $50 million in cash. This acquisition complements our existing oral fluid business and will help OraSure diversify into the fast-growing molecular diagnostic market. The DNA Genotek management team remains in place, and the two newly combined organizations are working extremely well together. We expect this new subsidiary to make strong contributions to our business for many years to come.

Our third quarter consolidated financial results were very strong, with revenues up over 14% compared to the third quarter of 2010. These numbers include approximately six weeks of DNA Genotek results following the closing of the acquisition. Excluding the DNA Genotek results, we exceeded our financial guidance previously provided for OraSure's base business on both the top and bottom lines.

This afternoon Ron will start with a financial review for the third quarter, and I will follow with some additional comments on our progress and business. We will then take your questions.

And with that, I will turn the call over to Ron.

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

Thanks, Doug, and good afternoon, everyone.

Third quarter 2011 revenues were $21.7 million compared to $19.0 million reported in 2010. Revenues for the current quarter included $2.0 million from our DNA Genotek subsidiary. Excluding DNA Genotek's results, our revenues increased 3% as higher sales of our infectious disease and cryosurgical systems products were partially offset by lower sales of our substance abuse testing and insurance risk assessment products and lower licensing and product development revenues.

Infectious disease testing revenues were $11.9 million in the third quarter of 2011 compared to $10.8 million in the third quarter of 2010. The overall 9% increase was driven by a 108% increase in international OraQuick® HIV sales and the inclusion of $425,000 of OraQuick HCV revenues.

HCV revenues in the third quarter of 2010 were minimal. International HIV sales increased largely because certain private and government customers were able to make purchases for HIV testing during the quarter. Domestic OraQuick® HIV sales were flat when compared to the prior year period.

Third quarter 2011 cryo revenues increased 13% compared to the third quarter of 2010. Professional sales in the US increased 21% and international professional sales increased 23%. OTC sales were down 4%. The higher domestic professional sales reflect the continued efforts of our manufacturers' sales representatives, improved focus by our distributors, and an increase in sales to governmental entities. International sales increased across all regions in the quarter. Our new Australian distributor made its first purchase in order to stock its inventory, and sales into Europe increased primarily as a result of higher sales in France.

OTC cryo sales during the quarter decreased $41,000 when compared to 2010, largely as a result of lower sales to our European and Latin American distributors.

In substance abuse testing, revenues decreased from $3 million in the third quarter of 2010 to $2.8 million in the comparable period of 2011, primarily as a result of lower QED sales caused by a temporary disruption of production. However, we resumed production again in October, and are now shipping product and working our way through the backlog.

Our insurance risk assessment sales decreased from $1.5 million in 2010 to $1.4 million in 2011. This is largely the result of the loss of one of our customers who changed its underwriting methodology to move away from oral fluid testing and now instead simply uses a signed questionnaire to screen applicants.

Turning to gross margin, our overall margin for Q3 of 2011 was 63% compared to 62% reported for the third quarter of 2010. OraSure's original core business generated a margin of 66% while DNA Genotek generated margin of 33%. OraSure's core business gross margin for 2011 benefited from improved product mix coupled with more efficient manufacturing operations. DNA Genotek's gross margin included a $763,000 of increased costs of products sold due to a non-cash inventory adjustment.

We recorded a purchase accounting adjustment of approximately $892,000 related to the write-up of the acquired DNA Genotek inventory to fair value. The adjustment is commonly referred to as a "stepped-up value" adjustment and is charged to cost of products sold as the related finished goods inventory is sold. We expect the remaining inventory subject to this adjustment to be sold in the fourth quarter. Had we not recorded this purchase accounting adjustment, DNA Genotek would have generated a gross margin of 70%.

Our total operating expenses for the third quarter increased $6.3 million compared to the third quarter of 2010. Third quarter 2011 expenses included $1.5 million of DNA Genotek operating expenses. R&D expenses increased by approximately $2.5 million, reflecting higher clinical trial costs associated with our OraQuick® HIV OTC program. Sales and marketing expenses increased largely due to higher consulting and staffing costs. G&A expenses increased primarily as a result of transaction costs associated with the acquisition of DNA Genotek.

From a bottom line perspective, we reported a GAAP net loss of $3.9 million, or $0.08 per share for the third quarter of 2011. This compares to net income of $274,000, or $0.01 per share, for the same period of 2010. If we strip out the DNA Genotek results, the purchase accounting adjustment discussed earlier and the investment banking fees that became payable upon closing of the acquisition, the OraSure base business would have generated a net loss of $1.6 million, or $0.03 per share. I would note that this number does reflect the impact of other transaction-related expenses such as legal, accounting and consulting costs, as we had included an estimate of these costs in our guidance for the third quarter.

