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Justin Reid Zelin *Canaccord Genuity Corp., Research Division - Associate*

PRESENTATION

Operator

Good morning, ladies and gentlemen, and welcome to the Palatin Technologies First Quarter Fiscal Year 2020 Operating Results Conference Call. As a reminder, this conference is being recorded.

Before we begin our remarks, I would like to remind you that statements made by Palatin that are not historical facts may be forward-looking statements. These statements are based on assumptions that may or may not prove to be accurate, and actual results may differ materially from those anticipated due to a variety of risks and uncertainties discussed in the company's most recent filings with the Securities and Exchange Commission. Please consider such risks and uncertainties carefully in evaluating these forward-looking statements and Palatin's prospects.

Now I'd like to introduce you to your host for today, Dr. Carl Spana, President and Chief Executor -- I'm sorry, Chief Executive Officer of Palatin Technologies. Please go ahead, sir.

Carl Spana - *Palatin Technologies, Inc. - Co-Founder, President, CEO & Director*

Thank you. Good morning, and welcome to the Palatin Technologies First Quarter Fiscal year 2020 Call. I'm Dr. Carl Spana, CEO and President of Palatin. With me on the call today is Steve Wills, Palatin's Executive Vice President, Chief Financial Officer and Chief Operating Officer. On today's call, we will provide financial and operating updates.

I'm going to turn the call over to Steve, who'll provide the financial update. Steve?

Stephen T. Wills - *Palatin Technologies, Inc. - CFO, COO, Executive VP, Treasurer & Secretary*

Thank you, Carl. Good morning, everyone. Regarding Palatin's quarter ended September 30, 2019, financial and operational highlights, with respect to Vyleesi, the first as-needed treatment for premenopausal women with acquired generalized hypoactive sexual desire disorder, or HSDD.

AMAG Pharmaceuticals, our North American licensee, launched Vyleesi nationally in September with its established women's health sales force of approximately 125 sales representatives. In the 4 weeks since the September national launch, more than 1,300 health care providers have prescribed Vyleesi, which has resulted in more than 3,000 prescriptions received by AMAG's specialty pharmacy partners.

Palatin is entitled to receive tiered royalties on net sales ranging from high single-digit to low double-digit percentages. And sales milestones based on escalating annual net sales thresholds, the first of which is $25 million, triggered at annual net sales of $250 million.

Regarding Vyleesi collaborations for territories outside the currently licensed territories of North America, China and Korea, we have excellent interest, and we are in due diligence and advancing discussions and negotiations with multiple parties from multiple regions.

With respect to corporate, cash and accounts receivable balances at September 30, 2019, totaled $96.8 million. This is sufficient to cover planned operations through at least calendar 2021, which means we have sufficient cash to go past calendar 2021.

Debt and related liabilities of $0.8 million at June 30, 2019, were fully paid off in July of 2019.

Regarding our internal warrant buyback, in September 2019, Palatin's Board of Directors approved a plan to offer to purchase and terminate certain outstanding common stock purchase warrants through privately-negotiated transactions. This initiative was undertaken to reduce or minimize hedging or shorting strategies of certain warrant holders. The purchase and termination program have no time limit and may be suspended for periods or discontinued at any time.

To date, Palatin has repurchased and canceled in the aggregate approximately 6.5 million warrants at an aggregate buyback price of approximately $2.5 million.

Regarding Palatin's at-the-market, or ATM facility, Palatin has an up to $40 million at the market ATM offering available for financing flexibility. And we may, from time to time, opportunistically sell shares at prices we believe are advantageous to the company and its shareholders.

To date, we have sold approximately $12.3 million of the available $40 million offering at an average price of $1.30. Approximately $10.6 million was sold during June of 2019, and $1.7 million was sold over a few days during September and October. At the current stock price levels, we do not anticipate utilizing the ATM facility in the near future.

Moving over to financial results. Regarding the quarter ended September 30, 2019, Palatin reported a net loss of $4.5 million or $0.02 per basic and diluted share for the quarter ended September 30, 2019, compared to a net loss of $5.7 million or $0.03 per basic and diluted share for the same period in 2018.

The difference between the 3 months ended September 30, 2019 and 2018, was due to reductions in operating and interest expenses, combined with increases in reported license and contract revenue and also investment income.

Regarding the revenue, for the quarter ended September 30, 2019, Palatin recognized $97,000 in license and contract revenue compared to $34,000 in the quarter ended September 30, 2018. Both periods related to our license agreement with AMAG Pharmaceuticals.

