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OSUR - Q4 & FY 2014 OraSure Technologies Inc Earnings Call

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PRESENTATION

Rena George-Beck *- OraSure Technologies, Inc. - IR*

Good afternoon, everyone, and welcome to OraSure Technologies' 2014 full year and fourth quarter financial results conference call and simultaneous webcast. As a reminder, today's conference is being recorded.

(Operator Instructions)

OraSure Technologies issued a press release at approximately 4:00 p.m. Eastern Time today regarding its 2014 full year and fourth quarter financial results and certain other matters. The press release is available 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 real time on our website and will be archived there for seven days. Alternatively, you can listen to an archived recording of this call until midnight, February 11, 2015, by calling 855-859-2056 for domestic, or 404-537-3406 for international. The access code is 63824420.

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 remarks, 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, business plans, regulatory filings and approvals, and other matters. Actual results could be significantly different.

Factors that could affect results are discussed more fully in the Company's SEC filings, including its registration statements, its Annual Report on Form 10-K for the Year Ended December 31, 2013, 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 statement 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*

Okay, thanks, Rena, and good afternoon, everyone, and welcome to our call.

We had a very active fourth quarter, advancing our HCV rapid testing program, our molecular testing business and our Ebola development program. The Company's fourth quarter results exceeded our guidance on the top line and fell within our guidance for the bottom line.

Overall, 2014 was a very successful year. We had several noteworthy accomplishments, we delivered solid financial performance, and we advanced many programs that we expect to drive our future results.

Some highlights: For the first time in our history annual revenues exceeded $100 million. Our molecular collection systems business delivered strong growth in 2014 and ended the year up 17% over the prior year, and this increasingly important part of our business now accounts for over 20% of our annual consolidated net revenues.

We entered into an important HCV co-promotion agreement with AbbVie last year, and we believe this is a first-of-a-kind collaboration between a diagnostic company and pharmaceutical company and provides us with a significant opportunity to realize the full value of our rapid hepatitis C test and to accelerate the growth of our HCV business.

Our OraQuick HCV test continued to gain momentum, with 2014 product sales of $7.3 million. This represents a 42% increase over 2013. And these revenues, coupled with the exclusivity payments received from AbbVie, resulted in total HCV-related revenues of $14.8 million in 2014.

During the year we also instituted a new promotional strategy for our OraQuick In-Home HIV test, which is designed to bring this product to profitability. We generated almost $6.5 million in sales in 2014, and the adjustments we made to our strategy are expected to transition this product to profitability in 2015.

Our revenue growth in 2014 and prior years, coupled with continued cost management, has substantially improved our bottom-line performance. In 2014 alone we reduced our operating loss by 61%, and over the past three fiscal years this reduction was 71%. One significant byproduct of this improved performance is that we ended 2014 with almost $100 million in cash, which we can use to further grow our business.

I'd also point out the benefits we've realized by diversifying our product offerings. In 2014 our newest product lines, consisting of DNA Genotek, our HCV business and our In-Home HIV test, generated total net revenues of $45 million, or roughly 42% of our annual consolidated net revenues.

Later in this afternoon's call I'll discuss in further detail our HCV collaboration activities with AbbVie, developments at DNA Genotek, and the recent launch of our new Intercept collector, along with a panel of high-throughput drug assays. I will also briefly comment on our progress in developing our newest potential product, a rapid point-of-care test for Ebola on our OraQuick platform.

So with that introduction let me turn the call over to Ron for his financial review of the fourth quarter.

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

Okay, thanks, Doug, and good afternoon, everyone.

Starting with our revenues, our fourth quarter 2014 consolidated net revenues were $28.7 million, compared to $28.8 million reported in 2013. Our consolidated product revenues of $25.3 million decreased 12%, largely as a result of a change in revenue recognition policy related to our OraQuick In-Home HIV test, which increased fourth quarter 2013 revenues by $2.5 million.

You may recall that we transitioned to the sell-in versus sell-through model of revenue recognition in the fourth quarter of 2013. Without that adjustment, total revenues were actually up 9% quarter over quarter.

Licensing and product development revenues were $3.4 million in the current quarter and represent the recognition of exclusivity payments under the AbbVie agreement. There were no comparable licensing and product development revenues in the fourth quarter of 2013.