Turning briefly to our balance sheet and cash flow, our cash balance at September 30, 2011, was $21.4 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 quarter, we used $3.7 million in cash to fund operations compared to $3.3 million generated from operations in the third quarter of 2010.

Turning to guidance for the fourth quarter of 2011, we are projecting consolidated revenues of approximately $22 million to $23 million and a consolidated net loss per share of approximately $0.07 to $0.08 for the quarter.

And now back to Doug.

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

Okay, thanks again, Ron. I'd now like to spend the next few minutes outlining the progress we have made on our strategic initiatives. After a considerable financial commitment and years of planning and hard work, we are in the final stages for two of our key growth objectives.

Beginning with HIV-OTC -- the final phase of clinical testing, which involved the use of our test in an unobserved setting, is now complete. This marks a significant step forward in the approval process for this product. In total, we enrolled and tested over 5,600 subjects, and identified more than 100 previously undiagnosed HIV-infected individuals.

Enrollment and testing at all clinical sites in the study are complete, the database is locked, and we are now analyzing the final data, which will be used to prepare a final report. We remain on track to complete our FDA submission before the end of the year. As indicated on prior calls, our FDA filing is being submitted in three separate modules.

The first module, which contains data from all studies performed prior to the final phase, was filed in August and is under active FDA review.

The second module, which will contain information about our manufacturing operations and our Customer Care Call Center, is expected to be filed late this month.

And the final module, containing the results of the unobserved clinical trial, is scheduled to be filed by year-end.

We hope to get on the agenda for the FDA's Blood Products Advisory Committee during the first half of 2012.

During the third quarter, we continued planning for the commercial launch of our HIV over-the-counter test. We are completing an intensive interview process to select both an advertising agency and public relations firm to help market our test, and we are nearing a decision on the selection of a third party to manage our Customer Care Call Center.

In addition, we have initiated a new round of market research to refresh our messaging and product positioning and to sharpen our demand forecasts. These activities are expected to drive meaningful spend levels in the fourth quarter and ramp up as we approach commercial launch.

A major initiative that we have pursued for the last two years has been to extend the shelf life of our OraQuick ADVANCE® HIV professional product. We announced an FDA-approved extension to 30 months during our last earnings call, and since our at-home HIV test will consist of the same device as our professional product, we expect to have at least the same 30-month dating for our OTC test.

So we should be in good shape from a product dating perspective. And additionally, since we have FDA approval to manufacture OraQuick® on fully-automated equipment, we should have no difficulty meeting the demand likely to result from an over-the-counter approval and launch.

We are extremely excited about our over-the-counter product, and expect the updated market research to confirm the attractiveness of this opportunity. We received a bit of confirmation in a recent study reported in the July 2011 issue of the Annals of Internal Medicine.

In that study, which was conducted by Johns Hopkins in urban Emergency Departments, patients being tested for HIV were given the option of taking a self-test using either our OraQuick® oral test or a rapid fingerstick blood test. According to the article, 91% of the self-testers chose oral over blood, and an even higher percentage indicated they would "probably" or "definitely" use a home test if one were to become available.

This independent study is consistent with the market research we conducted several years ago. We believe this study is further evidence of both the value of oral fluid testing and the urgent need to make HIV home testing a reality here in the U.S.

Turning now to our OraQuick® HCV test, the primary focus has been on securing a CLIA waiver for this product. As you know, in response to an FDA request, we conducted an additional reproducibility study, which has now been completed. We are very pleased with the results, and we've submitted final data to the FDA. At this stage, we believe we have given the FDA all the information required for it to act on our CLIA submission and, hopefully, receipt of the CLIA waiver will occur shortly.

Even though we have not yet received a CLIA waiver, we continue to promote this product to customers licensed to use moderately complex tests. As Ron indicated, in the third quarter we reported over $400,000 in HCV sales. We believe this level of activity confirms that interest in this product is high.

In September, we supported Merck's "Step Up To The Plate" testing initiative with major league baseball that I mentioned during our last earnings call. Under this initiative, we sold over 7,000 OraQuick® HCV tests to Merck to be used for HCV testing by local public health agencies at various major league ballparks and within the communities that they serve. We believe initiatives of this type will help increase awareness and demand for HCV testing.

