THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

AUP.TO - Q2 2019 Aurinia Pharmaceuticals Inc Earnings Call

EVENT DATE/TIME: AUGUST 06, 2019 / 8:30PM GMT

THOMSON REUTERS

CORPORATE PARTICIPANTS

Dennis Bourgeault *Aurinia Pharmaceuticals Inc. - CFO & Secretary*

Glenn Schulman *Aurinia Pharmaceuticals Inc. - SVP of Corporate Communications & IR*

Michael R. Martin *Aurinia Pharmaceuticals Inc. - Co-Founder & COO*

Neil Solomons *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

Peter S. Greenleaf *Aurinia Pharmaceuticals Inc. - CEO & Director*

Simrat Randhawa *Aurinia Pharmaceuticals Inc. - Senior VP of Clinical & Medical Affairs*

CONFERENCE CALL PARTICIPANTS

Antonio Eduardo Arce *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

PRESENTATION

Operator

Greetings, and welcome to Aurinia Pharmaceuticals Inc. Second Quarter 2019 Conference Call. (Operator Instructions). Please note, this conference is being recorded.

I would now like to introduce you to today's host, Dr. Glenn Schulman. Thank you. You may begin.

Glenn Schulman - *Aurinia Pharmaceuticals Inc. - SVP of Corporate Communications & IR*

Thanks, Kevin, and good afternoon, everyone. Welcome to Aurinia's Second Quarter 2019 Results Conference Call. Joining me on today's call from the Aurinia team are Mr. Peter Greenleaf, President and CEO; Dennis Bourgeault, our CFO; Dr. Neil Solomons, Chief Medical Officer; Michael Martin, Chief Operating Officer of Aurinia; and Dr. Simrat, our Head of Medical Affairs. This afternoon, we issued our press release detailing our second quarter 2019 financial results. The press release and associated financial statement package is available on our website at www.auriniapharma.com and a 6-K was filed as well with the SEC.

I'd like to remind you that today's call is being webcast live on Aurinia's Investor Relations website and a replay will also be available following the call.

The content of today's call is Aurinia's property and cannot be reproduced or transcribed without our written prior consent. During the course of this call, we may make forward-looking statements based on our current expectations. These forward-looking statements are subject to a number of significant risks and uncertainties, and our actual results may differ materially. For a discussion of factors that could affect our future financial results and business, please refer to the disclosure in today's press release, our most recent filings with the Canadian Securities Authorities and reports that we file on Form 6-K with the U.S. Securities and Exchange Commission.

All of the statements made during today's call are as of today, August 6, 2019, and based upon information currently available to us. Except as required by law, we assume no obligation to update any such statements as of this date.

With all that, let me turn the call over to Aurinia's CEO, Mr. Peter Greenleaf. Peter?

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

Well, thanks, Glenn. And it's a pleasure to have you all on the call with us today. So during the past quarter, it's really been an exciting and interesting time here at Aurinia. Over the course of my short tenure, it's been an absolute pleasure to get to know the team here at Aurinia and get in depth with the voclosporin program and current trajectory of the organization. I'll also briefly mention that in and around the time of our Annual General Meeting, I was humbled to have had the opportunity, both personally and through other spokespersons here at Aurinia, to hear from a vast array of our shareholders and sufficient to say that we're pleased with the proxy results and the outcome there. And want to reiterate that from our directors down throughout the organization, we are aligned to realize the full potential of all that has been invested in voclosporin to date. Beyond that, it's also been a learning period for me as I dive in depth into our development programs and really work to ensure that Aurinia is ready for not only the upcoming AURORA Phase III clinical trial results in lupus nephritis, which I can tell you remains on track to be reported by the end of this year, but also to prepare for the NDA process and potential launch of the compound, all the while expanding our development portfolio to capitalize on other potential indications for this molecule.

