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PRESENTATION

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

Good afternoon, everyone, and welcome to OraSure Technologies' 2016 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. (Operator instructions.) To allow time for as many questions as possible, questioners are asked to limit themselves to only one single question with no more than one follow-up question related to the same topic. Once the follow-up is completed, a questioner can rejoin the queue for further questions.

OraSure Technologies issued a press release at approximately four p.m. Eastern Time today regarding its 2016 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 11, 2016 by calling 855-859-2056 for domestic, or 404-537-3406 for international. The access code is 83627952.

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, (inaudible) and markets, business plans, regulatory filings and approvals, expectations, and strategies. Actual results could be significantly different. Factors that could affect results are discussed more fully in the Company's SEC filings, including its registration statement, its Annual Report on Form 10-K for the year ended December 31, 2015, 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 are based solely on information available to management as of today. The Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call.

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

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

Great. Thank you, Rena, and good afternoon, everyone, and welcome to our call. We're very pleased to report that we exceeded expectations on both the top and bottom lines for the first quarter of 2016.

Consolidated net revenues for the first quarter were \$29.1 million, a 7% increase over the same period of 2015. This growth was driven by higher sales of our OraQuick HCV, molecular collection systems, and cryosurgical systems products. Domestic HCV sales increased 59% over the first



quarter of 2015. Total HCV-related revenues, which include exclusivity payments under our HCV co-promotion agreement with AbbVie, were \$6.3 million for the quarter.

Molecular collection systems revenues rose 3% from the prior year quarter largely due to higher sales to customers in the academic research market. Cryosurgical systems revenues rose 53% to \$3.9 million for the quarter. The revenue growth, combined with higher margins and lower operating expenses, generated \$2.4 million in consolidated net income for the first quarter. Ron will provide further detail on our first quarter financial performance along with our expectations for 2Q of 2016. I will then discuss some additional developments in our business.

So, with that, let me turn the call over to Ron.

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

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

Our first quarter 2016 consolidated net revenues increased 7% to \$29.1 million compared to \$27.1 million reported in 2015. Our consolidated net product revenues of \$25.2 million increased 6% largely as a result of higher sales of our cryosurgical systems, OraQuick HCV, and molecular collection systems products, partially offset by lower sales of our professional OraQuick HIV product and the absence of sales of our OraQuick Ebola product.

Other revenues were \$3.8 million in the current quarter, of which \$3.3 million represents the recognition of exclusivity payments under the AbbVie HCV co-promotion agreement, and \$482,000 represents revenue associated with Ebola-related funding we received from the Biomedical Advanced Research and Development Authority, or BARDA. Other revenues in the first quarter of 2015 also included \$3.3 million of AbbVie exclusivity payments.

HCV product revenues increased 34% to \$2.9 million in the first quarter from \$2.2 million in the prior year. Domestic OraQuick HCV product sales increased 59% in the first quarter of 2016 to \$1.9 million from \$1.2 million in the prior-year period. This continued expansion of our core domestic HCV business resulted from higher sales to current customers who have expanded their HCV testing programs, along with the addition of new programs primarily in the public health market.

International sales of our HCV test in the first quarter of 2016 increased 3% to \$1 million from \$972,000 in the same period last year, primarily due to the expansion of our business in Asia. Total HCV-related revenues, including the AbbVie exclusivity payments, increased 14% to \$6.3 million in the first quarter of 2016 compared to \$5.5 million in the first quarter of 2015.

In 2015, we began selling our OraQuick Ebola Rapid Antigen Test to the CDC for field-testing in Africa. Sales of this product contributed \$364,000 in product revenues during the first quarter of 2015. We did not have similar sales in the first quarter 2016. We do believe Ebola sales in future periods are likely, given the current status of the disease and international surveillance efforts.

Our domestic sales of our professional HIV product decreased 5% to \$5.7 million in the first quarter of 2016 compared to \$6.0 million in the first quarter of 2015. As we've previously communicated, we expect continued pressure on our professional HIV business in 2016.

International sales of our professional HIV product decreased 10% to \$854,000 in the first quarter of 2016 compared to \$948,000 in the first quarter of 2015. This decrease reflects lower sales into Africa as a result of customer ordering patterns and the variability of project-based business in that region, partially offset by an initial shipment in support of an HIV self-testing program launched in Africa, and higher sales in Europe. Sales of our OraQuick in-home test remained relatively flat at \$1.5 million in the current period from \$1.6 million in the first quarter of 2015.

