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OSUR - Q2 2014 OraSure Technologies Inc Earnings Call

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PRESENTATION

Editor

Presentation

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

Good afternoon everyone, and welcome to OraSure Technologies 2014 second quarter financial results conference call and simultaneous webcast.

As a reminder, today's conference is being recorded. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer period.

(Operator Instructions)

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, the questioner can rejoin the queue for further questions.

OraSure Technologies issued a press release at approximately 4:00 p.m. Eastern time today regarding its 2014 second 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 archive of this call until midnight August 13th, 2014 by calling 855-859-2056 for domestic or 404-537-3406 for international. The access code is 74668640.

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 filing, including its registration statements, its annual report on Form 10-K for the year ended December 31st, 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.

Our financial performance for the second quarter was strong, as we met our guidance on the top line and exceeded it on the bottom line. Consolidated net revenues for the quarter were \$26.4 million, an 8% increase from the second quarter of 2013.

Our HCV business had a particularly good quarter with sales growth of 134% from the prior year period. Our molecular collection systems revenues rose 5% over the prior year, despite the absence of revenue from DNA Genotek's largest customer.

We are also pleased to report a consolidated net profit of \$2.5 million, primarily due to a \$5.5 million payment we received in connection with the termination of our drug assay collaboration with Roche Diagnostics.

In June we announced a significant new agreement with AbbVie for the co-promotion of our OraQuick HCV rapid antibody test. The Company granted exclusive promotion rights to AbbVie for the OraQuick HCV test in certain US markets, and in exchange for these rights and certain other services will receive up to \$75.0 million in payments over the term of the agreement, which runs through December 31, 2019.

In addition, the Company is eligible to receive annual fees based on performance. These fees can range from \$3.5 million to \$55.5 million per year, and will be based on the number of patients that test positive with our OraQuick HCV test and enroll into a patient support program sponsored by AbbVie.

Since the announcement, we have received the first payment from AbbVie under that agreement, and recognized a portion of that payment as revenue during the second quarter. In addition, we have made great progress in preparing for the launch of our co-promotion activities, which get underway in earnest this month. I will provide additional details on these activities later in the call.

So with that, let me turn the call over to Ron for his financial review.

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

Okay. Thanks Doug, and good afternoon everyone.

Let me start with our revenues. Our second quarter 2014 consolidated net revenues were \$26.4 million, compared to \$24.3 million reported in 2013. Our consolidated product revenues increased 6% as a result of higher sales of our OraQuick HCV, cryosurgical systems, and molecular collection systems products. These increases were partially offset by lower domestic sales of our OraQuick professional HIV product, OraQuick In-Home HIV test and insurance risk assessment products. Licensing and product development revenues were \$775,000 in the current quarter compared to \$274,000 in 2013.

Our overall infectious disease testing revenues increased 6% to \$12.7 million in the second quarter of 2014, compared to \$12.0 million in the second quarter of 2013. Aggregate sales of our OraQuick HCV professional product, in both the domestic and international markets, increased 134%.



Higher demand in the domestic market among new and existing customers contributed to the increase in sales of our HCV test in Q2 to \$1.2 million from \$690,000 in the prior year. International sales of our HCV test in the second quarter of 2014 increased to \$974,000 from \$247,000 in the same period last year, primarily due to sales in support of a significant testing program with an international NGO. We expect sales to this NGO will be at a much reduced rate in Q3 and Q4.

Domestic sales of our professional HIV product decreased to \$7.7 million in the second quarter of 2014 from \$8.1 million in the second quarter of 2013. This decrease was a result of continued pressure on government budgets, some customer migration to automated fourth generation immunoassay HIV tests, as recommended under new testing guidelines issued by the CDC, and changes in customer ordering patterns. We expect these headwinds to continue for the foreseeable future.

During the current quarter, net sales of our OraQuick In-Home HIV test were \$1.7 million compared to \$2.0 million in the second quarter of 2013. Net revenues for these periods were not recorded using the same revenue recognition policy and are not readily comparable. Revenues in the current quarter were recognized upon shipment to the distribution channels, while revenues in the second quarter of 2013 were recognized upon consummation of a sale to the end user.