In anticipation of receiving a CLIA waiver, we have been working closely with Merck to prepare training and deployment plans for the Merck sales team who will start detailing our product to physicians as soon as possible after the CLIA waiver is received. We will be utilizing Merck's National Business Group, which is a customer-facing headquarters sales team that capitalizes on technology to meet the needs of customers and business.

Additionally, Merck's HCV Specialist Organization will also be detailing the product. We expect to have training completed by early December.

And on the international front, we also continue to collaborate with Merck through their various country organizations. Detailing efforts continue to progress. Currently, our HCV sales are growing above plan expectations due in part to the work of our two organizations.

Finally, we continue to see strong performance by our HCV test when it is used in studies conducted by third parties. For example, a study published in the Journal of Infectious Disease in September compared our test with two other rapid hepatitis C assays that have not been approved by the FDA. Although all three tests had comparable specificity -- that's the ability to correctly detect true negatives -- the study reported that the OraQuick® HCV test had better sensitivity -- which is the ability to correctly detect true positives -- and was more accurate when used to test individuals infected with HIV.

Another study by the Centers for Disease Control and Prevention that was published in October in Clinical Infectious Diseases reported similar performance for our OraQuick® test compared to the other non-approved rapid HCV tests when used to identify HCV infection in prospective testing of human subjects.

Finally, the New York City Department of Health reported results of a study of the use of our product in oral fluid in the November issue of the American Journal of Public Health. This study showed that our oral fluid test had accuracy comparable to blood-based hepatitis C immunoassays performed in a laboratory and was preferred over laboratory tests by the clinical staff conducting the study. The study concluded that an oral rapid test could help reach individuals who are unaware of their HCV status and extend testing into non-clinical settings such as mobile testing units.

On the HIV testing front, we were very pleased to see this past Monday the policy statement issued by the American Academy of Pediatrics regarding HIV testing for adolescents. The policy advocates regular, routine HIV screening for all adolescents 16 to 18 years of age in health care settings when the prevalence of HIV in the patient population is more than 0.1%.

We believe this policy statement, which also acknowledges the use of rapid oral fluid testing and its high acceptance by youth, will lead to more testing of individuals in this age group.

In substance abuse, we expect to begin launching several of the high throughput oral fluid drug assays developed with Roche Diagnostics this coming quarter. As you know, the FDA issued 510(k) clearances for assays for PCP, cocaine, opiates, methamphetamine and amphetamine for use with our Intercept® oral fluid collection device.

As for the THC assay, the final clinical studies have begun, and they are expected to be completed around year-end. As soon as they are completed and the data is compiled and analyzed, Roche will submit this assay for 510(k) clearance, likely during January of the New Year.

Another area I'd like to address is our OraSure QuickFlu™ test. As you know, flu testing is a seasonal business that is affected by the timing and severity of the flu season each year. In contrast to last year, the current flu season has been relatively mild. Nevertheless, we have been assisting numerous customers in their evaluation of our product and, overall, customer interest in the QuickFlu™ test is high. We will continue to aggressively promote this product as the flu season evolves during the rest of this year and into early 2012.

And last, but certainly not least, I'd like to reiterate how happy we are to have DNA Genotek as part of the OraSure family. The company has built an excellent business in the collection and stabilization of genetic material in oral fluid samples. Their products are industry-leading, and they enjoy a strong and loyal customer following, especially in the academic and commercial research areas.

Activities are well underway to integrate a few critical business processes and our respective management teams are now focused on developing strategies to maximize the respective strengths of the companies and grow our combined businesses.

So before we move to take your questions, I would like to take the opportunity to thank the employees of both OraSure and the newest members of our team from Canada for their efforts in helping deliver a very strong quarter. We are excited to have added DNA Genotek and its exceptional products, and we look forward to pursuing the opportunities this acquisition provides in the large molecular diagnostic market.

Moreover, the completion of our final HIV-OTC study was a fantastic achievement and was years in the making. We were also able to provide the FDA with the additional information they requested on our CLIA submission for HCV, all while delivering strong quarterly financial results that exceeded the guidance for our base business exclusive of DNA Genotek. We firmly believe that these successes will serve as the foundation for future growth at OraSure.

And with that, I will now open the floor to your questions. Operator, please open the line.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Sameer Harish, ThinkEquity.

