# THOMSON REUTERS STREETEVENTS **EDITED TRANSCRIPT** OSUR - Q1 2015 OraSure Technologies Inc Earnings Call

EVENT DATE/TIME: MAY 06, 2015 / 9:00PM GMT

THOMSON REUTERS STREETEVENTS | www.streetevents.com | Contact Us

©2015 Thomson Reuters. All rights reserved. Republication or redistribution of Thomson Reuters content, including by framing or similar means, is prohibited without the prior written consent of Thomson Reuters. 'Thomson Reuters' and the Thomson Reuters logo are registered trademarks of Thomson Reuters and its affiliated companies.



# **CORPORATE PARTICIPANTS**

**Doug Michels** *OraSure Technologies - President, CEO* **Ron Spair** *OraSure Technologies - COO, CFO* 

# CONFERENCE CALL PARTICIPANTS

Shaun Rodriguez Cowen and Company - Analyst Peter Lawson Mizuho Securities - Analyst Mark Massaro Canaccord Genuity - Analyst Jose Haresco JMP Securities - Analyst Nicholas Jansen Raymond James - Analyst

# PRESENTATION

# Operator

Good afternoon, everyone, and welcome to OraSure Technologies 2015 first 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)

OraSure Technologies issues a press release at approximately 4 PM Eastern Time today regarding its 2015 first 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 May 13, 2015 by calling 855-859-2056 for domestic or 404-537-3406 for international. The access code is 19423338.

With us today are Doug Michels, President and Chief Executive Officer, and Ron Spair, Chief Operating Officer and Chief Financial Officer. Doug and Ron will begin with opening statements which will be followed with 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, shipment, and market, business plans, and regulatory filings and approvals. Actually results could be significantly different.

Factors that could effect results are discussed more fully in the Company's SEC filings, including its registration statement, its annual report on form 10K for the year ended December 31, 2014, its quarterly report on form 10Q and 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 - President, CEO

Okay. Thanks, Rena. Good afternoon, everyone, and welcome to our call. As indicated in our press release, 2015 is off to a very good start. Our first quarter financial results exceeded our guidance on both the top and bottom lines. Our molecular collection systems business delivered another strong quarter with revenues up 17% over the prior year period. Sales of our OraQuick rapid HCV test increased 39% over the first quarter of 2014. This represents 24% sequential growth from Q4 of last year. Together with the \$3.3 million in exclusivity payments recognized under our HCV



agreement with AbbVie total HCV related revenues were \$5.5 million for the quarter. The revenue growth along with prudent expense management generated a slight profit for the first quarter. Later in the call I will provide an update on our HCV business, developments at DNA Genotek, the progress we've made on our new rapid Ebola test and the performance of our in-home HIV test product.

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

# Ron Spair - OraSure Technologies - COO, CFO

Thanks, Doug, and good afternoon, everyone. Our first quarter 2015 consolidated net revenue increased 15% to \$27.1 million compared to \$23.5 million reported in 2014. Our consolidated product revenues of \$23.8 million increased 1%, largely as a result of higher sales of our molecular collection systems OraQuick HCV and Intercept products. Other revenues were \$3.3 million in the current quarter and represent the recognition of exclusivity payments under the AbbVie agreement. We did not record similar revenues during the first quarter of 2014.

Our overall infectious disease testing revenues increased 4% in the first quarter of 2015 compared to the first quarter of 2014. Total HCV related revenues, including the recognition of AbbVie exclusivity payments increased 252% to \$5.5 million in the first quarter of 2015 compared to \$1.6 million in the first quarter of 2014. Our HCV product revenues increased 39% to \$2.2 million in Q1 from \$1.6 million in the prior year. Sales of our OraQuick HCV professional product in the domestic market increased 81% in the first quarter of 2015 to \$1.2 million from \$663,000 in the prior year. This increase is largely due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs.

Our international sales of our HCV test in the first quarter of 2015 increased 8% to \$972,000 from \$896,000 in the same period last year primarily due to higher sales into certain Asian markets as a result of regional expansion, partially offset by lower sales to Europe. Domestic sales of our professional HIV product decreased 9% to \$6 million in the first quarter of 2015 compared to \$6.6 million in the first quarter of 2014. This decrease was a result of customers moving some of their testing to fourth generation automated HIV amino assays, price competitions, and the timing of orders. We expect continued pressure on our professional HIV business for the foreseeable future.