Our overall infectious disease testing revenues decreased 2% in the fourth quarter of 2014 compared to the fourth quarter of 2013 after eliminating the $2.5 million HIV OTC revenue adjustment.

Sales of our OraQuick HCV professional product in the domestic market decreased 3% in Q4, to $1 million, from $1.1 million in the prior year. This decrease is largely due to the timing of orders placed by our public health customers.

International sales of our HCV tests in the fourth quarter of 2014 decreased to $707,000, from $860,000 in the same period last year, and that's due primarily to reduced sales and support of a testing program with an international NGO.

Domestic sales of our professional HIV product were $8.4 million in the fourth quarter of 2014, largely unchanged from the fourth quarter of 2013.

International sales of our professional HIV product were $587,000 in the fourth quarter of 2014, compared to $907,000 in the fourth quarter of 2013. This change was primarily due to an order received in the fourth quarter last year from a Mexican customer that did not repeat in 2014.

During the current quarter, net sales of our OraQuick In-Home HIV test were $1.5 million, compared to $3.9 million in the fourth quarter last year. Excluding the $2.5 million accounting adjustment, sales of this product increased 7%, largely as a result of higher sales to our distributors and smaller retail accounts.

Our molecular collection systems revenues, primarily representing sales of the Oragene product line, decreased to $6.3 million in the fourth quarter of 2014, compared to $6.8 million in the fourth quarter of 2013. This 8% decrease was the result of approximately $1.9 million in lower sales to 23andMe, partially offset by higher sales in the academic markets. Sales to DNA Genotek's other customers grew 34% in the current quarter and substantially offset the lower sales to 23andMe.

Our fourth quarter 2014 cryo revenues decreased 5%, to $3.4 million, from $3.6 million in the fourth quarter of 2013, primarily as a result of lower sales of our professional and OTC products in the international markets, partially offset by higher professional and OTC sales in the US.

Our substance abuse testing revenues increased to $2.3 million in the fourth quarter of 2014, compared to $2.1 million in 2013. This increase is largely due to higher sales of our Intercept device as a result of ordering patterns and market growth due to improved economic conditions and increased interest in oral fluid testing.

Turning a moment to gross margin, our gross margin for the fourth quarter of 2014 was 63%, compared to 60% reported in the fourth quarter of 2013. The current quarter margin benefited primarily from the $3.4 million of licensing and product development revenues recognized from our AbbVie relationship, as well as a more favorable product mix, driven largely by increased DNA Genotek sales to higher margin customers. These improvements in margin were partially offset by a decline in overhead absorption for the quarter as a result of manufacturing downtime associated with facility equipment replacements.

Our consolidated operating expenses for the fourth quarter of 2014 increased to $20.5 million, compared to $11.1 million in the fourth quarter of 2013. This increase was primarily due to the absence of an $8.3 million contract termination payment from Roche which was received in the fourth quarter of 2013. This payment, coupled with lower promotional expense associated with our OraQuick In-Home HIV test, were partially offset by increased expenses incurred under the HCV agreement with AbbVie and higher costs -- higher R&D costs and higher staffing expenses.

From a bottom line perspective, we reported a net loss of $2.7 million, or $0.05 per share, for the fourth quarter of 2014, compared to net income of $6.2 million, or $0.11 per share, on a fully diluted basis, for the same period of 2013.

Turning briefly to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Our cash and short-term investment balance at December 31, 2014 was $97.9 million, compared to $93.2 million at December 31, 2013. Cash used by operating activities in the fourth quarter of 2014 was $858,000, compared to $11.5 million generated in the fourth quarter of 2013, which benefited from the $8.3 million payment received from Roche.

Turning to guidance for the first quarter of 2015, we are projecting consolidated net revenues of approximately $26.5 million to $27 million and a consolidated net loss per share of approximately $0.01 to $0.02 for the quarter.

And with that I'll now turn the call back over to Doug.

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

Okay, thanks, Ron.

As you know, our HCV business has been and will continue to be an important growth driver for the Company. A major component of this business is our co-promotion agreement with AbbVie, which is organized around several principal initiatives.

The largest initiative and the one to which we and AbbVie are devoting most of our resources is focused on primary care and specialty physicians. During the past several months, the AbbVie sales force has continued detailing our OraQuick HCV test to physicians around the country. At the same time, we've also been promoting our HCV test primarily through several large med-surg distributors and manufacturer representative organizations, or MROs.