Sameer Harish - *ThinkEquity - Analyst*

I thought I would just start off -- some clarification on the guidance side. Can you maybe, Ron or Doug, talk about what you are including in terms of expectations for the DNA Genotek side and flu in the quarter?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

As we have done historically, Sameer, we have really looked to give guidance more on the general overall business as opposed to breaking it down by the individual business segment components. And so we'll continue to do that, going forward. I think Doug had mentioned that in the third quarter, and I had talked about it as well, we had about $2 million worth of revenues from DNA Genotek for the six-week period.

And so I think that might be somewhat representative of a rate that you might want to think about for your own models, if you will. As far as breaking it down specifically to product lines, we're going to stick at the top line.

Sameer Harish - *ThinkEquity - Analyst*

All right, just to press on that -- I know you don't want to give a number for that guidance, but in terms of the cyclicality of the DNA Genotek business, do they get a substantial portion of their revenue in the back half of the quarter or is it more evenly distributed?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

I would say that it's more evenly distributed.

Sameer Harish - *ThinkEquity - Analyst*

Okay, got it, that helps. And just in terms of the flu side, can you call out a flu number in terms of revenues for the quarter?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

We have not in our financial disclosures, but it was not a significant amount of revenues that we generated. I think most of our activity, as Doug spoke about, was really geared towards educating a number of potential customers about the benefits of our flu product and doing demonstrations in the hospital setting to compare our product against the competition.

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

Let me add a little bit on that, Ron and Sameer. So I don't think it's a secret both the hospitals and the CDC have indicated that flu is off to a relatively slow start. As a matter of fact, many of our customers are still waiting to see the 15 to 25 patients that

they need who are potentially infected to actually do the crossover studies that they want to do comparing our new test to that that they may have used in the past.

All that said, we've got hundreds of opportunities in our sales funnel, and we've done hundreds of demonstrations of the product. So we're quite confident that as the season develops, that we're going to capitalize on the initial interest in the product, and we'll keep you posted on how that goes.

Like Ron said, third quarter revenues were not significant enough to report out separately, but our expectation is we'll have a good fourth quarter and, hopefully, that will continue into 2012.

Sameer Harish - *ThinkEquity - Analyst*

Okay, great. And just last question in terms of the hepatitis C side, it's great to see that strong initial traction for that product. Can you talk a little bit about where you're seeing uptake? Is that primarily on the public health side or -- obviously, Merck purchased a little bit of product there, but in terms of the clinician side -- where exactly are you seeing progress there?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

Obviously, without the CLIA waiver, it's primarily coming out of either the public health sector where they can use the test in a moderately complex environment or in special kind of promotional situations like we had with Merck.

But we were very encouraged with the results of the product in the third quarter given those limitations. Our customers continue to express a high level of interest and expected demand, once we get the CLIA waiver, which I mentioned we hope to have very soon. We were very pleased with the results of that additional reproducibility study that we executed when we told you we were going to. So, hopefully, we'll get that CLIA waiver real quickly and, as I mentioned, Merck is going to be ready to detail the product soon after we have that approval.

Operator

Jeff Frelick, Canaccord.

Jeff Frelick - *Canaccord - Analyst*

Doug, could you give us an update on anything you're hearing on the BEST-C study from CDC? When we can expect some updates there and possible updates to the guidelines?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

Yes, so, as previously communicated, the CDC had indicated that they were going to issue new guidelines. Initial guidance from them was that it was going to come out during the first quarter. They haven't changed that, although from our perspective our thinking is safely they'll be out during the first half of 2012, hopefully in the first quarter when the CDC has promised.

The BEST-C study has continued to progress, and based on my understanding where it's at, the CDC does have enough data and information to inform their new guidelines. And our belief is that those new guidelines will include some kind of a broad scale screening recommendation for individuals within that birth cohort -- individuals born between 1945 and 1965. That would be a one-time screening for those individuals, and then, of course, a continuation of the risk-based recommendations that are currently in place.

That's our understanding.There's been no official communication from the CDC that says that's what the revised recommendations are likely to be, but it certainly makes sense based on all the data that we've seen and hopefully we'll see those early in 2012.

Jeff Frelick - *Canaccord - Analyst*

Just one follow-up, Doug, on the HCV topic. Can you comment on where most of the HCV sales are covered? Is that in the US, or is that in Europe?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

I'll let Ron correct me -- I think it was about three-quarters US and about a quarter outside the US.

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

That's correct.