International sales of our professional HIV product increased 70% to \$948,000 in Q1 compared to \$558,000 in the same of last year. This change was primarily due to higher sales in Asia and Africa, partially offset by a decline in Europe. During the current quarter, net sales of our OraQuick in-home HIV test decreased 20% to \$1.6 million compared to \$2 million in the first quarter of 2014. The decline can be attributed to our decision in the second half of 2014 to focus our marketing and promotional efforts at the retail outlet level and away from broad based consumer advertising. As a result of the savings in advertising and promotional costs, this product line achieved profitability for the first quarter of 2015.

Our molecular collection systems revenues, primarily representing sales of the Oragene product line increased 17% to \$6.7 million in the first quarter of 2015 compared to \$5.8 million in the first quarter of 2014. Commercial sales increased 32% as a result of the timing of orders placed from certain existing US customers as well as incremental revenues from new customers. This increase was partially offset by a 7% decline in sales to academic customers due to variability in ordering patterns. Our substance abuse testing revenues increased 15% to \$2.1 million in the first quarter of 2015 compared to \$1.8 million in 2014. This increase is largely due to higher sales of our Intercept device as a result of the recovery of customers previously lost to competition and improved domestic employment conditions.

First quarter 2015 cryo revenues decreased 36% to \$2.5 million from \$4 million in the first quarter of 2014. Domestic sales of our professional product decreased 57% to \$661,000 in Q1 from \$1.5 million last year as a result of distributor consolidation and competition from new private label brands. Sales of our OTC products in the international markets decreased 30% to \$1.5 million in the first quarter of 2015 compared to \$2.1 million in the first quarter of 2014 due to lower sales to both our European distributor, Reckitt Benckiser, and to our Latin America distributor, Genomma. The decline in sales to Europe was due to customer ordering patterns. The decline in sales to Latin America was due to ordering patterns and challenges faced by Genomma, including declining economic conditions in Argentina.

Turning to gross margin, our gross margin for the first quarter of 2015 was 63% compared to 59% reported for the first quarter of 2014. The current quarter margin benefited primarily from the \$3.3 million of revenues recognized from our AbbVie relationship. Operating expenses, our consolidated operating expenses for the first quarter of 2015 decreased to \$17.3 million compared to \$19.5 million in the first quarter of 2014. This decrease was



primarily due to lower promotional expenses associated with the OraQuick in-home HIV test, partially offset by higher R&D costs associated with the development of our fully automated, high throughput, drugs of abuse assays and higher legal fees.

From a bottom line perspective, we reported net income of \$113,000 or breakeven per share for the first quarter of 2015 compared to a net loss of \$5.6 million or \$0.10 per share for the same period of 2014.

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 March 31, 2015 was \$89.5 million compared to \$97.9 million at December 31, 2014. Cash used by operating activities in the first quarter of 2015 was \$6.6 million compared to \$7.7 million used in the first quarter of 2014.

Turning to guidance for the second quarter of 2015, we are projecting consolidated net revenues of approximately \$29 million to \$29.5 million and consolidated net income per share of approximately breakeven to \$0.01 per share for the quarter.

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

# Doug Michels - OraSure Technologies - President, CEO

Thank you, Ron. Our HCV business continued to grow in the first quarter with 24% sequential growth and 39% growth over the first quarter of 2014. We shipped product to over 460 customers during the first quarter and 86% of our revenues came from repeat customers. We also added 64 counts during the quarter that had not previously ordered HCV tests from OraSure. And you know a major focus of our HCV business has been and will continue to but employer our copromotion agreement with AbbVie. We've been pursuing several major initiatives under this collaboration. As we have executed against each initiative we've gained important knowledge and adjusted our strategy in response to evolving market conditions.

The market for HCV drug therapies has been developing very rapidly during the last year. As you might be aware, decision today regarding which pharmaceutical products will be most accessible to patients are often influenced by insurance companies and other payers. In many cases in an effort to reduce costs, payers negotiate discounted prices for drug therapies in exchange for giving those therapies a preferred or exclusive status on their formularies. Not surprisingly, the competition among HCV drug manufacturers to secure this favorable formulary status has been intense. This competition and the outcome of these negotiations influence where manufacturers focus their resources in order to provide the highest potential yield of new scripts for patients.