To better evaluate the performance of this product as compared to the year ago period, we can look at the number of units purchased by consumers. Based on available point of sale data, unit consumption declined by approximately 1% in the second quarter, which we believe was due to a decrease in broad-based media advertising.

Second quarter 2014 cryosurgical revenues increased 18% to \$4.9 million from \$4.2 million in the second quarter of 2013, primarily as a result of higher OTC sales in Europe and Latin America. OTC sales increased to \$3.2 million in the second quarter of 2014 from \$2.4 million in the second quarter of 2013 due to higher sales to our European distributor as a result of the launch of our product into new geographic territories, continued market penetration, and the ordering patterns of our Latin American distributor.

Our molecular collection system revenues, primarily representing sales of the Oragene product line, increased to \$4.9 million in the second quarter of 2014 compared to \$4.7 million in 2013. This 5% increase was the result of higher sales in the academic market due to the timing of orders placed by our distributors and studies performed by several larger academic customers. Commercial sales remained flat despite the fact that the current quarter did not include any sales to DNA Genotek's largest commercial customer. The prior year quarter included approximately \$1.7 million in sales to this customer.

Licensing and product development revenues were \$775,000 in the second quarter of 2014 and represent the amortization of revenues from AbbVie under our HCV collaboration agreement. In July we received the first payment of \$15.0 million as required under the agreement. Second quarter 2013 licensing and product development revenues were \$274,000 and represent royalties paid on domestic out sales of Merck's OTC cryosurgical wart removal product.

Turning to gross margins, our gross margin for the quarter ended June 30, 2014 was 61% compared to 60% reported for the quarter ended June 30th of last year. The current quarter margin benefited primarily from a more favorable product mix, driven largely by the increase in DNA Genotek sales to higher margin customers.

Our consolidated operating expenses for the second quarter of 2014 decreased to \$13.5 million during the second quarter of 2014 compared to \$20.1 million in the second quarter of 2013. Our current quarter expenses were reduced by a \$5.5 million settlement payment from Roche Diagnostic under the terms of the termination of our oral fluid assay collaboration agreement.

Also contributing to the decrease in operating expenses was lower advertising and promotional spending related to our OraQuick In-Home HIV test. Our advertising and promotional expenses for our OTC HIV test were \$3.0 million in the second quarter of 2014, compared to \$5.4 million spent in the second quarter of 2013. This decrease was partially offset by an increase in G&A expenses due to higher legal, staffing, and consulting costs.



From a bottom line perspective, we reported net income of \$2.5 million, or \$0.04 per share on a fully-diluted basis, for the second quarter of 2014, compared to a net loss of \$5.3 million, or \$0.10 a share, for the same period of 2013.

Turning briefly to our balance sheet and cash flow, our cash and short-term investment balance at June 30th, 2014 was \$80.3 million compared to \$93.2 million in cash at December 31st, 2013. Cash used in operating activities in the second quarter of 2014 was \$2.7 million compared to \$1.6 million used in the second quarter of 2013.

Lastly, turning to guidance for the third quarter of 2014, we are projecting consolidated net revenues of approximately \$27.0 to \$27.5 million, and a consolidated net loss per share of approximately \$0.04 to \$0.05 for the quarter.

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

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

Okay. Thanks, Ron. As you know, there have been many positive developments in our OraQuick HCV business. The most recent was the execution of a major agreement under which AbbVie and OraSure will co-promote our OraQuick rapid hepatitis C test here in the United States. A redacted copy of this agreement was filed today with the SEC along with our second quarter Form 10-Q. And it's available now and we encourage you to review this document.

Under our agreement with AbbVie, we will be focusing our co-promotion efforts on several specific markets in the US. As you might expect, a significant amount of work has already begun under this agreement.

The largest market segment consists of primary care and specialty physicians. AbbVie has agreed to detail our hepatitis C test into this market segment, and we will be targeting in excess of 10,000 physicians. Training of the AbbVie representatives on our product has already occurred, and product detailing started this week. To support these efforts, AbbVie will be launching its patient support program later this month to assist patients who screen positive for HCV. This program will help patients understand the implications of their diagnosis and the steps they can take to address their infection.