Regarding operating expenses, total operating expenses for the quarter ended September 30, 2019, were $5 million compared to $5.7 million for the comparable quarter in 2018. The decrease is primarily related to operating expenses, decreases in salaries and other employee-related expenses.

Regarding cash position and working capital, Palatin's cash, cash equivalents and accounts receivable were $96.8 million at September 30, 2019. That breakdown is $96.7 million in cash and $100,000 accounts receivable. This was compared to September 30, 2018, and more specifically, June 30, 2019 of $103.8 million, and a significant component of the $103.8 million at June 30, 2019, was related to the $60 million milestone payment that Palatin was due on the approval of Vyleesi that we received in July of 2019.

Current liabilities were $1.9 million at September 30, 2019, compared to $4.2 million at June 30, 2019.

Cash and cash equivalents at September 30, 2019, of $96.7 million is sufficient to cover planned operations through at least calendar year 2021. And as I mentioned prior, that means well past the period 2021.

Carl?

Carl Spana - *Palatin Technologies, Inc. - Co-Founder, President, CEO & Director*

Thank you, Steve. I'll start the operational update with Vyleesi, a first-in-class melanocortin agonist and the only as-needed product approved by the FDA to treat hypoactive sexual desire disorder.

Commercial sales of Vyleesi in the U.S. are the responsibility of our Vyleesi North American partner, AMAG Pharmaceuticals.

In late September, AMAG made Vyleesi available nationally, with prescriptions being processed by 2 specialty pharmacies. On the November 1 conference call, AMAG discussed the results from the first 4 weeks of Vyleesi launch. I'm happy to report that over 1,300 doctors wrote over 3,000 Vyleesi prescriptions. We believe that this is a good start, and that AMAG with a strong commercial presence in female health is well positioned to grow Vyleesi sales.

Outside of North America, we continue to work with our Chinese partner, Fosun Pharma, and our South Korean partner, Kwangdong Pharmaceuticals, to advance Vyleesi development in those territories towards regulatory filings.

With the recent FDA approval of Vyleesi, commercial interest for unlicensed territories continues to grow, and we are now actively engaged with multiple potential partners that are evaluating Vyleesi in all available territories.

We are working to determine who the best potential Vyleesi partners are and to executing additional Vyleesi licensing and commercialization agreements. Our goal is to have Vyleesi partnerships for all the major global territories done by the end of calendar year 2020.

We believe our Vyleesi licensing strategy will maximize the return on our investment and allow us to focus our resources on our pipeline programs.

In the past quarter, we continued to advance our earlier-stage programs in autoimmune and inflammatory diseases. We have developed new families of highly selective melanocortin receptor agonists with potential broad applications in the treatment of a variety of autoimmune and inflammatory diseases, including dry eye, uveitis and retinal diseases and inflammatory bowel disease.

Our clinical development candidate, PL-8177, is a highly selective and potent melanocortin-1 receptor agonist, which we believe will have broad applicability as a treatment for autoimmune and inflammatory diseases.

We have already completed 2 Phase I PL-8177 clinical trials, setting the stage for us to conduct proof-of-principle clinical studies in 2 indications: noninfectious uveitis and ulcerative colitis, which will both be enrolling patients in the first half of 2020.

We are also developing melanocortin-based compounds for other ocular autoimmune and inflammatory diseases. Our compound, PL-9643, has demonstrated excellent activity in animal models of dry eye disease and retinal inflammation.

We have developed an eye drop formulation of PL-9643 as a potential treatment for dry eye disease, and we are currently completing the preclinical activities required to file an investigational new drug application and start clinical studies.

Our plan is to begin patient enrollment in a PL-9643 Phase II dry eye disease clinical study in the first half of 2020, with top line data reading out by the end of the year. We are also developing selective melanocortin receptor agonists for retinal indications such as diabetic retinopathy and macular edema.

In preclinical studies, our compounds have shown significant efficacy and potential to affect the underlying disease process. We believe our approach has the potential to provide substantial clinical benefit, and we are looking forward to advancing a compound into clinical development.

We have 2 programs that are supported by our research on the natriuretic peptide system, PL-3994, a selective natriuretic peptide receptor A agonist, is scheduled to start a Phase II trial sponsored by the American Heart Association, which will be conducted by 2 major medical academic research centers. The trial has received required regulatory approvals, and we anticipate patient screening by year-end 2019.

Although still preclinical, we are very excited about our compound PL-5028, a dual natriuretic peptide A and C receptor agonist, for potentially treating cardiovascular and fibrotic diseases. The preclinical models of cardiac, liver and pulmonary fibrosis completed in the last year PL-5028 has produced encouraging results. Our development plan for PL-5028 is to complete additional preclinical efficacy studies in models of fibrotic disease, and if these are positive, to begin the preclinical activities required to file an IND and begin clinical studies.

