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OSUR - Q4 2013 OraSure Technologies, Inc. Earnings Conference Call

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PRESENTATION

Operator

Good day ladies and gentlemen. Welcome to the OraSure Technologies Incorporated fourth quarter 2013 earnings conference call. At this time all participants are in a listen-only mode. Later we will conduct a question and answer session, and instructions will follow at that time. (Operator Instructions). As a reminder, this conference call is being recorded. I would now like to introduce your host for today's conference Judy Clarke, you may begin.

Judy Clarke - OraSure Technologies, Inc. - IR

Thank you. Good afternoon everyone, and welcome back to OraSure Technologies 2013 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 speaker's remarks, there will be a question and answer period. (Operator Instructions). To allow time for as many questions as possible, questioners are asked to limit themselves to only a single question with no more than one follow-up question related to the same topic. Once the follow-up is completed, a questioner can rejoin the queue for further questions.

OraSure Technologies issued a press release approximately 4.00 PM Eastern Time today regarding its 2013 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 Press Releases.

This call is also available realtime on our website, and will be archived there for seven days. Alternatively, you can listen to an archive of this call until Midnight, February 12, 2014 by calling 855-859-2056 for domestic, or 404-537-3406 for international. The access code is 37105448. With us today are Doug Michels, President and Chief Executive Officer, Ron Spair, Chief Operating Officer and Chief Financial Officer, and Kathy Weber, Senior Vice President and General Manager, Consumer Products. Doug and Ron will begin with opening statements, which will be followed with a question and answer session.

Before I turn the call over to Doug, you should know that this call may contain certain forward-looking statements, including statements with respect to revenues, expenses, profitability, earnings or loss per share and other financial performance, product development, performance, shipments and markets, and regulatory filings and approvals. Actual results could be significantly different.



Factors that could affect results are discussed more fully in the Company's SEC filings including its registration statement, its Annual Report on Form 10-K for the year ended December 31st, 2012, its quarterly reports on Form 10-Q, and its other SEC filings. Although forward-looking statements help to provide complete information about future prospects, listeners should keep in mind that forward-looking statements may not be reliable. The Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call.

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

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

Thank you Judy. Good afternoon everyone, and welcome back to our call. About an hour ago, we issued a press release in which we announced excellent fourth quarter results, and a strong finish to a very good year in 2013. Consolidated net revenues for the fourth quarter were almost \$29 million, and total revenues for the year were just under \$100 million. Both are records for OraSure.

The major growth drivers were our Infectious Disease and Molecular Collection Systems businesses. Infectious Disease revenues were up 30% for the quarter, and 19% for the year, primarily because of sales of our OraQuick In-Home HIV test, and growth in our HCV business.

Our Molecular Collections Systems business continues to deliver exceptional results. Net revenues for this segment grew 60% in the fourth quarter, and 43% for the full year compared to 2012. During the fourth quarter, we continued to execute our new marketing campaign for the OraQuick In-Home HIV test, and our OraQuick HCV business gained momentum.

We also entered into a new strategic collaboration for our Intercept substance abuse testing business, which we expect will help us resume growing this business. I will provide additional insight into these and other items later in the call, but first let me turn the call over to Ron to recap our financial performance. Ron.

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

Thanks Doug, and good afternoon everyone. So starting with our top line, our fourth quarter 2013 consolidated net revenues were \$28.8 million, compared to \$22.1 million reported in 2012. Our consolidated product revenues increased 31% as a result of higher sales of our Molecular Collection Systems, Infectious Disease Testing, and Cryosurgical Systems Products. These increases were partially offset by lower sales of our Insurance Risk Assessment products.

Our Molecular Collections Systems revenues primarily representing sales of the Oragene product line increased to a record high of \$6.8 million in the fourth quarter of 2013, compared to \$4.3 million in 2012. This 60% increase was the result of higher sales in the commercial market. Our Infectious Disease Testing revenues were \$15.4 million in the fourth quarter of 2013, compared to \$11.8 million in the fourth quarter of 2012. The overall 30% increase was primarily a result of \$3.9 million in net sales of our OraQuick In-Home HIV test, compared to \$546,000 in the fourth quarter of 2012, the period in which we began selling this product.