Operator

Thank you. (Operator Instructions) Caroline Corner, McNicoll, Lewis & Vlak.

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

A question on the gross margin in fourth quarter. How much more of that purchase accounting adjustment should we expect to see looking into the fourth quarter?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

There's about another $115,000 that will flow through in the fourth quarter related to that stepup for the inventory. We also have ongoing amortization expenses that we will have, as well, for the fourth quarter and prospectively, even, as we go out through 2012.

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

Okay, I'm just looking at your guidance for the fourth quarter on the bottom line -- it's pretty close to what you did in the third quarter, but in the third quarter we had $0.03 of loss from the transaction costs, et cetera. Can you just walk us through what's going on with operating expenses, as you see it, in the fourth quarter? Is it based on clinical trial spending? Or why are we seeing that one being the range you mentioned?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

So we have a couple of different things in play here, Caroline, one of which is the meaningful amount of spend related to preparatory work for the HIV OTC launch, if you will. So we're going to engage some firms that will provide some assistance to us, and we'll spending in that area.

We will also have additional noncash charges that will be part of the ongoing operation of the Company related to the acquisition of DNA Genotek, and that will also figure into our EPS, our GAAP EPS, going forward.

And so we're going to talk -- cost of goods sold will be affected somewhere in the neighborhood of about $300,000-some-odd per quarter prospectively. And then you are also looking at operating expenses being impacted by approximately $0.5 million or so of noncash amortization charges related to trademarks and customer relationships. And that's, again, is a recurring charge that we'll have.

So, all in, about $800,000 impact of operating expenses, or total amortization charges and $115,000 for the inventory adjustment and then also the higher spend levels for HIV OTC. And then we also have some additional consulting activity that we're going to be engaged in in the fourth quarter that we expect to be driving a little bit higher expense levels than normal.

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

Okay, very good. And then looking at the revenue breakout from DNA Genotek, you said it was about $2 million in six weeks during the acquisition period. Given that the company was being acquired at that time and that all of the things that happen around an acquisition, it seems like that was a pretty good performance in that six-week period given that they made about $14 million in the previous year. Given this run rate of revenues that were thought to about $17 million for a year -- what's going on with DNA Genotek? Where are they seeing their growth there? Because that's pretty impressive.

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

Their business is performing quite well across all the different segments so, obviously, the biggest part of their business is the genetic testing business led by their flagship product, Oragene. They've seen decent performance in their animal and livestock business. So pretty consistent performance across the board and pretty consistent performance across geographies. So business is performing pretty well.

Operator

Jeff Frelick, Canaccord.

Jeff Frelick - *Canaccord - Analyst*

Okay, great, thanks for the follow-up. Hey, Ron, can you just comment on the strong gross margin on the Orasure side of the business -- the 66%?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

Sure, be happy to. So that, again, reflects manufacturing efficiencies and great execution from our ops group, together with a nice impact from higher cryo sales in the professional marketplace here domestically, which, as you know, has an above-average gross margin contribution. So -- those two factors certainly assisted us in putting 66% or so gross margin up for the third quarter. And that's really the root cause and explanation for the gross margin of 66%.

Jeff Frelick - *Canaccord - Analyst*

Okay, and then with respect to the Customer Care Center, how far advanced do you need to lock that down prior to FDA approval?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

So the Customer Call Center was actually live and now has been validated through both the observed use study as well as the unobserved study that was just completed. The Call Center scripts and the whole operating system will be submitted as part of the second module that is going to go into the FDA as part of our submission in November.

So it's locked down, if you will. So our effort right now is in interviewing Call Center operators. We're pretty far advanced in that process. I think we interviewed eight or 10, visited a number of those, and they've come in for their final proposals, and we're in the final stage of selecting who will actually run our Call Center for us. And, obviously, you can imagine this is going to be a 24/7 operation. It's dealing, you know, in a regulated environment. So we're going to have a top shelf organization that has experience in dealing with FDA-approved products and in serving our consumers completely and professionally.

Jeff Frelick - *Canaccord - Analyst*

And then any timing on a marketing partner for HIV OTC?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

No, and we have no plans right now to have a marketing partner. It doesn't mean that one might not materialize, and we still maintain open dialog with potential partners. But there is nothing imminent on that front. And so our plans, as I described them, as Ron referenced in terms of the financial implications, we're far along in the selection process for an advertising agency, for a public relations agency. We're going to work with a separate sales organization. We'll also have our own resources that will be supporting that. Meetings with the trade need to happen at the appropriate time.