As a result of these efforts, approximately 2,200 physicians, encompassing more than 1,700 practices, have indicated a strong interest in the product and a desire to be trained on its use. These accounts are split approximately 40% gastroenterologists and 60% general practitioners and other specialists. Interest in our test is broad among the physicians we've contacted.

We also are finding that the AbbVie patient support program is viewed positively by the physicians who have reviewed it, and at this time over 1,200 providers are trained or scheduled to be trained on our product, and over 600 physician practices have actually received training and either have started purchasing product or are in the process of deciding whether to purchase and use the test.

Our experience over the past several months is that the final decision by a physician to offer our test and the AbbVie patient support program is difficult to predict. Our initial estimate, based on our prior experience selling the OraQuick HCV test to physicians, was that it would take from six to eight weeks from the time a physician's office initially expresses interest, completes training and makes a purchase decision. Our experience to date indicates that this process is taking a bit longer than expected. We and AbbVie are continuing to adjust and refine our tactics to help accelerate this decisionmaking process where possible.

A second primary initiative is focused on commercial long-haul truck drivers. Working with two organizations dedicated to improving the health and wellness of professional truck drivers, we conducted four testing and awareness development events last year. Some limited testing was completed at these events and indicated prevalence rates higher than the general population, as we expected. Although these results are preliminary, they confirm the importance of building awareness and implementing test programs for truckers in 2015.

In November we formed an advisory board consisting of fleet representatives, individuals representing independent truck drivers and industry consultants in order to obtain additional guidance on strategic and tactical planning for this initiative. We gained insights into how to educate truckers, the potential environments for testing and the concerns of the industry with the high cost of treatment for individuals who test positive for HCV. We will continue to do more work in these areas during the first quarter as we develop and refine our plans.

Working closely with AbbVie and our industry partners, we intend to complete development of a provider portal and trucker app designed to provide education and awareness about the disease and the need to get tested. The next major truck testing event will be at the Mid-America Truck Show to be held in Kentucky at the end of March.

A third market initiative is focused on national and regional retail pharmacies and retail clinics. Together with AbbVie, we've continued our discussions with a growing number of retail clinics and specialty pharmacies regarding the role they can play in expanding HCV awareness and testing.

At the same time, we are planning for and in the next few months we expect to initiate pilot programs with two national retailers and one regional retail chain, with the goal of developing sustainable models for offering rapid HCV testing along with AbbVie's patient support program through their retail outlets. The discussions we've had with retailers to date have been encouraging, and we expect the financial impact of the upcoming pilots to be realized in the second half of 2015.

Overall, we remain confident that our efforts with AbbVie will help educate many individuals on the importance of knowing their HCV tested and the need to get tested. We also believe we have the right focus and resources to successfully execute on our initiatives under this important collaboration.

And apart from our AbbVie collaboration our existing HCV business continues to grow. We shipped product to over 1,000 customers during 2014, with over two-thirds of our shipments being delivered to repeat customers. We also added over 300 new customers during this period. The 42% revenue growth in 2014 reflects the results of a lot of hard work, and we believe this is the beginning of a longer term growth trend for this product line.

A second area I want to address is our molecular collection systems business. We are very pleased with the continued excellent performance by DNA Genotek. While total revenues for Q4 declined compared to the same quarter in 2013, this reduction was entirely due to lower year-over-year sales to a single large customer, 23andMe.

Total DNA Genotek revenue for Q4 was down approximately $600,000 from the prior year's quarter, despite a $1.9 million net revenue decline from 23andMe. As Ron stated, sales to DNA Genotek's other academic and commercial customers actually grew 34% in the fourth quarter of 2014 and almost completely offset the reduction from this one large customer.

For the quarter, DNA Genotek's academic revenues was up 15%, reflecting strong sales of our Oragene product. The Company had particularly strong quarterly sales in the UK, generating over $1 million of orders from UK-based academic institutions in December alone, and we continued to sell to academic institutions running studies in human genetics in many other countries.

We are also pleased with the continued progress in DNA Genotek's commercial business. In Q4, the Company experienced continued strong sales to our largest commercial customers, who use the Company's technologies for pharmacogenomics testing. We also picked up several new commercial customers in Q4, and we expect these customers to purchase increasing volumes going forward.