During the current quarter, gross sales of our OraQuick In-Home HIV test were \$4.3 million, which included a \$2.7 million adjustment made in December to account for a change in our revenue recognition policy related to this product. Total gross sales were offset by \$349,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances. Net sales of this product included approximately \$101,000 of direct sales of our OraQuick In-Home HIV test to public health customers.

Sales of our OraQuick HCV professional product in the domestic and international markets increased 65%. International sales of our Professional HCV test in the fourth quarter of 2013 increased to \$860,000 from \$326,000 in the same period last year, primarily due to sales and support of a significant testing program with an international NGO. Higher demand in the domestic market contributed to the increase in sales of our HCV test in Q4 to \$1.1 million from \$847,000 in the prior year. International HIV sales increased to \$907,000 in the fourth quarter of 2013 from \$773,000 in the fourth quarter of 2012. This increase was partially offset by a decline in domestic HIV revenues which were down \$710,000, or approximately 8% due to reductions in government funding and the timing of customer purchases.



Fourth quarter 2013 Cryosurgical revenues increased 32% to \$3.6 million from \$2.7 million in the fourth quarter of 2012, primarily as a result of higher over-the-counter sales. OTC sales increased to \$1.3 million in the fourth quarter of 2013 from \$526 million in the fourth quarter of 2012. This increase was primarily a result of the timing of orders placed by both our Latin American and European distributors. Our Insurance Risk Assessment revenues decreased to \$827,000 in the fourth quarter of 2013 from \$1 million as a result of reduced demand in the domestic life insurance markets, as well as the adoption by some underwriters of a simplified issue policy.

Our gross margin for the quarter ended December 31st, 2013 was flat when compared to the year ago quarter. Our consolidated operating expenses for the fourth quarter of 2013 decreased to \$11.1 million during the fourth quarter of 2013 compared to \$19.4 million in the fourth quarter of 2012. The decrease was primarily due to the inclusion of an \$8.3 million settlement payment received from Roche Diagnostics for the termination of our oral fluid assay collection agreement. Advertising and promotional activities related to our OraQuick In-Home HIV test also decreased to \$4.6 million in the fourth quarter of 2013, compared to \$5.2 million spent in the fourth quarter of 2012.

From a bottom line perspective, we reported net income of \$6.2 million, or \$0.11 per share for the fourth quarter of 2013, compared to a net loss of \$5.9 million, or \$0.11 per share for the same period of 2012.

Turning briefly to our balance sheet and cash flow, our cash balance at December 31st, 2013 was \$93.2 million, compared to \$87.9 million at December 31st, 2012. Cash provided by operating activities in the fourth quarter of 2013 was \$11.4 million, compared to \$1.4 million used in operating activities in the fourth quarter of 2012. Cash generated in the fourth quarter of 2013 included the \$8.3 million payment from Roche Diagnostics.

Turning to guidance for the first quarter of 2014, we are projecting consolidated net revenues of approximately \$23 million to \$23.5 million, and a consolidated net loss per share of approximately \$0.13 to \$0.14 for the quarter.

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

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

Thanks Ron. Let me start out and say the fourth quarter was the first full quarter of implementation of our new marketing campaign for the OraQuick In-Home HIV test, which was entitled, Life As We Know It. This campaign which launched in September in conjunction with National Gay Men's HIV Awareness Day has focused on the need to significantly increase brand awareness among MSM, or men that have sex with men, as well as among African American consumers. As explained in prior calls, this new campaign has targeted urban high prevalence markets, and has incorporated influence and trusted spokespeople from within the target communities that we serve.