Our molecular collection systems revenues, primarily representing sales of the Oragene product line in the genomics market, increased 3% to \$6.9 million in the first quarter of 2016 compared to \$6.7 million in the first quarter of 2015. Sales to academic customers increased 37% largely due to customer ordering patterns of existing customers coupled with the first quarter shipment of product to support a study on the epidemiology of aging.



Commercial sales decreased 20% primarily as a result of two large purchases in the same period last year that did not repeat in this quarter. New customer sales helped to offset the absence of those purchases. We remain very confident in our ability to capitalize on the sample collection market.

First quarter 2016 cryo revenues increased 53% to \$3.9 million from \$2.5 million in the first quarter of 2015. Domestic sales of our professional product increased 135% to \$1.6 million in the first quarter of 2016 compared to \$661,000 in the first quarter of 2015, largely due to distributor ordering patterns.

International sales of our professional product decreased 34% to \$235,000 from \$357,000 in the comparable period of 2015 due to increased competition from private label product. Sales of our domestic OTC product increased to \$378,000 in the first quarter of 2016 from \$55,000 in the first quarter of 2015 due to the launch of private label product for two additional large pharmacy chains. Sales of our OTC products in the international markets increased 17% to \$1.7 million in the first quarter of 2016 compared to \$1.5 million in the first quarter 2015 primarily as a result of the ordering patterns of our Latin American distributor.

Our gross margin for the first quarter of 2016 was 70% compared to 63% reported for the first quarter of 2015. Margin for the current quarter benefited from a more favorable product mix, reductions in both royalty expenses and scrap and spoilage costs, and the Ebola-related funding received from BARDA.

Turning to our operating expenses, our consolidated operating expenses for the first quarter of 2016 were \$17.6 million compared to \$17.3 million in the comparable period of 2015. This increase was the result of higher detailing costs associated with our HCV co-promotion agreement with AbbVie, and increased staffing, commission, and consulting costs, partially offset by lower R&D spending and a favorable change in the exchange rate between the Canadian and US dollars.

From a bottom-line perspective, we reported net income of \$2.4 million, or \$0.04 per share on a fully diluted basis, for the first quarter of 2016 compared to net income of \$113,000, or breakeven per share, for the same period of 2015.

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, 2016 was \$102.2 million compared to \$101.3 million at December 31, 2015. Cash generated by operating activities in the first quarter of 2016 was \$4.7 million compared to a use of \$6.6 million in the first quarter of 2015. During the first quarter of 2016, we used \$2.7 million in cash to buy back stock under our previously authorized stock repurchase program. No additional purchases are currently planned under this program.

And lastly, turning to guidance for the second quarter of 2016, we are projecting consolidated net revenues of approximately \$30.5 million to \$31.5 million. We are also projecting consolidated net income of approximately \$0.04 to \$0.05 per share.

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

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

Okay. Thanks, Ron.

As noted earlier, DNA Genotek's revenues increased in the first quarter of 2016. We remain very enthusiastic about the future prospects for this business as we continue to bring on a steady stream of new customers.

We continue to generate the vast majority of our molecular collection systems revenues in the genomics market, split between academic and commercial customers. During the first quarter, these revenues were split in roughly equal parts, which is a departure from our recent trend of 65% commercial and 35% academic research revenues. As this part of our business returns to higher growth rates in future quarters, we would expect the revenue split to move closer to the historic norms.

During the last earnings call, I mentioned several examples of where our genomics business is becoming more diversified. We had a customer acquire product to support the longitudinal study on the epidemiology of aging that we discussed during our last call.

We also provided collection kits, custom packaging, and fulfillment services for a large, long-term study on autism conducted by the Simons Foundation Autism Research Institute. This customer launched an online research initiative called SPARK, S-P-A-R-K, to recruit 50,000 individuals with autism and their family members. This is a three-year project that aims to be the largest autism study ever undertaken in the United States to advance understanding of the causes of autism and develop new treatments and support protocols.

DNA Genotek is providing a customized solution designed to facilitate home collection of DNA samples by study participants. A large order was placed for this study in the first quarter, and it will be fulfilled over the next several years.

I also mentioned that we've begun selling product to a personal genomics company in China for use in providing genetic analysis of ancestral traits, health risks, disease screening, drug reactions, genetic characteristics, and nutrition metabolism. We received our first order from this customer in the fourth quarter of last year, and we began shipping kits to them in March.

We've also previously mentioned two new business opportunities, the microbiome market and the infectious disease market focused on tuberculosis testing. With additional microbiome revenues in the first quarter, our outlook for this important market continues to be quite positive.

Interest in our products is growing with both new and repeat customers, and we're seeing more investment directed toward therapeutics and diagnostics in the microbiome space. Sample quality for these customers is important as they embark on early-stage research and clinical trials, and we believe our product offerings can address this need.