These developments have affected our copromotion efforts with AbbVie. One example of this is our largest initiative directed to primary care and specialty physicians. Our approach under this initiative has been to combine detailing by the AbbVie sales force with our promotional activities through several large med-surg distributors and manufacturer representative organizations or MROs. As a result of increased focus on its new HCV therapy, AbbVie reduced the physician detailing activities by its sales force for our HCV test during the first quarter. While not unexpected, this lower level of detailing will likely last through the second quarter as the competition for scripts settles out in the marketplace. We anticipate AbbVie's detailing of our product will resume to a more normal level sometime in the third quarter of this year.

In the meantime we've adjusted our approach by increasing the focus and efforts of our distributors and MROs to more effectively generate sales leads and customer interest within the physician market. We've also continued working to address workflow matters, reimbursement questions and other issues raised in the field that might delay or prevent a purchase decision by physicians offices. We will continue working with these customers to accelerate the decision making process.

A second initiative is directed at national and regional retail pharmacies and retail clinics. As indicated during our last call, we are planning to initiate several pilot programs with the goal of developing sustainable models for rapid HCV testing in retail outlets. One national pilot and a regional pilot will begin later this month and we expect a second national pilot to start shortly thereafter. The goal of these pilots is to develop a retail program that can be deployed on a national basis. Any revenue contribution from this initiative this year will be modest but our expectation is that these pilots will be successful and that the retail market becomes a substantial contributor in the future.



A third initiative covers employer groups and was initially focused on the commercial long-haul trucking industry. This initiative has not developed the way we expected in part because of the competitive market conditions I just mentioned. As a result, we've terminated some of our industry-specific collaborations under this initiative, although we still believe truck drivers represent a potentially attractive target market.

In an effort to broaden our approach to employers beyond trucking, we're working with AbbVie to identify other work groups that may offer opportunities to promote both the use of our OraQuick HCV test along with AbbVie's patient support program. We believe a number of attractive employer groups will be identified through this screening process. Together with AbbVie, we are finalizing this review and we expect to focus our resources on new employer groups that are identified.

AbbVie and OraSure have also been looking at ways to expand our collaboration beyond the current agreement. One potential growth area is in the public health market. Many public health customers are already using our rapid test for both HIV and/or hepatitis C and this provides a great opportunity to promote either the initial or expanded use of our hepatitis C test. Given the limited resources in public health jurisdictions, a program such as AbbVie's patient support program is something that our public health customers find attractive.

Based on initial discussions with over 100 public health customers, interest is quite high for combining the use of our rapid Hepatitis C test with AbbVie's patient support program. Overall both OraSure and AbbVie remain committed to our copromotion agreement. We continue to believe it represents significant opportunities for both companies and we intend to devote the focus and resources needed to maximize the success of this important collaboration.

Another area I will touch on is our molecular collection systems business. As Ron explained, DNA Genotek continued its run of strong quarterly performances with 17% revenue growth over the prior year quarter. DNA Genotek's revenues were split 60% commercial customers and 40% academic which is consistent with past performance. During the first quarter all of the growth occurred in DNA Genotek's commercial business while academic sales declined compared to the prior year.

One particular strength on the commercial side is in the area of pharmacogenomics which uses genetic testing to study a person's expected response to a particular drug treatment. Our pharmacogenomics customers accounted for double digit growth during the first quarter compared to 2014.

Another growing part of DNA Genotek's business is in the area of reproduction genetics and breast cancer screening. We now believe that DNA Genotek is the primary DNA collection device supplier for a majority of the leading companies in both areas. As you may know, the breast cancer screening market in particular is growing rapidly and we expect this part of the market to continue to deliver strong results in future periods.

During the first quarter, DNA Genotek was successful with 23andMe, its largest commercial customer, in obtaining FDA 510k clearance for the Oragene-Dx saliva collection product. 23andMe uses this device to collect samples from its customers. Our 510k clinical study confirmed that the Oragene-Dx device is reliable and easy to use for consumers at home while also providing high quality DNA samples for processing in a laboratory.