We are beginning to see positive results from this new campaign. Retail sales have increased over the last several periods, with average weekly sales through major retail accounts up about 7% in December versus November of last year, and up about 8% in January of 2014 versus December of 2013. Additionally, we believe that a greater portion of our sales are now coming from channels not tracked by the Nielsen service such as internet sites and independent drugstores. We estimate that these outlets represented at least 13% of our total retail sales, and 24% of total product shipped during 2013.

In addition, social media mentions and website traffic increased significantly during the fourth quarter, and continued to build in 2014. Daily visits to our OraQuick.com website since the launch of the new campaign are up about 10% compared to Q2 of 2013, and up about 82% compared to Q3 of 2013. Visitors to our website are showing strong purchase intent, with about 40% indicating that they will purchase at retail or online after their site visit. Average daily social media impressions, a key measure of the impact of our campaign, reached a record high in January of \$1.1 million, which is an 80% increase over June of 2013. We expect our marketing plan will continue to deliver increased levels of impressions and increased product sales as we work through the first quarter.

In January, we added a significant new element to the campaign with the launch of our sponsorship of the hit BET series, Being Mary Jane, which premiered on January 7. Being Mary Jane was the number one original cable series debut for the 2013/2014 season among adults and women

aged 18 to 49 with 5.2 million viewers tuning in to the premiere night. Our sponsorship includes a custom TV commercial featuring journalist and TV personality Jackie Reed, and digital advertising through BET Properties.

We also launched the print element with our partnership with Essence Magazine, with an advertorial in the February Love edition. We are continuing a strong digital program, and will expand our reach with new properties throughout the first quarter of this year. To reach gay men, we are continuing our logo TV partnership, and look forward to our sponsorship of RuPaul's drag race, Logo's top-rated show beginning in February. This will be in addition to our digital programs and planned scheduled events targeting the gay community. We also continue to work with our distinguished panels of influencers within our targeted communities, including Magic Johnson, Dr. Rachael Ross, Demetria Lucas, Jackie Reed, Ross Mathews, and others. These celebrities are being used in advertising, public relations, and social media.

The FDA recently issued new guidelines on social media that provide manufacturers greater liberty in the social media space. Although these guidelines were specifically written for the pharmaceutical sector, we believe the principles will be applied to manufacturers of medical devices. And this change is expected to allow greater flexibility to take advantage of social media in the months ahead, and utilize a higher proportion of unpaid media for our promotional activities.

As you probably know, low product awareness among key consumer targets has been an issue, in December we completed a study to measure awareness among the MSM community. UnAIDed product awareness among gay men is now 15%, and AIDed awareness is 47%. This is an area we are continuing to work to improve, and we expect our new marketing campaign to aid in that effort. We plan to complete a similar study to measure awareness within the African American community later in February. Our In-Home HIV test also continues to receive strong support from the major retail chains, and we are making great strides in understanding how to maximize our impact in store, and leverage the power of our broad distribution.

Starting in the first quarter of this year, we expect to launch several new retail programs. In January, we launched an innovative new program using the OraQuick In-Home HIV test, and the retailers distribution networks to assist public health entities in accessing hard-to-reach audiences. We will also launch our first major merchandising program, with display units planned in close to 2,000 high volume retail outlets. These displays will increase visibility of the product in store, and ensure adequate inventory to support key promotions. We will also continue to use a combination of tactics to attempt to reduce or remove barriers to consumer access at retail, although this remains a key challenge as described in prior calls. These tactics include store-level retail coverage to remove barriers and ensure product inventory, as well as the development and pilot of a theft allowance for retailers to encourage them to remove security devices.

We expect to be able to measure the impact of these tactics more fully later in the first quarter. Although the product is now only available domestically, global interest in our In-Home HIV test is growing, largely due to the public health benefit and positive experience seen here in the United States. As an example, it is expected that the long-time ban on home HIV testing in the UK will be removed in or around April of 2014. We have been approached regarding collaborations in Latin America, Europe, Asia and the Middle East, and are currently conducting volumetric studies in several markets. We are also engaged in active discussions with government authorities, advocates, and potential commercial partners in several international markets. And we are increasingly optimistic about our prospects for international expansion.