You can find additional information on our programs on our website, www.palatin.com.

In closing, we are encouraged by the early data coming by Vyleesi launch in the U.S. and the ability of AMAG Pharmaceuticals to grow Vyleesi sales. We believe that Vyleesi is a significant treatment for premenopausal women dealing with the physical and emotional impacts of HSDD.

The milestone payments from our Vyleesi licenses, the revenue that we will receive from new Vyleesi licenses and royalties in our financing efforts have given us a strong balance sheet to support the advancement of our exciting pipeline programs.

We believe that the approval of Vyleesi provides a validation of the melanocortin system as they target for drug development, and we are excited by the potential of our melanocortin autoimmune and inflammatory development programs.

During calendar year 2020, the primary focus will be on our PL-8177 clinical development programs for noninfectious uveitis and ulcerative colitis and our PL-9643 dry eye disease program. By initiating these 3 Phase II proof-of-principal studies in 2020, we anticipate receiving initial clinical trial data beginning in the second half of calendar 2020.

In addition, we will be looking to advance a melanocortin agonist into clinical development for retinal autoimmune and inflammatory indications. Thank you.

We will now open the call to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We'll take our first question from John Newman with Canaccord.

Justin Reid Zelin - *Canaccord Genuity Corp., Research Division - Associate*

This is Justin Zelin on for John Newman. I just had a question on the Vyleesi launch. Do you have a sense from AMAG on how setting up pricing and reimbursement is going with commercial plans? And do you see any prior authorization requirements for the drug?

Stephen T. Wills - *Palatin Technologies, Inc. - CFO, COO, Executive VP, Treasurer & Secretary*

Yes. Thanks for the question. This is Steve. I mean since we're not the commercial partner, AMAG is, I'm pretty much just going to repeat what they've publicly disclosed in their filings and their press releases and conference calls. The initial launch -- the national launch in September, AMAG is utilizing their 125 -- approximately 125 direct sales force. And they're also having the prescriptions initially go through their -- these 2 specialty pharmacies. At the same time, they are working on procuring the reimbursement. I believe they publicly disclosed that their target is, whether it's over the next 4 or 6 months post the national launch in September, they would anticipate getting in that somewhat rule of thumb, 70%, 75% of covered lives. I'm not aware of any issues that they're having from a barrier standpoint with their prescriptions as we reflected, but we actually reflected it post the reflection by AMAG.

And if you actually listen to their call, they seem to be very positive on the launch. It's tracking towards their projections. And I think they've done an excellent job with making sure there's no barriers for the women that would be seeking this treatment, i.e., the first script is, there's no charge for that. And then they have that maximum $99 out-of-pocket related to future scripts. So what they've reported is over the next 6 months, they will have the reimbursement coverage at a very significant number of covered lives.

And I think your -- second part of your question was related to, is there a pre-approval there? I really can't comment on that. I know certain -- just if you take me personally, if I have something in my shoulder and maybe need an MRI, I have to get a pre-approval. So I'm not sure if anything is needed in that regard. But I can circle back with AMAG and then circle back with you.

Operator

And next we'll go to Joe Pantginis with H.C. Wainwright.

Joseph Pantginis - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Steve, first, a logistical question. If my calculation is correct, then do you still have about 9 million or so warrants outstanding? And how is that exchange process going?

Stephen T. Wills - *Palatin Technologies, Inc. - CFO, COO, Executive VP, Treasurer & Secretary*

Yes. We actually have a little bit more than that, Joe, the -- there's certain of the warrants that -- they're going to expire very shortly. So I didn't really -- Carl and I didn't attack those types of warrants. As I stated in the script, there's a number of warrants out there. Palatin has a pretty significant short position. And we're very confident that we're -- that we have the data that a number of our warrant holders have and continue to use the warrants for shorting, to cover their shorting there. So our plan was to -- is to reduce and minimize that strategy. So the -- in a nice way, you'll also know who the -- who those types of funds are. So we've been targeting those funds a bit more than the others. So the plan, Joe, what I'm trying to get across is we're not looking to take out all the warrants, we're just looking to the warrants that we think are affecting the share price. And if we can get the right value for that, then we will continue to buy back those warrants and retire the warrants accordingly.

Joseph Pantginis - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Got it. No, that's helpful. And then just switching more towards Vyleesi, and some of my questions might be a little too early to ask, but I'm going to ask them anyway. And certainly, I guess, should be posed to AMAG as well. But do you know what kind of visibility we could expect with regard to, say, initial refill rates as an example? Are there any data being accumulated with regard to, say, switches from Addyi? So things along those nature.