As you may recall, DNA Genotek is also pursuing 510k clearance of its ORAcollect device. I am happy to report that this clinical work is progressing well and we expect to submit our 510k application to the FDA during the third quarter of this year.

And finally, as you know DNA Genotek is based in Ottawa, Canada and the strengthening US dollar relative to the Canadian dollar delivered both expense savings and foreign currency exchange gains during the first quarter, all of which positively contributed to our consolidated bottom line results.

I am going to switch now and talk about Ebola, and as we discussed on prior calls, our newest product in development is a rapid Ebola antigen test on our OraQuick platform. During the past several months, we've been working diligently to fully develop, to fund, and to deploy this new product. During the first quarter we locked the design of a prototype device that appears to deliver analytical performance similar to PCR tests when evaluated on stored samples from infected patients.



During the first quarter, we also recognized revenues from the initial sales of this product to the CDC for investigational use in Africa. The data generated from this field testing along with other clinical and non-clinical studies that we will perform is expected to be used in an application to obtain emergency use authorization from the FDA during the next several months. We also intend to use this data for similar approvals internationally.

We've also continued discussions with governmental agencies in an effort to obtain external funding for these development efforts. Good progress has been made and we are optimistic that we will be able to share some positive news on this funding effort in the very near future.

On a parallel path, we've engaged with many governmental and other entities to identify and secure one or more purchase commitments for the product once approved for use. As explained previously, our ability to successfully obtain developmental funding along with substantial and sustainable product purchase commitments is critical to the future of this product.

And a final area I will briefly touch upon is our OraQuick in-home HIV test business. Because we've implemented a more cost effective promotional strategy, I am happy to report that this product line achieved profitability during the first quarter of 2015 and we expect this product to be profitable for the full year 2015.

We also intend to continue to look for ways to grow this business in a profitable manner. And along these lines we're pleased to announce that we recently received CE Mark approval for our OraQuick in-home HIV test. We're continuing to assess various go-to-market strategies in certain European markets and we will only launch in these additional markets if we can demonstrate a pathway to profitable expansion.

So, as you've heard today there's no shortage of exciting growth opportunities before the Company. We believe we have the right strategy and the resources in place to achieve our goals and objectives for the year and we look forward to updating you on our progress during our next call.

So, with that, I'll now open the floor to your questions. So, Operator, if you'd please proceed.

# QUESTIONS AND ANSWERS

# Operator

(Operator Instructions) Shaun Rodriguez, Cowen and Company.

# Shaun Rodriguez - Cowen and Company - Analyst

Hi, guys. Good afternoon. Thanks for taking the questions. So, first on HCV, just an update here, so last quarter you talked about two sizable public health orders didn't materialize as hoped in Q4, you talked about expecting these in the first half. So, to clarify, were either of these in the Q1 report and are either of these reflected in Q2 guidance?

# Doug Michels - OraSure Technologies - President, CEO

One was in Q1 and we expect the second to be reflected in Q2 guidance.

#### Shaun Rodriguez - Cowen and Company - Analyst

And so it didn't look like -- and obviously you did see a sequential increase in Q1 over Q4. But I guess -- can you just give us a sense of the magnitude of the contribution of that order?



6

#### Doug Michels - OraSure Technologies - President, CEO

We generally don't break out specific orders, but as you highlight we saw good growth both quarter on quarter as well as sequentially in both the domestic and international markets. Domestic in particular on a quarter on quarter basis grew over 80% versus 2014. Domestic was up over 16% sequentially.

So, as I think we spoke about after last quarter's call, our objective and we're quite confident we're going to continue to see a sequential growth through the remainder of 2015 and most importantly significant sequential growth in the domestic market as a result of all these different initiatives we have going on.

#### Shaun Rodriguez - Cowen and Company - Analyst

Maybe asked a different way. Is the magnitude of the second order comparable to the magnitude of the one that already was recorded?

# Doug Michels - OraSure Technologies - President, CEO

Once again, we're really not going to comment on the magnitude of the different orders. I mentioned those two because they were orders that we were expecting in Q4 that didn't materialize and we wanted just to explain that.