Turning next to our OraQuick HCV test, as discussed in prior calls, there have been a number of encouraging developments during the past year that we expect will positively impact demand for this product. First and foremost are the new therapies that are becoming available for the treatment of Hepatitis C infection. In December of last year, Gilead Sciences received FDA approval for its sofosbuvir medication and AbbVie's CEO recently indicated on a recent earnings call that he expected the US launch of AbbVie's new therapeutic to occur later in 2014. Other pharma companies such as Johnson & Johnson and Bristol-Myers Squibb have similar drug approvals pending before the FDA. These treatments are expected to be more effective with fewer side effects, and will very likely drive increased demand for HCV testing.

During 2013, the US Preventive Services Task Force issued final recommendations giving HCV screening for both at-risk individuals and baby boomers a B grade. Any service receiving an A or B grade from the Task Force is expected to be covered by insurance without cost sharing. The B grade for screening baby boomers represents a significant step by the Task Force, and brings its final recommendations into line with the CDC's recommendations that all persons falling within the baby boomer birth cohort be tested at least once for HVC, due to the higher risk of infection within that population.



On October 23rd of last year, the State of New York passed a law requiring that doctors offer Hepatitis C testing as a routine part of healthcare provided to baby boomers. The law went into effect on January 1st this year. We believe this could be the start of a trend among the States, and at least two, Pennsylvania and Florida, have introduced HCV testing legislation. We also believe similar legislation may be in the planning stages in Ohio, Maryland, Georgia, and the District of Columbia.

Recently the American Association for the Study of Liver Diseases, AASLD, and the Infectious Diseases Society of America, issued updated guidance on HCV testing and linkage to care. This guidance recommends HCV antibody testing at least once for persons born between 1945 and 1965, and for other individuals who have been identified to have increased risk of HCV infection. Our OraQuick HCV test is specifically mentioned in the guidance as an FDA approved antibody test that should be considered for this broad-based testing.

We are starting to see positive signs in our business as evidenced by our most recent financial performance. Fourth quarter HCV revenues rose 65% over the year ago period, with full year revenues increasing 32% over 2012. These increases were driven by higher demand in the US and international markets. For the full year, 2013, we added over 400 new HCV customers, and we continue to see growth in the average order size for this product in all markets, both domestic and international.

As we look forward, we believe the recent market developments, and in particular the approval of new more effective treatment therapies, will continue to drive demand for Hepatitis C testing and the use of our test. We expect to see continued growth domestically, especially as our public health customers expand existing testing programs and start new ones, and as hospitals and physician offices more widely implement testing of baby boomers. International growth should continue as well, as we expect continued purchases from the large NGO we began supplying in the second half of last year. We are also continuing discussions with the pharmaceutical companies offering treatment for HCV, and we are enthusiastic about the prospects of working more closely with them to increase HVC testing and getting those individuals who are diagnosed the care that they need.

Another area I want to address is our Molecular Collection Systems business. As Ron mentioned, this part of our business delivered record revenues for both the fourth quarter and full year, and has been a key growth driver for the Company. DNA Genotek's commercial business fueled this exceptional growth. This represents a shift in customer mix as DNA Genotek has historically received the majority of its revenues from academic customers. However the revenue split between commercial and academic customers was approximately 80/20 for Q4, and for the total year was approximately 60/40.

The business is continuing to see the benefits in the commercial market from having the only 510K cleared device for collecting and stabilizing DNA from saliva for genetic testing. These benefits are translating into longer-term purchasing agreements from some commercial customers which are driving growth and predictability. The Company's investment in the academic market is also generating new opportunities. Although the US and European academic markets are still facing significant funding pressure, DNA Genotek continues to win new academic projects in both of those territories. We have also spoken previously regarding efforts to increase DNA Genotek's production capacity. These efforts are ongoing and they are on track. We expect to be ready with increased production capacity later in Q1 of 2014.