Stephen T. Wills - *Palatin Technologies, Inc. - CFO, COO, Executive VP, Treasurer & Secretary*

The -- it's Steve here. It's -- that definitely would be an AMAG question. They obviously have all that data. It's -- we're -- that data is going to be disseminated once -- only through AMAG. Of the 2 specialty pharmacies that are handling the scripts, only one of them is reporting pharmacy. So even third parties, if you're checking with the IMS and some of the other companies to track that data, you're not going to get an accurate or reflective take on that. So like -- as I mentioned prior, they're -- AMAG, this is -- we think they're a great partner. We're well aligned. We're very supportive, whatever they need us to do, we'll be helpful where we can. But for those types of numbers, that's going to come from AMAG, and more than likely, just as they're updating their quarterly results.

Joseph Pantginis - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

No. Sure. So I'll ask it a little differently. So from your personal experience then in your discussions, maybe even anecdotally talking with physicians or patients, anything that you could share from your personal experience with regard to, say, switching or refills?

Stephen T. Wills - *Palatin Technologies, Inc. - CFO, COO, Executive VP, Treasurer & Secretary*

We -- I don't think it's best for us to report on the anecdote, because in a nice way, it's going to be a limited and it's very early in the launch, Joe. I mean, I appreciate you asking it two different ways. Hopefully, you're not going to do it a third way. But we just have to let the launch play out, right? Because they're -- it's -- as I mentioned, I think AMAG has done a great job with their reach, big social media push. And with the first script not costing any out-of-pocket money. The -- notwithstanding, having these women come in and get this treatment for an issue that they have, the better factor is going to be the repeat, right, the uptake. And it's not just taking scripts from Addyi because Addyi doesn't have a lot of scripts out there to take. So our target and AMAG's target is the millions of women that are -- that have this disease, this disorder, that are going to be seeking treatment. So it's really going to be over the next several quarters where you can get a gauge of how well the product is doing. But that's going to come from AMAG's -- updates on AMAG -- from AMAG with their quarterly and conference meetings.

Joseph Pantginis - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Yes. No. Very good point. Not a good comparator for a very low base line from Addyi. And I guess, just lastly, real quick. With regard to your BD, obviously, you're very, very busy. For multiple territories, you've given prior updates, obviously, for the larger territory of EU, any anecdotes -- or not anecdotes or any sort of update you can share with regard to where those stand for EU discussions?

Stephen T. Wills - *Palatin Technologies, Inc. - CFO, COO, Executive VP, Treasurer & Secretary*

Yes. I mean, it's -- Carl and I, we were probably a little bit ambitious at the last call where we stated that we fully expect to have deals soon. That -- our enthusiasm hasn't changed, Joe. What's transpired is post the approval, there were a lot of inbound calls coming in. And this is something that -- a phrase that Carl and I sort of lived by here at Palatin, we're not day-driven, we're data-driven. So Carl is over in Europe. He's talking to people, I'm talking to people there. We're trying to figure out who's the best partner, not who's the quickest partner. And I can't stress enough that there's not a region that we're -- we don't have advancing discussions with. We're under CDA in the data room due diligence with. When I say multiple, it's multiple, multiple companies. And what you -- what I'd like you to appreciate is Europe is the largest market outside of, say, the U.S. and a number of these European-based companies, they play in other -- in areas greater than just Europe, i.e., going into Asia Pacific, the Australia-New Zealand region, and importantly, the Latin American region. So what we're trying to balance is, what's the -- it's like the chess pieces. What are the best -- there could be another 3, 4, 5, 6 partners. When you're looking at Europe, there's Europe and even within Europe, sometimes there's Eastern Europe. Sometimes there's Europe and Asia Pacific. So we're not in any way trying to come up as being defensive. What we're -- what I'm trying to convey is, Carl and I want to make sure that we're making the most informed decisions. So we're not just going to do a Latin American deal until we are a little further along, so we can see how all the chess pieces come together. And more than likely, it's going to be multiple partners because even within Latin America, there's -- the Brazilian market is very, very indigenous to Brazilian companies there. So some companies, and these are some large companies, only play in Brazil not outside Latin America. So again, there's a number of chess pieces we're trying to move around here. But it's -- I can't stress enough that we're still very enthusiastic, and we had significant interest across -- I'm not sure there's a region we're not talking to. I'm looking over at Rob Jordan. He just wanted me to give him a shout out on this call. He handles all of our programs. And he's my copilot with business development and Carl's copilot also. So we're quite busy, and we're looking forward to announcing not 1 deal, but announcing multiple deals.