There may be opportunities, Jeff, for co-promotion to promote our product with other products that might be in the sexual health area like condoms or lubricants or things like that. Those will be opportunities we'll explore.

And then the final area of preparation is just from an operations perspective. This is a different kit despite the fact that the product is the same product that's being sold into the professional market and will come off the same manufacturing line -- automated manufacturing line that our professional product comes off. It will be packaged very differently. It will have different instructions for use, different pamphlets, and a different presentation to the consumer.

So those negotiations and discussions are well along, also, and we're validating the third party that's going to assemble the finished product on our behalf so that we can fulfill demand.

So lots going on, and like Ron said, it's going to ramp up here in the fourth quarter. That will continue to ramp in the first part of 2012 as we prepare for ultimate approval and commercialization -- very exciting time for the Company.

Jeff Frelick - *Canaccord - Analyst*

So would that be [Sieber] that's reviewing the PMA submission, Doug?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

Yes, it is, and it turns out that it's the same review team -- lead reviewer that's reviewed OraQuick from our initial approval, through every enhancement we've made to the product -- all the manufacturing approvals and data extensions that we've had. So Sieber is very familiar with the product.

Remember, we anticipate going back in front of one more advisory committee and, hopefully, after we get our final submission in December, the FDA will move quickly to get that scheduled. Our hope is that that will be scheduled in the first half of 2012, and that we'll get a positive nod from the advisory committee, and then it's off to the races. So we're excited.

Jeff Frelick - *Canaccord - Analyst*

And then just last question -- will they fit you into the BPAC schedule or will they schedule a meeting specifically to review?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

I don't know, Jeff. But, generally, the BPAC has met on a three-times-per-year kind of rhythm and, generally, they've got a spring meeting in the March-April timeframe. They've got a midyear meeting sometime in the July-August timeframe, and then something near the end of the year, October-November.

We're going to get everything into them as early in December as we possibly can so that they can move quickly with their review, and hopefully they'll schedule us early.

I think the modular submission that we've begun and that we agreed to at the FDA works to our benefit there, right, so a huge bulk of data went into them in August, and that was the data from all the clinical studies that had been completed prior to this final study we just closed up here this quarter.

They've got a nice head start on things, and we'll continue to keep you abreast on any dialog. We know that that initial module that went in in August is under active review.

Operator

Charley Jones, Barrington Research.

Charley Jones - *Barrington Research - Analyst*

Good afternoon. Congratulations on a nice quarter.

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

Hey, Charley, thanks.

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

Hi, Charley.

Charley Jones - *Barrington Research - Analyst*

Hey, Ron. Thanks a lot, guys. So I realize you might not want to answer some of these, but let's see what we can do here. I was wondering what kind of additional expenses we can expect for a Call Center? Can you at least bracket what kind of expense we could see in the earlier years of a Call Center?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

I think it's a little premature to put that out there until we've finalized our negotiations and selected a Call Center operator.

Charley Jones - *Barrington Research - Analyst*

Did we have any of the expenses of that Call Center in the third quarter or is it all going to be additional?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

All of the expenses associated with the Call Center that were incurred for the clinical trial, they are all included in R&D and have been for the last phase of this trial. And every time we've had the Call Center up and running, including the observed user study that we conducted previously. So, yes, those expenses are already embedded in R&D. What they will do is they'll move up to cost of goods sold, obviously, once you go live and commercialize the product.

Charley Jones - *Barrington Research - Analyst*

Obviously, there's a variable component to that, but it's more fixed and then a stairstep as you move, right. It's going to be somewhat of a fixed cost for a period of time then? It gets more variable after that or is it kind of variable out of the gate?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

No, I think that's the way to look at it. So there's going to be a base level of support that's going to be required. We're going to have to have some level of redundancy across three shifts 24/7 including weekends. And as we go out and get more experience relative to when we can expect the highest call volume, we'll be able to adjust those resources accordingly.

After you've got that base level resource, then it really does become more of a variable expense as you ramp volume.

Charley Jones - *Barrington Research - Analyst*

Great, thank you. I was hoping you could help us thematically about some of your other operating expenses like R&D. I've always thought of them really trailing off pretty heavily as soon as you get these two products approved. Is that still the game plan, would you say?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

There is definitely a downward slope here as we tail off in 2011 here, as we close out the year, Charley. And there is -- our operating plan we're putting together currently, and we'll probably have more to say about our expectations on that in the early part of 2012.