#### Shaun Rodriguez - Cowen and Company - Analyst

That's fair and somewhat related, but on the sales and marketing, that looks obviously a significant sequential drop. So, the question here is about whether -- given the changes in AbbVie's, let's call it efforts at least in the first half of the year, was the AbbVie component of your spend there what dropped off? If so, how do we think about that and if not, what underlying there explained the sequential downtick in sales and marketing?

# Doug Michels - OraSure Technologies - President, CEO

So, the sequential downtick, Shaun, was in fact partially related to our activities with AbbVie and related expenditures, so costs associated with detailing were probably down and as we talked about even on the calls late last year, there were some expenditures that were associated with the startup of various support activities that we engaged in during the latter part of 2014. And so that was also to be expected. So, that's pretty much the answer.

#### Shaun Rodriguez - Cowen and Company - Analyst

Okay. Thanks. I'll get back in the queue. Thank you.

#### Operator

Brandon Couillard, Jefferies.

#### **Unidentified Participant** - Jefferies - Analyst

Hi, this is Kate in for Brandon. Back on HCV, can you comment on the doctors that you had previously mentioned had completed training? I think there was over 600. Have you seen any flow through orders from them or would that be something you expect once AbbVie returns to detailing in later this year?



#### Doug Michels - OraSure Technologies - President, CEO

I think -- so the answer to that is indeed, we've seen increases in new accounts start as well as increases in orders. And as AbbVie comes back into more diligent detailing of our product and the patient support program in the back half of the year, I would expect we're going to see improvement at that time as well.

#### **Unidentified Participant** - Jefferies - Analyst

Okay. And likewise, is the sales tied pretty closely with the ability to sign people up into this patient support program or was there -- can you comment on any -- how the patient support program has added value to date?

#### Doug Michels - OraSure Technologies - President, CEO

We haven't given any specific numbers to that and that's intentional given some of the constraints related to that aspect of our copromotion agreement, but we have seen increasing numbers of individuals enrolled into the patient support program. Those numbers are increasing at an increasing rate and we expect to see significant increases over the next several months and obviously through the remainder of 2015.

We have this pretty well scheduled out and we're working against our own internal targets in that regard and as you know there's incentive payments tied to the enrollment of individuals into the patient support program. We've indicated previously that we do intend to achieve at least the initial incentive payment during 2015 and that's still our objective.

#### **Unidentified Participant** - Jefferies - Analyst

Okay. Great. And one last one, just switching over to the Genotek business, as you continue to add commercial customers, can you just comment on how the overall margin of that business should trend?

#### Doug Michels - OraSure Technologies - President, CEO

I would say that the margin is still in the GAAP 70% range from a GAAP perspective and of course there are some non-cash charges included in the cost of goods sold there related to amortization of some of the intellectual property that we acquired upon acquisitions.

So, if you strip that out, and you look at really what the cash flows and margins are, some of that incremental business is coming in around 80% gross margin range for us.

# **Unidentified Participant** - Jefferies - Analyst

Okay. Great. Thank you.

#### Operator

Peter Lawson, Mizuho Securities.



## Peter Lawson - Mizuho Securities - Analyst

Hi, Doug. Hi, Ron. Just wondering if you'd go back to the HCV testing detailing by AbbVie, what gives you the confidence that it would return in I guess Q3? That'd be helpful.

## Doug Michels - OraSure Technologies - President, CEO

I am sorry what gives you the confidence that it will return in Q3? Oh, I am completely confident that they are going to return in Q3 for several reasons, not the least of which is we're planning that together, number one.

Number two, as part of the contract that we have, there's a minimum number of details that AbbVie is obligated to perform on an annual basis. They don't specifically state when in the calendar year those need to be completed and the agreement was structured that way, anticipating some of the uncertainty as to how activities would play out in the marketplace. So, we are in literally daily contact with our AbbVie counterparts, planning and executing on all aspects of the copromotion agreement. So, this is part of our plan and it's considered and planned jointly.

#### Peter Lawson - Mizuho Securities - Analyst

But how far are we through that, that range of test detailing that they have to do for the year?

# Doug Michels - OraSure Technologies - President, CEO

For 2015? Hardly started on their contractual obligations.