Our manufacturing representative organizations, the MROs, and our infectious disease sales team are coordinating with their AbbVie counterparts on all aspects of this co-promotion. We are providing product samples to qualified accounts, along with personal and web-based training on the use of our product for physicians. We are also implementing a co-payment assistance program to help reduce the costs for commercially insured and uninsured patients. Additionally, we are offering a telephone hotline for comprehensive customer support. Product sales driven by the co-promotion effort will be handled through our distributors and our direct sales team.

A second market segment targeted for co-promotion consists of employers, or employer groups, that are at high risk for hepatitis C and desire to make HCV testing available to their employees. Our initial focus is in the transportation industry, and specifically on commercial truck drivers, who are five times more likely to have hepatitis C than other Americans according to a study published in the American Journal of Public Health.

We have been working closely with the Healthy Truckers Association of America, or HTAA, which is a trade association focused on improving the health and wellness of professional truck drivers. With HTAA's assistance, OraSure and AbbVie will work to increase awareness about hepatitis and the benefits of our OraQuick rapid HCV test. We will be specifically promoting the use of our test in physician offices, health clinics and in retail pharmacies where truckers receive their health care, as well as at driving schools where newly-hired drivers are required to take and pass a physical exam.

In addition, we will be promoting our test for use at health events sponsored by HTAA, where truckers can take advantage of a variety of health and wellness services. We will be kicking off these efforts with the trucking industry in the third week of August with a major testing event organized by HTAA at the Great American Trucking Show in Dallas, Texas.



Another major market segment we are working on consists of national retail pharmacies and retail clinics. As you know, an increasing number of vaccines and diagnostic tests are becoming available to consumers through local retail pharmacy outlets. OraSure and AbbVie are in discussions with several major retail pharmacies and clinics and are making good progress on this initiative.

As you might suspect, the market segments covered by our collaboration with AbbVie are substantial. A great deal of work is required to build awareness, promote our test and implement the various support services that are needed, including product training, co-payment assistance and patient support. Although we are working to implement this collaboration as quickly as possible, we will likely not see any significant impact from these efforts until 2015.

Apart from all the work being done on the AbbVie collaboration, we continue to drive revenue growth in our existing hepatitis C business. The \$2.2 million in revenues reported for the second quarter was a record, and included a record \$1.2 million of revenues here in the United States. We shipped product to over 500 customers during the quarter, with 82% of our shipments being delivered to repeat customers. We also added over 90 new customers during the quarter.

As previously discussed, a number of states have passed laws that require doctors to offer hepatitis C testing as a routine part of healthcare provided to baby boomers. New York was the first state to pass such a law earlier this year. Legislation is now pending in at least eight other states and, recently, Colorado, Massachusetts and Connecticut have all passed laws requiring the offering of hepatitis C testing to baby boomers.

In addition, in June the Centers for Medicare and Medicaid Services, or CMS, posted a final national coverage determination indicating that Medicare will now cover hepatitis C screening for persons at high risk for contracting the disease, and for individuals that do not meet the high risk definition but fall within the baby boomer generation because they were born from 1945 through 1965. The CMS determination is consistent with recent recommendations from the United States Preventive Services Task Force, which assigned a B rating for this type of preventive service.

So as we plan for the future, we are very optimistic about this part of our business. We expect continued growth, especially here in the United States, to be driven by the continued positive market developments affecting hepatitis C testing and from our hepatitis C collaboration with AbbVie. And I look forward to providing you with updates on this part of the business in future calls.

Turning now to our HIV over-the-counter business. As Ron explained, the lower net sales of our In-Home test during the second quarter are not really comparable to the year ago period because of the change in our revenue recognition policy last year. An alternative measure is to compare actual shipment of product to retailers, which increased 54% in Q2 versus the comparable quarter of 2013.