You are all aware that 23andMe is working to clear its Personal Genome Service test with the FDA, and although I can't comment directly on this regulatory process, I want to emphasize that we are doing everything possible to support their efforts. In the face of these regulatory challenges, however, we are impressed with 23andMe's business progress, including global business expansion in the second half of 2014 along with some recent business expansion announcements in Q1 of this year. We look forward to continuing our strong relationship with 23andMe for many years.

Turning to our substance abuse testing business, our program to commercialize high throughput drug assays with our new Intercept collector is progressing nicely. I'm pleased to report that we recently launched six high-throughput, fully automated oral fluid assays along with our new Intercept i2 collector into the unregulated criminal justice and drug treatment markets.

These assays consist of a NIDA-5 panel for the detection of amphetamines, methamphetamines, cocaine, opiates, PCP and THC, and we expect to launch a second group of six additional assays into these markets sometime in the second half of this year. This will result in a menu of 12 high-throughput, fully automated assays eventually being offered with the Intercept i2 device, which we believe will meet the needs of our many customers.

We are also working to complete the appropriate 510(k) submissions for these products as quickly as possible. We expect to submit filings for all 12 assays along with our Intercept i2 collector later this year. Assuming we meet that deadline, we expect to receive clearances and begin commercial sales into the workplace testing and other regulated markets during 2016.

And the last topic I'll cover this afternoon is the development and possible commercialization of a rapid test for Ebola. During the past several months, we achieved significant clinical and product development milestones and have substantially advanced our development program.

We are very close to finalizing the design on a prototype device which would be available for field testing in Africa, subject to receipt of external funding. Early indications from testing by the Centers for Disease Control suggest that our prototype test can provide very good performance when evaluated on whole blood samples. We are highly encouraged by these results, and we hope to continue evaluating the device in more extensive clinical studies.

Despite the progress we've made on the development front, whether this product will ultimately contribute to our business depends on a number of factors.

First, we are seeking funding for the development efforts from a variety of federal agencies. The costs to complete development and obtain the regulatory approvals needed to build this product into a real business are not insignificant. We anticipate a positive response from one or more of these agencies and expect to hear back from them in the very near term.

As we complete our clinical development and prepare for field testing, we are also in discussions with various government agencies regarding product procurement. Our goal is to obtain external development funding along with substantial and sustainable product purchase commitments. Should we be unsuccessful in achieving one or both of these objectives, we will likely discontinue our work on this project.

So, as you've just heard, there's many growth opportunities on the table for the Company, and we're keenly focused on the successful execution of all of the initiatives I have outlined today. We're excited about the Company's prospects and we look forward to delivering a very successful 2015, including full year profitability.

And with that I will now open the floor to your questions, so, operator, if you'd proceed.

QUESTIONS AND ANSWERS

Operator

Thank you.

(Operator Instructions)

Brandon Couillard, Jefferies.

Brandon Couillard - *Jefferies and Company, Inc. - Analyst*

Doug or Ron, could you elaborate on the sequential revenue decline in the domestic HCV business? You called out public health customers. Is this a handful? Is it one? And to the degree you're able to comment, would love your input on how you view the trajectory of that business going into the first quarter.

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

Yes, the sequential decrease is really accounted for by a couple of very significant public health orders that we were anticipating in the quarter that actually pushed into 2015. And had those been realized the sequential growth would've been significant.

Brandon Couillard - *Jefferies and Company, Inc. - Analyst*

So should I interpret that as them falling in 1Q? Do you have any visibility around timing?

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

Yes, they pushed into 2015, I would expect in the first half. Whether they come in Q1 or Q2, that's a TBD.

Brandon Couillard - *Jefferies and Company, Inc. - Analyst*

Okay. And then could you give us an update in terms of the doc training cycle times? You mentioned it being a little bit longer than the, I guess, the six to eight weeks that you initially anticipated. Just what are you seeing in terms of after docs get trained, what is the hurdle to them actually putting through orders for tests?

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

I think what we're trying to describe there are that this is a continuous learning process, and certainly we went into this whole effort with some expectations, some assumptions in terms of what that time frame would be from the time a physician expressed interest to the time they got trained to the time they'd place their first order to the time that they began testing patients and enrolling patients into that process.