# Peter Lawson - Mizuho Securities - Analyst

Thank you. And then I mean that's why you think you will see that inflection point around HCV as that detailing kicks in?

# Doug Michels - OraSure Technologies - President, CEO

Well, that and the other initiatives that I described in the prepared remarks for sure.

# Ron Spair - OraSure Technologies - COO, CFO

Also just to comment on that with respect to the detailing, Peter. So, that will skew the expenses associated with that for us towards the or into the second half of 2015. So, for modeling purposes the expenditures associated with that detailing effort will be nested within the second half of the year. The sales and marketing should step up from the Q2 levels into Q3 and Q4.

#### Peter Lawson - Mizuho Securities - Analyst

Have you seen already sort of traction from initial detailing? Can you kind of correlate that detailing with the sales?

#### Doug Michels - OraSure Technologies - President, CEO

Somewhat and obviously our objective is to continue to drive efficiency and yield through those activities, through follow up and deployment.



#### Peter Lawson - Mizuho Securities - Analyst

And is that a month or two delay or is it several days?

#### Doug Michels - OraSure Technologies - President, CEO

No, it's generally a function of weeks, until we start to see contribution.

#### Peter Lawson - Mizuho Securities - Analyst

Okay. Thank you so much. I'll jump back in the queue.

#### Operator

(Operator Instructions) Mark Massaro, Canaccord Genuity.

#### Mark Massaro - Canaccord Genuity - Analyst

Thanks for taking the questions. So, on the DNA Genotek side, I saw one of your customers in a New York Times article in April, and with respect to breast cancer. So, I'd love to kind of hear your thoughts on some of the incremental opportunities you're seeing both in breast cancer and reproduction genetics. I'd love to know perhaps how many customers you have within the pharmacogenomics umbrella and maybe an idea of your funnel and how you think that this just might accelerate?

# Doug Michels - OraSure Technologies - President, CEO

So, as we look at pharmacogenomics it goes across a pretty broad marketplace. So, we have customers in pain management and psychiatry -- psychiatric drugs and I would say we have at least half a dozen major customers who have a large national business and what we're seeing is very nice growth from those existing customers. We've actually added a couple of new customers over the last quarter in that space.

And I think as more and more physicians understand the power of doing some of these genetic profiles as a way to guide their therapeutic decisions, we're just going to continue to see more and more utilization. And DNA Genotek as I mentioned in the prepared remarks is in a great position particularly in the breast cancer screening market for BRCA testing to capitalize on all of this interest. We think that the vast majority of companies involved in BRCA testing are now using the Oragene collection system as their primary sample collection stabilization product.

# Mark Massaro - Canaccord Genuity - Analyst

Would that even include some of the reference labs both regional and larger?

# Doug Michels - OraSure Technologies - President, CEO

Yes.

# Mark Massaro - Canaccord Genuity - Analyst

And then on hepatitis C, Doug you talked -- you gave some good color on the competition to get into formularies and so forth. So, it sounds like you expect the competitive noise perhaps to wind down over the next quarter or so. Would just love to hear your thoughts on how this noise, if



you will, has impacted your expectations to maybe to hit one or more milestone payments? And I know you've communicated that you expected at least one. So, I am just curious to hear your thoughts on expectations around milestone payments this year?

#### Doug Michels - OraSure Technologies - President, CEO

I think I've stated that is still our expectation that we will achieve at least one of those milestone payments. So, our thinking on that hasn't changed and relative to the formulary discussion, I really think -- I am only uncomfortable talking about that. I think that's a better question asked to AbbVie CEO in their earnings call or the other folks that are involved in selling to the payers and the managed care organizations.

But nonetheless the competition for covered lives has been intense and once those formulary decisions get made, both Gilead and AbbVie in today's market are in hand-to-hand combat to secure as many of the treaters who control patients that where either AbbVie or Gilead can have access to those patients. The way these formularies work is a formulary can give preferred status to one or more of the drug companies but it's not necessarily mandatory. There may be excess opportunities for either of the drug companies to capture some of that business even -- when they are not on the preferred drug list.

So, it's been intense and that's required a lot of effort and energy, a lot of focus on the treaters by AbbVie and that's expected. We do expect that that's going to settle down in the back half of the year and based on our planning we expect they're going to get back refocused on detailing our test and driving the rapid diagnostics.