In this regard, we're working to broaden our portfolio by offering microbiome collection solutions for the tongue, for gums and plaque, as well as vaginal microbiome collections. We are also engaging with dozens of researchers planning population-scale microbiome-wide association studies which could eventually resemble the array-based genomics research studies of the early 2000s. Initiatives such as these further support our optimism for the microbiome market.

In the area of tuberculosis, we continue to pursue studies in support of the future endorsement of our TB products by the World Health Organization. We are also supporting many laboratories and researchers around the world as they conduct evaluations of our products. Overall, we're very pleased with our molecular collection systems business, and we expect sales in the genomics market to continue to be a strong growth contributor for our Company, and we are excited about the opportunity to expand our molecular business segment, especially in the microbiome marketplace.

Turning to our core infectious disease testing business, revenues were essentially flat when compared to the same quarter last year. Declines in our HIV professional business were offset by the continued strong growth in sales of our OraQuick HCV test.

As indicated during our last call, an exciting opportunity for growth in our HIV business is the sale of our OraQuick HIV self-test in the international marketplace. We continue to work with Population Services International, PSI, which is a leading global health organization, along with UNITAID, the WHO, and health officials from Malawi, Zambia, and Zimbabwe to implement the Self-Testing in Africa, or STAR, S-T-A-R, Project.

The STAR project is a pilot program being funded by UNITAID that will use the OraQuick HIV self-test we developed specifically for the African marketplace. Initial shipments of our product were made during the first quarter, and we expect to make additional shipments here in Q2.

As Ron noted, domestic HIV sales declined 5% compared to the first quarter of 2015, reflecting the continued impact of competition from fourth-generation automated lab tests and other lower-cost point-of-care tests. Although we expect the rate of decline in our domestic business to ease somewhat in 2016 largely due to some new marketing initiatives and a continued recognition of the value of our rapid HIV test, we expect the overall negative trend in this part of our business to continue.

HCV revenues for the first quarter grew nicely, largely driven by a 59% increase in domestic product sales compared to the first quarter of 2015. Growth in our hepatitis C business is being generated primarily through the addition of new customers and testing programs in the public health



market, and then having those programs expand over time. Within the public health market, we are currently seeing demand from large NGOs, from community-based health centers, and from Indian Health.

Turning to our OraQuick Ebola Rapid Antigen Test, we recently received FDA emergency use authorization, EUA, for the use of this test on oral fluid samples collected from cadavers. As you may know, the handling of cadavers has been identified as a significant source of Ebola transmission in Africa. We also received WHO approval to list our product for use with both blood samples from live patients and oral fluid samples from cadavers.

Our OraQuick Ebola rapid antigen test is now the only rapid point-of-care test approved for testing of both live patients and cadavers. The combination of these claims expands the utility of our test as new cases of Ebola continue to appear. And we believe there will likely be ongoing need for our test in light of the continued occurrence of the disease and the WHO's recommendation for ongoing surveillance in certain African countries.

Our success with Ebola has positioned us well to assist with the most recent global health issue, Zika infection. As you may know, Zika is transmitted primarily through infected mosquitoes, although there have been confirmed reports of sexually transmitted infections and infection through blood transfusion. While many infected individuals may experience mild symptoms or remain entirely asymptomatic, there is evidence that Zika infection in pregnant women is linked to microcephaly, a serious birth defect.

Accordingly, health officials have communicated the urgent need for an accurate point-of-care test for Zika. We are actively engaged in a development program for rapid Zika assays on the OraQuick platform, and we are currently pursuing external funding for these efforts.

On the organizational front, we recently announced that Doctor Michael Reed has been appointed Senior Vice President of Research and Development and Chief Science Officer for our Company. Mike brings more than 20 years of global experience in life sciences and diagnostics research and development across an extensive array of disciplines, including globally-regulated IVD development and commercialization of molecular and cellular applications and systems. Mike joins OraSure from Beckman Coulter, which is, I think you know, a global diagnostics and life sciences company within Danaher. We are excited that Mike's joined OraSure, and we certainly look forward to his contributions as a member of our senior management team.

And as a final point, I would like to mention that OraSure was recently recognized by Forbes magazine as one of the top 100 most trustworthy companies. The list was created from more than 2,500 publicly traded non-financial companies with market caps of \$250 million or more. The analysis defined the 100 top companies as those that have most consistently demonstrated transparent accounting practices and solid corporate governance. OraSure ranked number 22 in the small cap category and number 36 overall in the top 100. And we're very proud of that recognition.