That's a lot of factors that factor into that whole process, not the least of which is -- in the fourth quarter was holiday time. And you can imagine, as we described in the script, we have a lot of activity with a whole lot of interest, but convincing a physician practice to implement testing between Thanksgiving and the end-of-year holiday, when a lot of their staff is going to be out on vacation and this is going to be a change in their workflow, obviously is a difficult thing to influence. Those are just some of the factors.

The good news, good news is that things are progressing largely as expected. That doesn't mean that everything is going according to plan, and -- but that's why we have smart, committed people making the adjustments that are necessary, course correcting where we need to. And we've made a number of changes. Let me give you just some examples.

One of our processes has been that AbbVie, once they uncover a physician or a physician office practice that's interested in testing, they transfer that level of interest to OraSure. We then work with our third party, PSKW, to schedule that training, and then PSKW gets back to the physician's office to make those arrangements.

We found that all those different steps took too much time, and during the fourth quarter we actually developed a scheduling app that AbbVie's reps now have on their iPads. Think of it as OpenTable dinner reservation kind of program, where they can, while they're in front of the physician, access open training dates, schedule that training right there with the physician and commit to it at the moment. That's a substantial process improvement that's going to accelerate what we're trying to do here. But that's an example of the kind of adjustment that we're making as we work through this process.

I think we also need to be realistic in our expectations that the AbbVie organization, they just got their drug approved right before the holiday, and they're in a dogfight with Gilead right now. Gilead's been out talking about their drug for well over a year. AbbVie's just had the opportunity to begin talking about their drug for the last five weeks. And that's all understandable.

We've got plenty of opportunity right now with the number of physicians who've expressed an interest, with all these physicians and physician offices that have been trained, to drive this conversion from training to ordering to testing patients and driving them into the patient support program. And that's our focus right now.

So, like I said, things are progressing largely as expected. It doesn't mean that everything's working perfectly. But where we've identified opportunities for improvement we're making those improvements and progressing the different programs.

Brandon Couillard - *Jefferies and Company, Inc. - Analyst*

Super. Thank you.

Operator

Shaun Rodriguez, Cowen and Company.

Ryan Blicker - *Cowen and Company - Analyst*

This is Ryan Blicker filling in for Shaun. So just continuing with HCV, looking at the sell side models right now for HCV it's looking at around $15 million or $16 million for 2015. Given the implied acceleration from here, could you discuss whether this is still a reasonable target? Obviously it requires a lot from the AbbVie partnership. And are you still confident that you will reach that minimum earnout payment in 2015?

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

So, we really don't get into that level of granularity on some of our guidance discussions here other than to -- obviously the amortization of the exclusivity payments is a fixed component of revenue at $3.4 million per quarter. We've also indicated publicly before that we expect to hit a milestone payment in 2015. But as far as the total expectation related to annual revenues derived from the AbbVie relationship, we have not put a line in the sand, if you will, as to what our expectations are surrounding those revenues.

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

And we don't provide annual guidance on any of our businesses.

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

We're continuing to provide quarterly guidance.

Ryan Blicker - *Cowen and Company - Analyst*

Okay. Thank you. And then two more quick ones on HCV. You had previously said that when patients enroll in the AbbVie patient support program that it doesn't matter if they end up using Gilead's or AbbVie's drug for treatment as long as they enroll in the program, that it still counts toward your milestone. Is that still the case?

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

That's correct.

Ryan Blicker - *Cowen and Company - Analyst*

Okay. And then -- thank you. And then lastly you mentioned the AbbVie OpEx. Can you talk, or can you quantify exactly what the OpEx associated with the AbbVie agreement was in the quarter?

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

We're not prepared to give that level of granularity to our expenditures there.

Ryan Blicker - *Cowen and Company - Analyst*

Okay. Thank you.

Operator

(Operator Instructions)

Eric Criscuolo, Mizuho and Company.

Eric Criscuolo - *Mizuho Securities Co., Ltd. - Analyst*

Just filling in for Peter tonight. I guess just on the 23andMe partnerships that they've kind of announced beginning of this year, they seem to be, or at least the ones that are public, they seem to be more of a database querying of info that 23andMe already has. Is there additional opportunities for you to sell more tests based on those partnerships, or more collection devices to those partnerships to 23andMe, or is -- or are these collaborations more of like the data already being there and these companies just kind of looking into the database?