Retail out sales to customers, as measured in the accounts for which we receive point-of-sales data, declined 1% in the current quarter compared to 2013, and declined 5% versus the first quarter of this year. These declines in retail sales were not surprising given our recent decision to reduce promotional spending for this business.

As you may recall, we previously announced that we would implement a new promotional strategy which is focused on more cost effective methods of building awareness and consumer adoption at the retail store level. Early in the second quarter we began reducing the more expensive broad-based consumer advertising, and as of August 1st we had ceased this form of advertising except for some residual or make good media owed to us by our media vendors.

As predicted, we are seeing the initial impact of this reduction on our growth, with average weekly retail out sales in April and May down 9% and 8% respectively versus the prior month. However, the average weekly sales grew in June by 4% over May, and have remained roughly at that same level in July.

We may continue to see some sequential declines in August and September out sales as we fully implement our new promotional strategy. Our expectation is that these sales will eventually plateau and then resume growth in the fourth quarter, albeit at lower levels, driven by more tactical retail trade level programs we are implementing. On this front, we are working with retailers on select pricing promotions, in-store media and public relations tied to key moments of momentum for the category to drive awareness and purchase activation.



On prior calls we have noted the high proportion of stores that stock the product behind the pharmacy counter. As a result, we have undertaken a survey of pharmacists to identify the best tools to overcome this barrier and facilitate education and purchase at the retail level. Results indicate high product awareness, about 75%, and high acceptance and a desire for materials and coupons to be distributed to consumers to motivate actual purchases. We will begin implementing these tools in the fourth quarter.

As a result of all of our changed strategy, our promotional costs will drop to \$1 million or less starting in the third quarter. Our goal and expectation is to achieve profitability for this product line in 2015.

On the international front, we are pleased to announce the submission of an application for CE Mark approval, a requirement for marketing the product in Europe. We are also evaluating several additional foreign markets where we see good potential for regulatory and commercial success. Our US experience, and particularly the challenges we have seen in building this new brand here, will be factored into our commercial assessments of potential new international markets.

As previously explained, our OraQuick In-Home HIV test remains an important part of our business, and we remain committed to the profitable growth of this product line. We still believe in the long-term potential for the product, but we recognize that it is going to take time to build awareness and to stimulate further customer acceptance. Going forward, we will continue to align spending with revenues and drive this product line towards profitability.

Another area I want to address in our call this afternoon is our molecular collection systems business. DNA Genotek continued its strong performance during the second quarter by delivering \$4.9 million in revenue. This represents growth of 5% over 2013. Sales for the first six months of 2014, to both the academic and commercial markets, were up a combined 24% when compared to the first half of last year.

I believe this performance is outstanding, especially when you consider that DNA Genotek received over \$1 million less revenue from 23andMe in the first half of this year compared to 2013. In fact, revenues from all other customers increased 63% during the first six months of this year compared to 2013.

During the quarter, DNA Genotek also made significant progress in its efforts to commercialize new products. In June DNA Genotek began shipping early prototypes of sample management products for research related to gut microbiome and tuberculosis. These prototypes represent two new, long-term market opportunities that we are developing.

Gut microbiome studies are gaining momentum and our new sample management product will enable researchers to improve their results through better sample collection, storage and handling. In tuberculosis, we are again in the early commercialization stages of a product that is expected to improve the workflow for testing sputum samples for tuberculosis. We are excited about these new opportunities and we believe they represent a logical extension of our current molecular collections business.

The final area I want to address is our substance abuse testing business. The primary reason we reported a net profit for the second quarter was the \$5.5 million payment received in connection with the termination of our drug assay collaboration with Roche Diagnostics. A pre-condition for this payment was the submission of a final purchase order by the end of June for the high-throughput assays previously developed under this collaboration. We were able to submit this final order because of the good progress we have made under our new drug assay collaboration with Thermo Fisher Scientific.

As previously discussed, we signed an agreement with Thermo Fisher in November 2013 that will enable us to provide our lab customers with fully-automated oral fluid assays that can be used on existing clinical chemistry automated analyzers to process samples collected with a new version of our Intercept collector. These assays, along with improvements in our new Intercept device, will enable us to better serve the needs of our drug testing customers.