#### Mark Massaro - Canaccord Genuity - Analyst

And maybe my final question. With 90 million in cash on the balance sheet, could you maybe comment on some of the opportunity to acquire other businesses and would be curious to what extent are valuations at attractive levels or as you look at potentially to acquire businesses, is it a matter of maybe the technology or the subsector that it operates in, just curious on how maybe this -- that environment has changed in the last quarter or so?

# Doug Michels - OraSure Technologies - President, CEO

Well, that's a great number of questions embedded in that. So, I will try to attack it as best I recall it. And so there are some very interesting opportunities out there, to be honest, Mark and we're excited. So, it doesn't mean that everything is perfect but we have seen a number of different interesting opportunities. They are as we discussed previously more in the molecular diagnostic space and so it would be somewhat adjunctive to the DNA Genotek activity. We want to look at opportunities that are not research projects, so more towards commercialized opportunities or near commercialized opportunities that are not going to push us backward away from our goal of profitability for 2015. And so we continue to work very diligently but maintaining our discipline and making sure that we hit the criteria while bringing in hopefully products and technologies or companies that would be complementary to what we are doing.

#### Operator

Jose Haresco, JMP Securities.

#### Jose Haresco - JMP Securities - Analyst

Just housekeeping items. Could you remind us of what our expectation should be for the pace of AbbVie co-promote payments for the remainder of the year?



# Ron Spair - OraSure Technologies - COO, CFO

So, the amortization of the exclusivity payments if that's what you are inquiring about -- would be approximately \$3.4 million recognized each quarter over the balance of the year and actually through the balance of the contract period. And as far as the payments to them for their detailing, although we've not disclosed what those amounts are, I think as Doug indicated we're really in the early stages of our commitment to that effort in 2015 here. So, some of those expenditures will be in the latter part of the year.

# Jose Haresco - JMP Securities - Analyst

Turning to the HIV business, you noted that the decline was competition towards fourth-generation molecular testing, timing of certain orders and one other factor -- yes, competition. Could you help us parse out which one of those was the dominating factor, if any, number one? And number two, are you expecting the pace of the declines to be similar to what we saw this quarter or are you guys thinking about more of an acceleration as we get towards the back end of the year?

# Doug Michels - OraSure Technologies - President, CEO

I think it's difficult to predict. If you go back to Q4 we saw Q4 was pretty much flat versus the prior year. And if you look at the different segments within our HIV professional numbers, you kind of see that type of variation in the first quarter results. So, the public-health number quarter on quarter was relatively flat. We were down in hospital and a little bit in the physician office area but we were up substantially in the international space. Actually international had one of the strongest quarters that we've had in quite some time. And I would expect that as we move out through the year we're going to see some variability in that regard.

# Jose Haresco - JMP Securities - Analyst

Turning to the HCV business, could you help us understand what happened with some of the more - with the trucking group and why that didn't quite pan out the way you thought? And what is it about some of these other employer groups that you are looking at, that makes them perhaps little bit more amenable to a direct approach?

# Doug Michels - OraSure Technologies - President, CEO

So, that's a good question and we tried to give a little bit of color to that in the prepared remarks. What we learned particularly in the transportation and trucking industry is there is a substantial proportion of those lives were covered under formularies that that weren't necessarily favorable to AbbVie and I think that as we go through and evaluate other employers or employer groups we can identify those where that situation is a little more advantageous for AbbVie and consequently provides an opportunity for us to work together to promote our rapid test within those groups.

# Operator

Nicholas Jansen, Raymond James.

# Nicholas Jansen - Raymond James - Analyst

Not to beat the dead horse on this AbbVie discussion, but when you gave guidance in early February, I think by that time we kind of all saw the headlines and news surrounding kind of formularies, you saw Express and CBS all announced their decisions. And I guess the question is when did AbbVie decide during 1Q that were not going to be detailing? So, I just want to get a better sense of when this happened and kind of little bit more detail on, why all of a sudden 3Q that you think some of these battles aren't going to be taking place because it's my understanding that you have more therapies coming out next year and certainly just wanted to get a better grasp of that, acknowledging that there are some minimum commitments to be had?