Before moving to the next topic, I want to briefly address the FDA warning letter received by 23andme in late 2013. That letter resulted in 23andme reducing the scope of its services in the United States. Although these events will negatively affect sales at least in the near term, DNA Genotek continues to diversify its customer base. Consequently we expect our Molecular Collections Systems business to continue to grow in 2014.

During the fourth quarter, we announced a significant development affecting our substance abuse testing business. We terminated our ongoing collaboration with Roche Diagnostics for the development of high throughput fully automated oral fluid drugs of abuse assays for use with our Intercept collection device. As part of the termination we received an \$8.3 million payment, and Roche has agreed to continue to supply a number of the assays that had previously received 510K clearance for up to a 5-year period.

At the same time we announced that we had entered into a new agreement with Thermo Fisher for the development and supply of replacement fully automated assays for this part of the business. We are very excited about this new relationship, and we expect to launch a NIDA-5 panel of the new assays later this year, with our second generation Intercept device into the criminal justice and forensics market. The ultimate plan is to obtain 510K clearance for up to 12 of the thermal assays for use with our new Intercept device, and in the process, meet the requirements promulgated



under new oral fluid drug testing guidelines expected to be issued by SAMHSA. We believe this collaboration will have a significant beneficial impact on the Company, and allow us to resume growth in our substance abuse testing business.

Before we open the floor up to your questions, I wanted to let you know about an upcoming change in our senior management team. Dr. Stephen Lee, our Executive Vice President, Research & Development and Chief Science Officer, has announced that he will be retiring from OraSure effective at the end of February. This was a personal decision that Steve has made, and we have a plan in place for the orderly transition of his responsibility. Steve joined in 2005 and has made numerous contributions to our Company.

Under Steve's leadership, OraSure obtain FDA approval of and commercially launched our OraQuick HCV test, the first and only rapid HCV test approved by the FDA. He played a critical role in the Company's highly-successful efforts to develop and introduce the OraQuick In-Home HIV test. On behalf of our management team and the Board of Directors, I would like to wish Steve all of the best in his future endeavors.

As I mentioned previously, we have a transition plan in place for Steve's retirement. So today I am very pleased to announce the promotion of Dr. Eric Whitters from Director of Research & Development, to Senior Vice President of Research & Development, Regulatory, Quality and Clinical Affairs effective March 1, 2014. Eric will take over Steve's responsibilities. He will be a member of our Internal Executive Committee, and he will report directly to me. Eric joined OraSure in November of 2012, and has over 20 years of experience in the diagnostic industry. Before coming to OraSure, Eric served as Vice President of Research & Development at Novartis Diagnostics, and as a Director of Technical Operations at Siemens Healthcare Diagnostics. Eric has particular expertise and experience in Molecular Diagnostics, which is certainly an important growth opportunity for the Company. I look forward to the many contributions Eric will undoubtedly make to our Company's future success.

So with 2013 now complete, we intend to build on the strong momentum from the fourth quarter. OraSure has ample opportunities to grow in 2014 as we are in the early stages of penetration in several large markets. We expect that growth to be driven primarily by our Molecular Collections Systems and Rapid Hepatitis C testing businesses, as well as our In-Home HIV product. And we also expect to see some benefit in the substance abuse area from our new collaboration with Thermo Fisher later in the year. And with that, I will now open the floor to your questions. Operator, if you could please proceed.

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions). Our first question comes from the question of Jeff Frelick from Canaccord, your line is now open.

Jeff Frelick - *Canaccord Genuity - Analyst*

Good afternoon, folks.

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

Hey Jeff.

Jeff Frelick - *Canaccord Genuity - Analyst*

Hey guys.



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

Hi, Jeff.

Jeff Frelick - *Canaccord Genuity - Analyst*

A question on HCV sales, 400 customers now you mentioned, Doug. Could you give us a sense of the mix between how many physician offices versus clinics, and just as follow-up to that, can you give us a sense of the lead order rates? Thanks.