So, in closing, we're off to a very solid start here in 2016. We expect continued growth from our HCV and molecular collection systems businesses, with additional opportunities likely to come from the microbiome market and our rapid Ebola antigen test. With over \$100 million in cash and no debt, we are in a very strong financial position. And furthermore, we continue to explore opportunities to acquire products or companies that could enhance our growth rate, as well as options to improve our profitability. And we will share updates on these fronts as the year progresses.

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

QUESTIONS AND ANSWERS

Operator

(Operator instructions.) Mark Massaro, Canaccord Genuity.

Mark Massaro - Canaccord Genuity - Analyst

Hey, guys, thanks for the questions, and nice quarter.



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

Hey, Mark, thanks.

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

Thanks, Mark.

Mark Massaro - *Canaccord Genuity - Analyst*

On the DNA Genotek mix, I think you alluded to two customers that ordered in the prior year that did not order in Q1 of this year. My question is, are these customers that have left OraSure or DNA Genotek, or do you expect them to reorder in future quarters?

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

So, specifically to those customers, they did not move to any kind of a competitive product. So, whether they reorder in future periods is a TBD. I think what's important to appreciate from the quarter results is that academic was very strong. And you should know that we're highly confident that the commercial business will deliver strong year-on-year growth for 2016. That's one of the reasons why, in our prepared remarks, we said that in future periods, I think you're going to see a more customary mix of commercial and academic revenues, with commercial being the majority.

Importantly, too, as we look at the growth drivers for DNA Genotek, we're looking certainly for new customers, as well as new products. And so, as we mentioned, we continued to capture new customers in both the genomics as well as academic space, but, importantly, we're also looking forward to continuing the growth that we're seeing in our microbiome business. And we had a very strong quarter there, as well.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. And on Zika, have you started to develop capabilities for the Zika test? And if you have not, can you comment on where you're at? I know that you're pursuing external funding. Just curious, any commentary on how close you might be to getting it? Would love to hear any thoughts there.

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

So, as I mentioned in the prepared remarks, again, we certainly have learned a lot through our Ebola development efforts and through the work that we -- the successful result we had with Ebola and securing external funding. We're following a very similar course with regard to Zika. We know that there is an urgent need for a highly sensitive and accurate rapid diagnostic for Zika.

We've had significant discussions with leaders in different parts of our federal government, as well as in the public health community, as well as folks in the academic research market, not just here but around the world. In order to move this effort forward, we have invested some of our own resources to securing raw materials and samples which are essential to not only the development of functional prototypes, but also materials that will enable us to evaluate the accuracy and the effectiveness of those prototypes.

While that work is going on, and it continues, we are also pursuing development funding on a parallel track. And I don't have anything specific to update you on in that regard, but I am encouraged by the discussions that we've had, and I am quite hopeful that we will secure the development funding to enable the complete development of one or more rapid OraQuick tests for the detection of Zika infection.



Mark Massaro - *Canaccord Genuity - Analyst*

Great, and just one more from me. I know that Zika is oftentimes compared to malaria. Another company in this space obtained funding to develop an oral fluid malaria test. Wanted to maybe gauge your temperature on developing a similar test, and if you think there's a meaningful market for an oral fluid malaria test.

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

The malaria market, there are a number of rapid diagnostics in the malaria space today. I think they may be of varying quality. But, one thing is for certain, is they're being sold in a marketplace for extraordinarily low prices. So, it's hard for me to appreciate the business rationale for developing a test when the market price per rapid malaria test today is in the \$0.20 to \$0.25 per device.

Zika I think is very different. Certainly the number of Zika infections continues to expand significantly. The devastating effects of Zika infection in pregnant women is very concerning, new evidence that continues to be reported on every day about sexual transmission, and the risk of contracting Zika, increasing risk of contracting Zika as the mosquitos spread is, I think, causing everyone a great deal of concern.

So, we think we're in a great position to develop and provide a tool to help deal with this serious issue, and that's the direction we're heading. We really want some support for that, and I believe we'll get it.

Mark Massaro - *Canaccord Genuity - Analyst*

Great. Thanks again.

Operator

(Operator instructions.) Nicholas Jansen, Raymond James.

Nicholas Jansen - *Raymond James - Analyst*

Hey, guys, I've been hopping in and off the call, so apologize if this has been hit, and I'll just go to the transcript. But, it looked like your domestic HIV business performed a bit better relative to the trend line that we saw exiting 2015, and I think you mentioned some new marketing initiatives. Just wanted to kind of get your thoughts on what those are and how sustainable those initiatives can be.