12

# Doug Michels - OraSure Technologies - President, CEO

I don't think that there's been any change in our messaging, actually Nick. I think that we've been making decisions -- AbbVie has been making decisions on a real-time basis and these kinds of decisions in the marketplace are dynamic and as I mentioned just because a drug gets preferred status on a formulary doesn't mean that the other drug manufacturer doesn't have access and a lot depends on what the patient profile is and what the regional differences are in those formularies. So, I think the formulary question, like I have stated earlier is probably better directed to AbbVie but it certainly has some impact in where we focus and where we target our activities either in different segments or on a regional basis.

# Nicholas Jansen - Raymond James - Analyst

Thanks for that. Ron, on gross margin, some of it might have been related to cryo being weak year over year but you did roll off on the royalty. Just wanted to get your thoughts on gross margin, it's kind of the second consecutive quarter when you strip out the exclusivity payment where you might have at least missed our expectations and any color there would be helpful.

# Ron Spair - OraSure Technologies - COO, CFO

So, we did as you quite rightfully pointed out, we did have a step-down as a result of reduced cryo sales in the professional marketplace. We also actually had under-absorption due to some of the weather-related closings that we had up here in the Northeast during the first quarter which probably cost us about a little over a percent in gross margin points. And beyond that we had some lower margin sales of the HCV products outside the US to a couple of distributors that are more located in the Asian region and that I think would really account for pretty much all of that, Nick, as far as why we might be bending a little bit lower than your expectations.

# Nicholas Jansen - Raymond James - Analyst

And then lastly from me, just kind of looking at your portfolio as a whole, going back the last couple of quarters, if you strip out the exclusivity payment, product sales year over year really aren't growing. I don't think -- at least the 2Q guidance doesn't show much growth kind of at the midpoint, same with 1Q actual, I think if you strip out the OTC HIV timing in 4Q from the prior year, it kind of showed no growth either. I know you have some growth anchors in HIV and some of the other segments. But when do you think you're at a point of time where DNA Genotek and HCV are big enough contributors that can offset some of the legacy pressures and is there any ways to potentially monetize these legacy businesses if they're not necessarily contributing to overall shareholder value creation?

# Doug Michels - OraSure Technologies - President, CEO

Well, I think you are highlighting one of the challenges and that is that the good growth in HCV, the good growth in DNA Genotek, the good growth that we saw on our first quarter with SAP, contribution from Ebola, was in this quarter offset by substantial difficulties in the cryo business and generally we haven't seen that kind of a challenge with the cryo business. So, unfortunate but that was the quarterly experience that we had.

HIV professional was down a bit. HIV OTC, right, it was down quarter on quarter if you look at first quarter 2014 versus first quarter 2015, but it was actually up slightly on a sequential basis. And that'll play out and that will resolve itself as we move through 2015 because our expectation is that the HIV OTC business is going to grow. So, I think it's one of the situations where we keep -- put on the gas with hepatitis C.

DNA Genotek continues to deliver. We've indicated that our SAP business is going to grow this year and quite frankly that the first quarter of the SAP business was our best first quarter in many years. DNA Genotek's first quarter was the best first quarter they've ever had and one of their top three quarters ever. So, this good performance in those businesses unfortunately masked a bit by the challenge we had with cryo in the first quarter. I think as we move through '16 and '16 and beyond that.



#### Ron Spair - OraSure Technologies - COO, CFO

Just to clarify and expand a little bit on that. Nick, I think the cryo issues are likely to be with us for a little bit here. So, Genomma, our distributor in Latin and South America - Latin America, South America has definitely had challenges that they are wrestling with, as you may have read about. And so I suspect that we could see the weakness on the cryo line for 2015 compared to where we were in 2014.

#### Operator

Thank you. And that brings 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 - President, CEO

Okay. I just want to thank everybody again for being on the call this afternoon, for your continued support of the Company as well as interest in the work that we're doing. I hope you all have a great afternoon and a good evening. And we will talk to you soon.

#### Operator

Ladies and gentlemen, thank you for your participation in today's conference. This does conclude the program and you may all disconnect. Have a great rest of your day.

#### DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2015, Thomson Reuters. All Rights Reserved.