So in conclusion, we have high expectations for our business, particularly our OraQuick hepatitis C test and our molecular collection systems segment. We are on track to deliver record results in 2014, and our efforts in the second half of this year will be instrumental in laying the groundwork for a successful 2015.



And with that, I will now open the floor to your questions. So operator please proceed.

QUESTIONS AND ANSWERS

Operator

Thank you, sir.

(Operator Instructions)

Our first question comes from Shaun Rodriguez of Cowen & Company. Your line is now open.

Shaun Rodriguez - Cowen & Co. - Analyst

Hi guys. Good afternoon. Thanks for taking the question. So maybe first on the AbbVie partnership. I was hoping you could help us understand a bit better what's meant by the patient support program sponsored by AbbVie. Does this mean that these patients are taking AbbVie's drug regimen or can a patient be on Gilead's drug regimen and still be in AbbVie's patient program? Or is this just going to include all positives regardless of ultimately what drug regimen they're on?

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

This is Doug. And thanks, Shaun, for the question. So AbbVie's patient support program is an opt-in program for patients that are tested with a rapid OraQuick hepatitis C test. And the way that the performance payments work is, as we enroll HCV positive patients, tested with the rapid test, into AbbVie's care patient support program, that counts towards our annual performance milestones.

It is not necessary that those patients end up on AbbVie's therapy. But by being in the patient support program, those patients will receive information about hepatitis C. They'll receive information about the importance of getting a confirmatory test. And they will also understand their different options as to how they can manage their hepatitis C infection.

Shaun Rodriguez - Cowen & Co. - Analyst

Okay. So it sounds like there are two levels there then. There is having a positive test result, but also actually getting them to enroll into this program, and getting them to enroll is actually what counts towards the triggers. Is that the right way to characterize that?

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

So a patient can opt into the patient support program upon testing. We generate credit towards the annual performance milestones for those HCV positive individuals that opt into the patient support program.

Shaun Rodriguez - Cowen & Co. - Analyst

Okay. That's helpful. So I have a few, but maybe on 23 or Genotek, given 23andMe didn't buy in the quarter, that performance was really pretty impressive. But I guess were you expecting them to go to zero at any point in the quarter, or was this even surprising to you? And the follow up really is do you expect this to improve from here or do you think that they're going to be quiet for another few quarters?



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

Well, so it was in line with our expectations. Obviously we're in regular contact with 23andMe and have some visibility to what the future demand is expected to be. We do expect some demand in the third quarter, although it will not be substantial. And we don't have any visibility beyond that for the remainder of the year. It doesn't mean that there will be zero, but at this point in time we see some demand coming in Q3, and that's the extent of our visibility for right now.

Shaun Rodriguez - *Cowen & Co. - Analyst*

Okay. And then last, on the Q3 revenue guide, I guess I'm just trying to understand the components there. So what's included for revenue from the AbbVie partnership payments, if any? Has anything changed about those are going to be recognized? Because I'm just trying to understand kind of the sequential dynamics in the core business versus obviously these dynamics from these payments coming in. So can you help me understand that, Ron?

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

Sure, absolutely. So first off, with respect to the AbbVie revenues that are included in the guidance, and specifically related to the amortization of the \$75 million over the course of the agreement, we will include \$3.4 million worth of revenues, or they are included in the guidance that we have offered up to the street.

I think though what you need to do is to focus in on a couple other areas, specifically for Q3. Cryo, we expect that business to be down over \$1 million sequentially, as a result of the seasonal profile of that business. Additionally, we do expect the HIV OTC business to be down sequentially as a result of the perceived relationship between the promotional spend and consumption. And as Doug pointed out, the reality is that we're backing off on the spend levels there.

And lastly, our infectious disease business is expected to be down sequentially for the reasons given in our prepared remarks for both HIV and possibly, in the international space, for HCV. As I mentioned, the non-governmental organization, the NGO, will be purchasing at levels significantly lower than what they had done in Q2, Shaun.