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

Yes. So, for sure we saw the business stabilize a little bit more in the first quarter. I don't want to say that that's how it's going to play out for the year, because I think we're going to still experience some headwinds. But yes, we did see a dampening of the decline in Q1 for sure.

We do have some additional information that we put in the hands of our sales reps that speak to the sensitivity of the OraQuick platform, and this is newly generated data that the folks are out there detailing this to our customers and making sure our customers completely understand the strong performance profile of the OraQuick test, which you know has been in the market for more than 10 years. And we sold over 50 million of these units. It's highly sensitive, and highly specific, and highly accurate rapid diagnostics.

And we've got to make sure that the marketplace completely understands that, while some of these fourth-generation assays may be suited for testing in very high prevalence populations, for most of the screening that takes place in the United States, you're going to achieve near the same level of accuracy and sensitivity and positive predictive value with the OraQuick test as you will from a fourth-generation test. And that's what we're out promoting, and the reception to that's been quite positive.



I also want to emphasize, too, that our efforts to expand self-testing in other parts of the world, specifically in Africa and Asia through the STAR program, is going to be an important opportunity to help minimize the impact of some of the degradation we're seeing in the domestic HIV professional business, and then ultimately transition our HIV professional business to a growth business again. We're very, very excited about this opportunity, and we think it can scale substantially, not necessarily in 2016, although we're going to see nice contribution and nice growth, but certainly in 2017 and beyond. And the feedback from the pilots where we're now beginning to deploy tests has been very encouraging, and we'll continue to report on that in future calls.

Nicholas Jansen - *Raymond James - Analyst*

That's helpful. And then, maybe for you, Ron, gross margin exceeded my forecast quite nicely. It has to go back many years before we see a quarter like this from a margin perspective. And I'm sure the cryo outperformance helped from a mix perspective, but how do we think about the gross margin trajectory over the next six to 12 months?

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

Yes, that's a great question, and that was a great answer, as far as the cryo over-performance in the professional marketplace here in the US had a substantial impact. But, we also had lower scrap and spoilage costs that we've really been working hard on here from an operations standpoint. We also saw good comps with respect to the elimination of the Alere lateral flow patents from the prior year period, which helped us.

And so, I think that combined obviously with the mix led to the kind of margin performance that we had in the first quarter of 2016. Now, would I like 70% every quarter? Absolutely. Do I think that that's likely? We're probably more in the mid to high 60s over the next six to nine months. But again, mix is really a huge impact for gross margin, and it certainly helped us in the first quarter here. But, I would say that mid to high 60s would not be abnormal, going forward.

Nicholas Jansen - *Raymond James - Analyst*

And has the recent movement in the Canadian dollar played a role yet on your comps?

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

So, for the comparison to the prior year, it actually helped us by, say, probably about \$500,000 in expenses versus the 2015, and that would be reflected a little bit in the cost of goods sold, as well as in the operating expenses. So, I would suspect, though, that if the Canadian dollar stays where it is, we'll have to reevaluate the impact, particularly as we move out over the course of 2016, because we did see almost a quarterly decline in the value of the Canadian dollar right on through the end of 2015, and now it's turned around again.

So, we'll see what happens. I think [it's] highly influenced by what the Fed does on rate increases, as well as oil and gas, and also what the Canadian government does as far as their own economic policies go. Hard to handicap where that's going, but we'll keep an eye on it. And certainly the team up in Canada is incredibly diligent about managing their expenditures to make sure that we blunt as best we can the impact of currency movements on the business.

Nicholas Jansen - *Raymond James - Analyst*

Okay. And I guess my last question would be you continue to tout a very strong balance sheet. You kind of did a small amount of share repurchases. I think you kind of had foreshadowed that on your last call that you did a little bit in January. We've seen a couple diagnostic assets flip hands since your last call. Just wanted to kind of get your broader sense of the market from a deal perspective, and your relative excitement about the pipeline in the near-term.

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

So, we have evaluated a number of opportunities over the last quarter, and we continue to be keenly interested in adding technologies and/or companies that would complement our ongoing activities in the molecular collection systems business, and possibly the infectious disease business. So, we continue to see opportunities. We haven't pulled the trigger, as you see from our cash balances, but it's not for lack of trying, and we'll keep it up.

Nicholas Jansen - *Raymond James - Analyst*

That's it for me. Thanks, guys.

Operator

(Operator instructions.) 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, Inc. - President, CEO*

Okay. Thanks, everybody, for your participation on today's call, and of course for your continued interest in OraSure. We look forward to speaking with you again in a few months. Have a great afternoon and evening. Thanks again.

Operator

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

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