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

Right. So a lot of metrics around that, right? If you look at full year revenue mix, on a geographic basis about 56% of revenues came out of the United States, about 44% International. And that 44% International had a pretty decent distribution. A significant contribution of that was this large NGO we talked about, but about 12% was out of the EU, about 6% out of Asia, and the rest coming out of rest of world.

If you look at that 56% of revenues that came out of the domestic market, about two-thirds of that, maybe a little more was in the Public Health market. Obviously the Public Health jurisdictions have the infrastructure to adopt rapid Hepatitis C testing, because they have adopted Rapid HIV testing, and so we were able to penetrate that market more rapidly. Obviously we expect continued growth in the Public Health market, but also in the physicians office market, as both primary care as well as specialists begin to adopt some of these new testing recommendations, and we have also seen some growth in the hospital market, where some of the pharmaceutical companies in the therapeutic space have funded some grants to expand testing in the hospital market.

Jeff Frelick - *Canaccord Genuity - Analyst*

Just on the reorder rates that you are seeing?

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

We have seen at least half of those customers reorder in 2013. And obviously we expect that we are going to see that reorder rate increase. I think one thing that has been very encouraging for us is that the average order size in Q4 was literally double what it was previously, and that held up in each one of the different segments whether it was Public Health, hospitals, the physician office, or international. And additionally we are seeing some new types of customers come online. A major retail pharmacy here in the United States now is offering rapid HCV testing on a fee-for-service basis in 35 different locations, and we expect that to grow substantially in 2014.

Jeff Frelick - *Canaccord Genuity - Analyst*

Thanks Doug.

Operator

Thank you. And our next question comes from the line if Shaun Rodriguez, Cowen and Company. Your line is now open.

Shaun Rodriguez - *Cowen and Company - Analyst*

Hi guys. Good afternoon. Thanks for taking the question. So really strong Genotek quarter with early growth acceleration in Q4 amidst all of the 23andme developments. I was hoping you can give more detail on this strength based on the 80% commercial mix, that is clearly the area of strength, but was there any notable bulk purchasing in there, and also any detail on how 23andme behaved during the quarter? Obviously the



event there being the warning letter. Any detail on sort of their buying behavior before and after, so that we can get a sense for the outlook for their purchasing moving forward?

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

Yes, so first of all, Shaun, growth on the commercial front was pretty broad-based. Clearly 23andme was an important contributor to revenues in Q4, but we had strong growth from a whole host of other commercial customers, whether it was in the pharmacogenomic space, whether it was in different types of registries, and we expect that that is going to continue. We really didn't see any negative impact from the 23andme warning letter in the fourth quarter. As I mentioned, they were a strong contributor to the commercial revenues. But we do anticipate that we will see a reduced contribution from 23andme in 2014, until such time as they resolve some of these regulatory issues.

Their business is not going to zero in 2014, that is for sure. They continue to offer their full service offering outside of the United States, and they have scaled back on their product offer here in the United States, but they are still offering non-health-related genetic information and testing services. We know that because we are in regular contact with them that they are regular discussions with the FDA, and collaborating fully with the FDA, and they do intend to file for FDA approval of their healthcare product service offering, so that they can get back in the market with the full or near full service offering. Timing on that I think is best answered by 23andme, but we know that they are working on it very diligently.

Shaun Rodriguez - *Cowen and Company - Analyst*

That is helpful. I appreciate that color. And on potential partnerships with the HCV drug industry, obviously if you had something to announce you would have, and we have heard for some time that interest is high and discussions are active, but I was hoping to get a feel whether there is a priority for senior management, in terms of a view of what it could mean for the commercial potential of the test, but also in terms of any sense of urgency with regard to a window in which you would be really maximizing the opportunities here? I am not saying that you would take a bad deal just to get one done, but just really trying to get some color around how much priority you put on this?

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

Well, I can tell you it is a high priority. And we are engaged at a significant level in different discussions. We believe that one of the key growth drivers for HCV testing in 2014 and beyond is going to be the introduction of these new therapies and the adoption of these new therapies.