Charley Jones - *Barrington Research - Analyst*

And maybe we'll wrap up this line of questioning with this thought -- so let's say you get this big R&D drop next year, and you're not going to have a huge -- you're not going to have to add a huge bunch of selling people out there. You'll have to add, obviously, some sort of selling component to it, but will you likely be reinvested -- should we think about you reinvesting these additional operating expenses back into the business through your marketing campaigns, for example, for HIV direct-to-consumer? Or is there a period of time that it flows into the bottom line?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

I think that what you're going to find is that the reduction in expenditures on the R&D line to the extent that we are reducing will, in fact, be redeployed into the launch of our HIV OTC product. And launching a consumer product is an expensive proposition, and we are going to do it right and get it right the first time and make the necessary expenditures to accomplish that.

Just to add a little bit more to that, one of the products of some of the market research we're executing right now is to get a better idea on unit demand and where we anticipate that demand to come from. So how much is going to come through retail pharmacies, mass retailers or online? And the original data that we collected on that was back in 2005, 2006, and I think we all agree that over the last five years there have been tremendous developments in online purchasing capability as well as social media influence on consumers' buying habits.

And we're going out, over the next several months, and we're going to revalidate that data to get a better idea as to where that demand is -- what channel that demand is likely to come through. That will also impact our promotional efforts and the amount of spend required to generate that demand.

So some of these numbers still have to be refined as we continue our effort to get a better understanding through some pretty robust market research.

Charley Jones - *Barrington Research - Analyst*

That's helpful. So remind me again when you guys think you can have approval or get this product out to market -- I'm talking about the OTC.

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

The only things that we can control are, obviously, our submission and, like I mentioned, our final submission is going to go in in December, and then the ball is in FDA's court to schedule an advisory review, and --

---

Charley Jones - *Barrington Research - Analyst*

Yes, sorry, that was way too open-ended. Let me try and refine it a little bit. So from -- I'm sure you've had some sort of advisory review in some of these previous submissions. What kind of turnaround time from the review do you typically get approval?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

We have not had any other product go through an advisory committee review to approval. Most of our other approvals have been either 510(k)s or straightforward PMA submissions that weren't on a panel track.

Charley Jones - *Barrington Research - Analyst*

But is that three-month timeframe a reasonable estimate?

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

Well, here is our experience with this product. We've been in front of three advisory committees, and each one of them were very productive. And it was shortly after the advisory meeting that we had clear direction from the FDA as to what our next steps needed to be.

Obviously, we're predicting the future. Our plan is to submit a robust data set in December. It's going to be well organized and structured. Hopefully, the FDA will be able to get through it quickly. We'll have a review as quickly as they can get it booked, and hopefully we'll get a quick turnaround. I can't give you any more than that, Charley.

Charley Jones - *Barrington Research - Analyst*

Yes, that's fine. Last question here -- so if we just take the exact timing of that out of it and think about how long it takes to kind of fully implement your marketing spend and your advertising campaign, can we expect to see the majority of that spend, I mean, that kind of the high-water mark, I guess, within, I don't know, three or so quarters of approval? Or is this something that -- you know, so that we eventually see a dropoff in operating expenses sometime down the road? Or do you not even think that way?

Ron Spair - *Orasure Technologies, Inc. - COO, CFO*

Yes, let us give you a better view on that as we progress this market research and we get a little bit closer to launch. A lot depends on how much is direct advertising, how much is public relations. How much of that is ongoing? What kind of trade promotion expense we're going to have with the product once it's in the marketplace.

One thing that we believe is that post-approval, it will probably be six to eight weeks until we're able to get product on shelf, just because -- get the product into the channel and work with the retailers to make that happen.

We do believe that we'll be able to begin online sales and fulfillment in a shorter time period post launch. So, again, we'll try to give you as much information as we can on that a little bit later as we get closer to approval and availability.

Operator

Thank you. This ends the Q&A portion of today's call. Ladies and gentlemen, thank you for your questions today. I'd like to turn the call over to management for any closing remarks.

Doug Michels - *Orasure Technologies, Inc, - President, CEO*

I just wanted, on behalf of Ron and myself, I just want to thank you all again for joining us this afternoon, this evening on the call, and I appreciate your continued confidence in the business. We'll look forward to talking to you next quarter. Take care.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the program. You may now disconnect and have a wonderful day.