Shaun Rodriguez - *Cowen & Co. - Analyst*

Okay. The last quarter, so finally a follow up there. But last quarter you said you expected US HCV to be up sequentially every quarter for the year. It sounds like that's still on the table then as an expectation, and reflected within that guidance?

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

Absolutely. Yes.

Shaun Rodriguez - *Cowen & Co. - Analyst*

Okay.

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

Absolutely. The US domestic HCV business is doing very well.

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

Yes, and I should add, and we try to be realistic in terms of our expectations in terms of HCV product revenues that will result from the AbbVie OraSure co-promotion efforts, at least in the third quarter, and likely in the fourth quarter, simply because, as we mentioned, we've just trained the AbbVie reps. Actually we're training our MRO reps on all the different components of the relationship and how that's all going to play out in the field.

And this has all been very carefully orchestrated, and a lot of systems in place, to make sure that all organizations are working in concert. So that's rolling out right now. These different initiatives are going to roll out through the remainder of the year. And I think we'll really see the full impact of those beginning in 2015.

Shaun Rodriguez - *Cowen & Co. - Analyst*

Thank you guys.

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

You bet.

Operator

Thank you. Our next question comes from Brandon Couillard of Jefferies. Your line is now open.

Kate Ryan - *Jefferies & Co - Analyst*

Hi, this Kate in for Brandon actually.

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

Hi Kate.

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

Hi Kate.

Kate Ryan - *Jefferies & Co - Analyst*

Hi guys. First, I was just wondering if you could quantify if there are any SG&A or HCV related SG&A investments in the 3Q guidance, and maybe how that would expect to trend going forward.

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

Sure. That's a great question. And yes, there are investments that we are making in the program to support the initiatives that Doug spoke of in the prepared remarks. They are underway in the third quarter here of 2014, and they are included in our guidance. And actually our expectations are at the moment that they will likely be even higher in the fourth quarter of 2014 to support the program as more of the effort is captured for the entire quarter as opposed to a fraction of it in the third quarter here.



Kate Ryan - *Jefferies & Co - Analyst*

Okay, great. That's helpful. And then just back on 23andMe, is there any qualitative you can quantify how 23andMe sales in 3Q were relative to their 2Q order, of 2013, last year?

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

So in this most recent quarter, Q2, we did not record any revenues from 23andMe. And so the entire amount of revenues recorded here in 2014 of the \$4.9 million is all non-23andMe business. Whereas in the prior year's quarter we had a significant contribution from 23and Me, such that if you strip it out and compare apples to apples, you're probably looking at a growth rate, just in Q2 alone, of about 78% off of adjusted pro forma revenue base, stripping out 23andMe revenues.

Kate Ryan - *Jefferies & Co - Analyst*

Okay, great. Thanks. I'll jump back in the queue.

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

Okay.

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

Thank you.

Operator

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

Nicholas Jansen - *Raymond James - Analyst*

Hey guys, thanks for the time here. In terms of the professional base domestic HIV franchise, I think what you called some headwinds associated with the new testing, or recommendations from the FDA. And I'm just trying to get a sense of how large of a headwind that could potentially be over time. I'm just trying to get a sense to make sure we're modelling that appropriately as we look to 2015.

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

Well I think you know Ron highlighted a couple challenges there. The funding challenge, particularly on the public health front, is not new. And I think we have to look at it by segment. Our hospital business has been relatively stable, and we would expect that. Actually business has been growing in the physician office segment, and we do expect that segment to continue to grow. We also expect physician office testing to grow in total.

And the international component's been somewhat lumpy, and I think we're going to see some of that impact in Q3 because we had a nice contribution last year from a large international customer that's not going to repeat in Q3 of this year. Not that we've lost the business, but it's just the way some of these large government purchases go.



The competitive environment, and in particular the competitive impact of lab automation, is an issue that we've been wrestling with. It's here to stay, and I think that's going to continue to be a challenge on a go-forward basis. We mentioned in our prepared remarks the new CDC recommendation for laboratory testing of HIV and encouraging adoption of the laboratory base, you know the automated analyzer fourth generation assays, and a slightly different confirmatory algorithm. So that's a challenge that we're fighting.