Gilead's new drug is obviously off to a great start, and I am quite certain they are working through the large warehouse of HCV-positive patients that have not yet gone on therapy, but given the success of their product so far, they are going to work through that warehouse pretty quickly, and as these new therapies come online, there is going to be tremendous demand to identify more individuals that are chronically infected. We know that all of the pharmaceutical companies in this space have a keen interest in building awareness about HCV, but it is not just the pharma that are focused on that. Each of the Public Health jurisdictions are very keen on building awareness.

The different medical societies, whether it is AASLD, or the National Medical Association, or the CDC, or in the introduction of laws now that are mandating testing and connection to care, and we are actively involved in developing new screening programs. I mentioned a specific program that is going on with one of the major retailers here, and we are engaged with a number of different Public Health jurisdictions on some major programs as well. So it is a priority, but obviously as we engage in those discussions, we want to be thoughtful in terms of the types of relationships we are going to enter into. We want to make sure that they work for us as well as the communities that we are serving. And I remain hopeful that we will be able to get something done.

Shaun Rodriguez - *Cowen and Company - Analyst*

That is really helpful. Thank you for that. And lastly on HIV OTC spend, I think it was about \$1 million less than we had expected, some encouraging monthly trends the past few months, and you do sound relatively encouraged by the data you are seeing in terms of the traction from the new

promotional campaign. But how we should we think about spend over the last few quarters, because I think that you recently talked about trying to maintain some flexibility in reacting to the data that you are seeing before really committing to any incremental spend there?

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

I think that is a good way to characterize it. You should know that Kathy Weber is also here in the room with Ron and me, and she can answer any specific questions on the different HIV-OTC programs, and where we are headed with that. Do you want to make any comment, Ron?

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

I was just going to, the only thing I was going to say before you might want to elaborate, is that for the first quarter we have approximately \$5.6 million worth of spending included within our guidance numbers that we provided for HIV-OTC advertising and promotional efforts.

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

And I would say that while that is in the first quarter budget and we are committed to that, because we still have elements of this retooled and refined campaign that have yet to move out or roll out, I want to emphasize that we are keeping a very watchful eye on the returns that we are getting for our promotional spend, and frankly, we need to see better returns to continue investing at this level. And I can say that we won't continue at the current spending levels if sales remain on their current growth trajectory. So I want to be clear on that.

I also want to point out that it is too early to tell if the retargeted campaign is going to be successful or not. One of the key aspects of the campaign is to increase awareness amongst our target consumers. And that is tough sledding. And it requires investment and we are making that investment, and we are starting to see positive, positive results but we have to see better results to continue spending at this level, and so we are going to monitor this as I said. And as we get out through the first quarter, and evaluate the impact of all of these programs as they are fully rolled out, then we will continue to make prudent decisions.

Shaun Rodriguez - *Cowen and Company - Analyst*

Thank you guys.

Operator

Thank you, and our next question comes from the line of Brandon Couillard of Jefferies. Your line is now open

Kate Ryan - *Jefferies & Company - Analyst*

This is actually Kate in for Brandon. I was wondering if you could just go back to DNA Genotek for a second, go back to the growth and talk about if it is coming from the existing customer base, or are you signing up a good deal of new customers as well?

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

It is primarily from new customers but we continue to capture new customers both in the academic research space as well as commercial. And actually as we look to 2014, pro formaing out, if you will, 23andme where we expect somewhat reduced contribution, until they resolve the regulatory issues, we expect both our commercial business as well as our academic research business to grow, and to grow handsomely.



Kate Ryan - *Jefferies & Company - Analyst*

Okay. Thanks, that is helpful, and just one more on the HIV spend. Do you expect that the campaign, the current campaign will continue to grow out past the first quarter, or should we expect all of those impacts to fall in the first quarter?

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

Yes, this is Kathy. We expect the campaign to continue beyond the first quarter. As Doug said, we rolled some elements in the fourth quarter of last year, and we are continuing to add new elements throughout the first quarter, and we will continue to add elements over the course of the year. Again, against that focus of reaching the African American consumer and the gay man in the most efficient way possible, but yes, it will continue.