Joseph Pantginis - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

No. That's very fair. And if you don't mind, can I just switch to a little bit of the pipeline, if you would indulge me. So from a high-level standpoint first, it appears really in the space that the melanocortin pathway is really starting to increase in visibility. Obviously, until the last several months, the focus has been on Vyleesi, and -- while you've been giving very important updates and incremental updates about your pipeline progress. But now, obviously, you're seeing a big switch to more focus on your pipeline, internal development. And I guess, with that said, when you look at the competitive space of the melanocortin pathway, you look at Rhythm, you look at CannaWell, you look at drugs for dry eye, like Restasis and Xiidra. How are you looking to leverage the success and regulatory discussions of others that might benefit your melanocortin pathway programs?

Stephen T. Wills - *Palatin Technologies, Inc. - CFO, COO, Executive VP, Treasurer & Secretary*

Sure, Joe. I mean it's pretty interesting, we come into an interesting time for the melanocortin pathway, I mean, Vyleesi was probably one of the first products approved that are specifically -- directly activating receptors of the pathway. CannaWell, as you mentioned, they just got a product approved as well, and then Rhythm should be submitting for their -- some of their orphan indications, I think, late this year or early next year. Listen, all these things are all helpful, right? Because, one, it gives a lot of visibility to mechanisms, various mechanism -- underlying mechanism. Two, it continues to build the safety database. So regulatory authorities are looking at it on a broader basis, they're seeing more patients coming in, trying the pathway, so that it gives a higher degree of comfort. For us -- on -- the next step for us is, as I think is pretty apparent from the call is, we're focused a lot more now moving towards the autoimmune and inflammatory indications, and in particular, those in the ocular space where we think that there really remains very high medical need and an ability really for our compounds to be very distinguished based on the underlying mechanism. So you mentioned Restasis, for example, cyclosporine-based compound, multibillion dollar compound for dry eye. With that being said, patients use it. But compliance rates are very low. There's a lot of stinging to it. Some of the other drugs that have been approved, they are read or analogs of cyclosporine or Xiidra, which is the other approved class. They have compliance issue as well. So we think that we have a really nice position with 9643 for dry eye, and that we're seeing very good -- comparable efficacy in the animal models, if not better. Activity straight -- right away, no lag time, so you don't have to take it for a period of time before you see activity. And more importantly, we're not seeing any patient -- or any potential discomfort. So it should be no stinging, no viscosity, no off-taste, no odd flavors. And there should be no systemic absorption and no safety issues from that regard. The real driver for us that's exciting when you move past dry eye and you look at uveitis or you look at diabetic retinopathies is really the ability for this mechanism to impact the underlying disease. Even though the -- if you look at -- let's take a look at the diabetic retinopathy market, for example. That's a multibillion dollar market, and those patients predominantly eventually move on to the biologic therapy. But after 7 years, the disease is going to revert. They're just treating symptoms. They're not really getting at the underlying disease process. We believe, based on the data we're seeing, that we have a really -- potential ability to affect the fundamental immune process that's occurring. And maybe you get a -- an overall better response for a longer-lasting effect. That's where we're excited about the mechanism. That's where we're excited about what we're doing. Of course, it's early, we have to prove this in the clinic still. But the potential is huge, when we think about the ocular indications for the mechanism, and we're quite excited about what we're doing there. And that also falls over when we think about other autoimmune conditions like ulcerative colitis. It's not just treating symptoms, it's really -- can this mechanism impact underlying disease processes, therefore, giving a more durable effect or affecting patients that are not responding to current therapies. So that's in a nutshell kind of why we're excited and what we're -- why we're deploying the capital where we are in these new indications.

Operator

And I'll turn it back to Dr. Carl Spana for any additional or closing comments.

Carl Spana - *Palatin Technologies, Inc. - Co-Founder, President, CEO & Director*

I'd like to thank everyone for participating in the Palatin First Quarter 2020 Conference Call. I think as you can see, there's a lot of activity here at Palatin, a lot of enthusiasm and excitement about what we've accomplished with Vyleesi, and AMAG's handling of the launch of Vyleesi and really where we're going. 2020 is a big year for us. It's a transitional year as we move from a company that really has had 1 product in Vyleesi into now having multiple -- 3 new indications going into the clinic and more behind that.

So we're quite excited about what we're doing, and we're really looking forward to continuing to update you as the year passes by. So again -- once again, thank you for taking -- coming on the call. Have a great day, and we look forward to keeping you updated on our progress. Thank you.

Operator

And that does conclude today's conference. We'd like to thank everyone for their participation. You may now disconnect.