And at the same time, the benefits of rapid testing are clear to so many of our customers. They'll continue to use the product. The benefits of the oral application are clear. But you know we've got to understand what's going on in the environment and some of these things are somewhat out of our control.

Nicholas Jansen - *Raymond James - Analyst*

Thanks for the color there. And then switching gears to the AbbVie agreement, under the enrollment into the patient support programs, I'm just trying to get a sense of how easy that is for the customers, just to get a sense of how progress can be made towards some of these milestone payments that you are looking to achieve.

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

Well I don't want to share everything that's going on from a competitive perspective, but we believe that the collective offer is very compelling. You know there's nothing like a 20-minute test and knowing whether you're HCV positive or not. And receiving that news can be life changing.

And what we're trying to do is make it easier for both the patient and the provider to get through that process, to understand, particularly today, that being infected with HCV is something you can do something about. But first of all you've got to have that initial result confirmed, and then you need to get connected with the appropriate individuals that can support you, counsel you, and help you decide what the best treatment options are for your specific situation. And that's what the patient support program's all about.

So is it easy or hard? Yes, it's all the above, but we think we've got the right approach to this. And we've seen it. You know we've seen it in other disease states. We know in HIV, a space that we're intimately familiar with, that when patients have support, they're more apt to follow up on the things that they need to do to manage their infection, or hepatitis C get cured. They're more likely to be compliant with the treatment regimen that they ultimately select. And so they're likely to have better outcomes, and that's what we're working to deliver across the board to patients, to providers, and ultimately to payers as well.

Nicholas Jansen - *Raymond James - Analyst*

And if I might just squeeze one more in terms of the balance sheet. Maybe this one might be for you, Ron. But \$80 million in cash on the balance sheet at the end of 2Q, I believe you get the \$15 million cash payment from AbbVie in July, or you've already received it, plus the Roche payment as well. So you might have pro forma cash flow of around \$100 million sitting there today, pretty much earning very little. How do we think about your aptitude to deploying that in accretive fashions in the short to intermediate term? Thanks.

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

Yes, so our goal clearly is to continue the pursuit of business development opportunities. And we're looking hard at opportunities that are complementary, be they technologies, products, and or companies that we could bring into the fold here at OraSure. So that's the mission that we have been on for some time, but we're very careful in how we want to deploy those resources, because we consider them very precious. But yes, that's where our focus of activity has been.



Nicholas Jansen - *Raymond James - Analyst*

Thanks guys. Nice quarter.

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

Thank you.

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

Thanks, Nick.

Operator

Thank you.

(Operator Instructions)

Our next question comes from Mark Massaro of Canaccord Genuity. Your line is now open.

Mark Massaro - *Canaccord Genuity - Analyst*

Hi guys. Thanks for taking the question. So maybe if we could maybe discuss the \$3.5 million to \$55.5 million per year opportunity in front of you on the HCV test. How should we think, or how are you thinking about the number of folks who will opt into the patient support system?

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

So that's specifically defined in the agreement, but that has actually been redacted from the agreement that was filed as an exhibit to the 10-Q, which is available to you today. So I encourage you to get a copy of that, to look at that. It gives a lot of good information about both parties' responsibilities. And you can just assume that there's a scale and that it's directly tied to the number of HCV positive individuals that enroll in the patient support program.

Mark Massaro - *Canaccord Genuity - Analyst*

Okay. Great. I'll take a look at it for sure. The other question relates to opportunities potentially to sign a collaboration agreement outside the United States. I know you have a lot going on in the US market, but can you maybe share where you're at in terms of pursuing an international HCV collaboration agreement?

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

I don't have anything specific to report today, but we have had discussions and continue discussions about international opportunities. So as soon as I have more to report on that, I'll for sure do it.



Mark Massaro - *Canaccord Genuity - Analyst*

Okay. Great. And maybe just a final question from me. Could you maybe provide some more color on the opportunity with tuberculosis on DNA Genotek? How should we think about that as a potential, even incremental revenue driver in the next couple of years?