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

Well, so I think there's many opportunities to expand our business with 23andMe, certainly 23andMe's successful expansion of their product offering into other geographies. In -- earlier in 2014 they launched in Canada. In the fourth quarter they launched in the UK. And we are aware that they're planning other launches in other geographies around the world. We're not at liberty to say which those are or when those might come to fruition, but certainly those represent, we believe, nice opportunities for continued expansion.

Certainly as they work through and ultimately, we believe, resolve some of their issues with the FDA, their product offer is going to continue to become more attractive to consumers here in the United States. We believe that represents another opportunity. And all of this represents, and I think these examples, the announcement they made about their relationship with Genentech and others, just highlights the power of their product offer and the information that they're able to generate, together with consumers, which can provide some real insight into populations and as well as diseases.

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

And, Eric, just another point. Currently they've disclosed that their existing database of genomes is less than a million, but they have certainly indicated aspirationally to be well north of that as far as collections that they want to get into the database, which of course enhances the value of it from a query standpoint to pharma partners and others looking at relationships embedded within one's genetic database that they are going to amass. So I do think that there are plenty of opportunities yet to accrue to us in the form of being part of those collections.

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

I think it's also important to understand that our collection system, the Oragene collection system, has been at the foundation of all of those collections and represents trust and confidence in sample collection, sample integrity. And obviously it starts with a high-quality sample. And so their database is really dependent on having a good sample upfront, and obviously that's -- we expect that's going to continue as they amass more specimens and more data into their database.

Eric Criscuolo - *Mizuho Securities Co., Ltd. - Analyst*

Okay, thanks for the -- thanks for that color. And, I guess, going back to the HCV payments, the milestone payments potentially in 2015, I know you had just said there's potentially one milestone in there for the year. Are there more than one opportunities?

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

The only thing that we've indicated to date and still our messaging is that we expect to receive at least one payment in that milestone structure, and we're not able, really, to talk about how many positives we have to enroll. As you probably know, that was redacted from the agreement that was made public as part of our second quarter Q. But when we qualify to receive that we'll obviously disclose that at the time.

Eric Criscuolo - *Mizuho Securities Co., Ltd. - Analyst*

Could you say when in the calendar year that that potentially could occur? Is it the middle or the second half?

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

We'll announce it when we receive it.

Eric Criscuolo - *Mizuho Securities Co., Ltd. - Analyst*

Figured I'd try. All right, guys. Thank you very much.

Operator

Mark Massaro, Canaccord Genuity.

Mark Massaro - *Canaccord Genuity - Analyst*

Not to go into 23andMe too much, but I guess I would've expected maybe flattening revenue. So can you kind of talk about what drove the 8% decrease? Obviously there's different working parts obviously with the FDA ceasing their ability to market the test in the US, offset by launches, as you mentioned, in the other countries. So how should we think about it in Q1 and Q2 just directionally -- flattening out, or maybe lifting up a bit?

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

Right. So if you look at the 2013 quarterly number for the molecular collection systems, that $6.8 million, that included revenues from 23andMe that were $1.9 million greater than those enjoyed in the fourth quarter of 2014, in large part due to the fact that for the majority of that prior year's quarter they were able to sell their product into the US market, their Personal Genome Systems.

So I think you need to -- when you strip that out of there, Mark, and you get down to an adjusted number of in the $4.9 million range, that then neutralizes that incremental revenue and then allows you to understand that the total revenues were actually growing like 34% from the other components of the business, putting aside for a moment the contribution that 23andMe made in both the fourth quarter of 2013 as well as in 2014, so a very healthy business.

And, as you may recall, in the early parts of 2014 we had very little in the form of contribution from 23andMe on the revenue line. So I would think that as we move forward into 2015 here the comps in the early part will look pretty good for the business.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. That's helpful. And how should we think about the HCV NGO outside the US? Obviously I realize that can be lumpy. Should we expect that lost business to recur, and, for example, when do you think we'll see that lap, if there was a lost customer, or was that just a one-time blip in ordering?