Kate Ryan - *Jefferies & Company - Analyst*

Okay, thanks.

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

Thanks, Kate.

Operator

Thank you. (Operator Instructions). Our next question comes from the line of Eric Criscuolo of Mizuho. Your line is now open

Eric Criscuolo - *Mizuho Securities - Analyst*

Good afternoon, thanks for taking my questions, just filling in for Peter tonight. As more and more of these large genome studies are rolling out, like the UK study looking at large populations, how involved are you in these studies, and if it is a small amount, is there upside for you guys there?

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

I don't believe that we are involved in the UK study in a major way. But I think it represents the types of studies and the opportunities down the road that are certainly ripe for DNA Genotek to participate in. So I would say absolutely they represent great opportunities for the Company.

Eric Criscuolo - *Mizuho Securities - Analyst*

Okay, thanks. And then just on the 2014 budget that was approved, has that helped your Public Health customers kind of release funds for your products?

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

It actually should have some benefit. The AIDS Institute just recently put out a real nice analysis of the impact of sequestration on some of the federal programs, and I think based on their analysis, the overall impact particularly to CDC-funded programs was in the 8% to 10% range. We estimate that within our publicly funded customer base in 2013, we probably saw an impact somewhere between 6% and 8%. And now it looks like a number of those funding cuts are going to be largely restored, not completely, but the new budget for 2014 should provide some relief, not complete relief for those customers.



Eric Criscuolo - *Mizuho Securities - Analyst*

Alright. Thank you.

Operator

Thank you. And our next question comes from the line of Nicholas Jansen of Raymond James. Your line is now open.

Nicholas Jansen - *Raymond James and Associates - Analyst*

Just a quick question for you, Ron in terms of your cash balance, \$93 million at the end of the year, about 30% of your market cap. I guess the question is with the stock being somewhat of a laggard, over the last six months or so, how do we think about maybe you guys using some of that cash flow to buy back stock, or do something with it in terms of just M&A, or maybe something to extract more value out of it rather than just sitting on your balance sheet? Thanks.

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

It is a great question, and we clearly, Nick have a focused effort in the business development area, led by Jill Thompson, our Senior Vice President of Business Development, and we are always looking at opportunities whether that be in the form of potential M&A transactions, licensing deals, partnerships, all to evaluate and identify complementary technologies and products that would drive revenue growth for us. So we would welcome an opportunity to put that money to work in a way similar to how we did with DNA Genotek, and we are always on the lookout for that. Thank you.

Nicholas Jansen - *Raymond James and Associates - Analyst*

And then in terms of cash flow guidance, I know you don't give cash flow guidance, but how should we think about cash flow in 2014 relative to 2013? I have know you actually generated cash, even excluding the Roche settlement, how should we think about cash burn or maintenance of cash in 2014?

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

Yes, so although you are right, we are not giving guidance here, I think that if you look closely at the kind of cash flow from ops performance that we generated in 2013, even pro formaing out the \$8.3 million from Roche, we are hovering in and around the breakeven position, and so I think you can conclude from that we are going to run a fairly tight ship here, looking to maintain and protect our cash position so that we can utilize that for the type of transactions that I just previously discussed. So from a financing risk perspective if that ultimately is where you are going with this, it is not an issue for us in 2014.

Nicholas Jansen - *Raymond James and Associates - Analyst*

Thanks guys.

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

Thank you, Nick.



Operator

Thank you. And that brings an end to the Q&A session of today's call. I would now like to call the call over to Doug Michels for any closing remarks.

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

I would like to thank everybody for being on the call with us this afternoon, this evening, and we certainly appreciate your continued interest in the Company. I hope you all have a great afternoon and evening. Thanks again. We will talk to you in a few months. Bye bye.

Operator

Ladies and gentlemen, thank you for participating today's program. This will conclude today's program. You may all disconnect. Have a great day everyone.

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