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

Well, so understand that this is a pre-commercial product right now. But our tuberculosis collection and stabilization, and sample preparation product offering, actually includes two components. One is a reagent that stabilizes the sample -- the sputum sample upon collection, and enables transport to a laboratory at ambient temperature, really any temperature, for up to five days. And then a second reagent that once that sample is received in the laboratory, and that sample then, when received in a laboratory, is able to be cultured and then is able to also then be processed for molecular analysis.

We have a prep reagent that's been added to the sample once it's received in the laboratory, which actually enhances the assay sensitivity by generating a higher yield of intact DNA from the tuberculosis bacterium that's in the sample. This product's been in development for the last couple of years. It's out right now in the hands of researchers around the globe, and we're seeing some very, very promising results.

You know, TB is a huge, huge problem. Every year there's more than a million people that die from TB. And there's over nine million people that develop new active infections on a global basis. It's estimated there's somewhere between 80 million to 120 million sputum samples that are collected each year. And there's an estimated 600,000 people that are infected with multi-drug resistant, or extensively drug resistant strains of TB, and the cost of dealing with those drug resistant TB strains is extraordinary, and that continues to grow.

Only one out of five active TB cases are accurately diagnosed. And a lot of that has to do with sample collection, sample integrity when it gets into the laboratory. And the archaic means of treating those samples when they get into the laboratory, that bead beating method that's the standard of care, which really destroys a lot of the specimen and the material you're trying to diagnose.

What we've developed is an elegant solution to these two big problems. One, transport of a sputum sample in resource poor environments, you know where they don't have good cold chain, and the specimen ends up growing a lot of gunk and oftentimes gets to the laboratory and is non-viable, or you can't analyze it. And then second, a better way to break through that outer shell of the TB bacterium, which preserves more of the DNA, and enables better sensitivity in the laboratory, particularly for low titer samples.

And all this is being validated. It can be a real game changer we believe. And we're working with organizations around the world to validate that. Very excited about it. Big market.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. Thanks, Doug. And nice quarter.

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

Thank you.

Operator

Thank you. And our next question comes from Eric Criscuolo of Mizuho. Your line is now open.

Eric Criscuolo - *Mizuho - Analyst*

Hi, good afternoon. Thanks for taking my call, just (inaudible) tonight.

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

Hi Eric.

Eric Criscuolo - *Mizuho - Analyst*

So on the NGO purchases for HCV, what percentage did they make up of the international revenue?

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

We don't specifically cull that out, but I would say it's well more than 50% of the international, Eric. Yes.

Eric Criscuolo - *Mizuho - Analyst*

Got you. Thank you. And if I heard you right, I think you said that the HIV OTC shipments to retailers were up around 50% in the quarter, but retail sales were down 1%. Can you kind of maybe explain why the shipments were up so much and maybe the disparity between the shipments and the sales?

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

Yes. Part of it was some of our display volume that accounted for that. And the rest is just some inventory management on the part of the retailers.

Eric Criscuolo - *Mizuho - Analyst*

Okay. So I guess you expect that to kind of moderate in the third quarter?

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

That would be our expectation.

Eric Criscuolo - *Mizuho - Analyst*

Okay. Great.

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

Yes, I think the inventory levels, or the purchases actually are pretty much paralleling consumption, although we have seen some indication that in some retailers, as they're looking at their inventory levels, they may be ordering a little bit less than the consumption, which under the new revenue recognition model, would result in lower revenues despite comparable consumption metrics.

Eric Criscuolo - *Mizuho - Analyst*

Got you. And then just lastly, just a clarification on the HIV OTCs. Did you say you submitted for a CE Mark or you will submit?

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

No. We made our submission this past month.

Eric Criscuolo - *Mizuho - Analyst*

Okay. Great. Thank you very much.

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

Thank you.

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

Thanks, Eric.

Operator

Thank you. That does bring us to an end to the Q&A session of today's call. I will now turn the call over to Doug Michels for closing remarks.

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

Okay. I just want to thank everybody for participating on today's call, and obviously for your continued interest in OraSure. Have a good afternoon and evening everyone and we'll talk to you next time.

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

Good night.

Operator

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



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