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

Yes, it's not a lost customer. Be clear on that. It's really just a lumpy ordering pattern by the customer. And actually we've -- the customer has committed to continue using our product certainly through 2015 and likely beyond. So I would expect we'll see some variation in sales on a quarterly basis, but that customer is going to continue to be an important contributor to our international HCV revenues.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. And then are there any developments on the microbiome products that you're working on?

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

There have been, and the collection system continues to be evaluated by numerous opinion leaders around the world. We're actually starting to generate some revenues from that. But, as I think we've spoken about previously, we're really in the process of defining its value with key opinion leaders, in the early stages of commercialization.

But interest and enthusiasm for our product that's able to stabilize a fecal sample at the point of collection and really enable researchers to get a good idea of exactly what that bacterial makeup looks like as close to collection as possible is highly valuable, and we're in discussions with numerous researchers around the world where they're looking at significant-size studies of the gut microbiome and considering use of our product in those programs.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. And then maybe if I could sneak one more in, on the -- your comments that you made about the retail opportunity and how you could realize a financial impact in the second half of 2015, is there a scenario where there might be an upfront purchasing component as part of that, or will we see maybe test ordering start to trickle in in the second half?

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

Yes, I think that it'll be more of a gradual uptake. I think this is another example of learning, and certainly the retailers, as I mentioned, have very high interest in potentially offering rapid hepatitis C testing. But, as we mentioned, these are now pilots that are being scoped and planned, and, importantly, they are going to define actually how the retailer is going to roll this out to their either national or retail chain. So these are critically important to understand workflow as well as how the retailer is going to be reimbursed for these services.

And these involve multiple stakeholders, obviously, along with local stakeholders that are going to provide some of the follow-on services to the individuals that test positive. So we're very excited about these, as are the retailers, and look forward to kicking these off in the next couple of months.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. Thank you.

Operator

Nick Jansen, Raymond James.

Nick Jansen - *Raymond James and Associates - Analyst*

Two quick ones from me. You guys have been sitting on nearly $100 million in cash for some time now. Just want to get a sense of the M&A outlook, the prospects there, how we should be thinking timing or if anything with regarding to deal activity in 2015.

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

Nick, that's a great question. We continue to be in the market evaluating opportunities. We've looked at a number of them, but obviously we wouldn't comment on timing or whether there's anything that would be actionable at the moment. But we do have an interest in expanding our business through business development activities, whether they be partnerships, outright acquisitions, licensing transactions. So anything's fair in that regard, and we continue to be active in that area.

Nick Jansen - *Raymond James and Associates - Analyst*

That's helpful. And then on international HCV, I know you guys have talked in the past about maybe forming an affiliation there like you've done domestically with AbbVie. Any comments or discussion surrounding that potential source of opportunity in the near to intermediate term?

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

I would say nothing in the near term, but we continue to be active in dialog with multiple potential players.

Nick Jansen - *Raymond James and Associates - Analyst*

Okay. And then lastly, last night Gilead talked about a pretty significant price erosion in the HCV marketplace given the battle between them and AbbVie to sustain share. I would have assumed that that's actually maybe a good thing for your business, as they're going to need more volume to hit the revenue targets that they're discussing. So maybe talk to me a little bit about how you're viewing the pricing landscape and how that kind of impacts your business philosophy on HCV in the US longer term. Thanks.

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

I think we're a little more interested in the fact that more and more patients are being put on therapy, which is depleting the number of those patients that have been previously diagnosed in our warehouse, which that is the real driver for increased testing. And I read some of the transcript

from Gilead's remarks last night, and they talked about the capacity to put up to 250,000 patients on treatment, and those kinds of numbers deplete whatever is remaining in the warehouse patients very quickly.

We all know that AbbVie and Gilead are out there really in hand-to-hand combat, whether it's with providers or with payers. We would expect that's going to continue for some time. But in any case the need for increased testing is going to continue to escalate. I don't think we should lose sight of that. And we're in a wonderful position to capitalize on that, not only with our rapid test but with the relationship with AbbVie, and that's what we're working to capture and what we expect we'll do.

Operator

And I'm not showing any further questions in the queue at this time. I'd like to turn the call back over to Doug Michels for closing remarks.

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

I just want to thank everybody for coming on the call this afternoon and this evening, and appreciate your continued interest and support of the Company. Look forward to updating you on our progress in a few months. Have a good night, everybody.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program, and you may all disconnect. Everyone, have a good day.