When I had the opportunity to chat with everyone on our first quarter call, I discussed several priorities that were key upon taking the role of CEO here at Aurinia. First and foremost was to ensure that the company is fully prepared to transition from a late-stage clinical development organization and into a company that was prepared for the commercialization of voclosporin in the United States and our plans around the world. Further, it was imperative that we work to expand the pipeline around the breadth of indications that are possible for this novel C&I, both in rare renal diseases, such as FSGS and topically for the potential management of dry eye syndrome. As you'll note from this afternoon's press release, we've provided a full update on our plans for both indications, and I look forward to having Dr. Neil Solomons and Mike Martin from our team walk you through these developments. Aurinia continues its growth trajectory from an early-stage clinical company from a single indication to now a precommercial organization working to leverage our R&D infrastructure to pursue additional opportunities, including FSGS, dry eye syndrome, for voclosporin. From a corporate perspective, we've begun to build and scale the organization to prepare for this potential phase of growth. This means adding new leaders in building systems and processes that will take the organization to where it needs to go in order to be successful. As part of this work, we embarked upon a broader review of our company's strategy with our Board of Directors, which we will look forward to discussing with investors over the next few months. Key to both of these areas of work, we were pleased to announce last month the addition of Max Donley, who has extensive experience in corporate strategy development as well as managing internal operations that are required for this next phase of growth. In addition to that, we were also excited to bring Glenn Schulman onboard, who will head our Corporate Communications and overall Investor Relations efforts here on a full-time basis.

Beyond these roles, we're also in the process of making key hires in our regulatory medical affairs, CMC and our commercial groups. The overarching mission for this expansion is to support a projected commercial launch in 2021 of voclosporin as a first-line treatment in combination with mycophenolate mofetil, along with low-dose steroids for lupus nephritis.

So with that quick front-end review, I'd like to now turn the call over to Dr. Solomons to review the next steps for the VOS dry eye syndrome program. He'll detail the AUDREY clinical trial protocol and then provide an update recently made alongside of the FSGS study. Neil?

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

Thanks, Peter, and thanks to all for joining. And as mentioned, I'll first take a moment to go through the AUDREY Phase II/III clinical trial for dry eye syndrome and then provide some updates around FSGS with a brief status update report on the AURORA Phase III trial for lupus nephritis. With respect to the dry eye program, the pilot Phase II study reported earlier this year showed VOS to be well tolerated producing some striking superior clinical sign data and comparable tolerability results versus the current market leader for dry eye syndrome, cyclosporin opthalmics emulsion, also known as Restasis. Based upon the exploratory Phase IIa results generated in that study, we have initiated plans for a commercial focused development program with a Phase II/III study dubbed AUDREY, that's Aurinia Dry Eye Study, expected to begin enrollment of U.S. patients in the fourth quarter of 2019. This study will include certain critical regulatory requirements that the FDA has traditionally required for DES product approval. These requirements include both dose optimization requirements, along with a comparison versus the nanomicellar vehicle. In short, AUDREY will be a randomized double-masked, vehicle-controlled dose-ranging study to evaluate the efficacy and safety of VOS in subjects with DES. In all, approximately 480 subjects will be enrolled beginning later this year. The study will consist of 4 arms and encompass a 1:1:1:1 randomization schedule to either 0.2% VOS, 0.1% VOS, 0.05% VOS or vehicle with all arms being dosed twice daily for a total of 12 weeks.

The primary outcome measured for AUDREY will be the proportion of subjects with a 10 millimeter improvement in Schirmer Tear Test, or STT, at 4 weeks. Furthermore, secondary outcome measures will include STT at multiple time points; Fluorescein Corneal Staining, or FCS, at multiple time points; change in eye dryness, burning, stinging, itching, photophobia, eye pain and foreign body sensation at multiple time points; change in Symptom Assessments in Dry Eye, or SANDE, at multiple time points and additional safety endpoints.

So we're very excited to advance VOS and aim to address the persistent unmet medical needs associated with this condition.

Moving briefly to voclosporin for focal segmental glomerulosclerosis or more simply FSGS. As you will recall, Aurinia initiated a Phase II proof-of-concept open-label study for FSGS back in June of 2018. The study as it was designed and recently updated will continue to evaluate the role of voclosporin for patients diagnosed with primary FSGS. As a pilot study, our initial goal was to provide a first-line treatments option immediately following a patient's diagnosis of primary FSGS. Given the rare nature of this disease and increased awareness about its progress, we've recently implemented 2 strategies to understand the role of voclosporin for this orphan disease. From a clinical operations view, we have added additional clinical sites outside of the U.S. and specifically in the Dominican Republic. Beyond additional enrollment sites, we've also adjusted the protocol and broadened entry criteria in this study. This protocol amendment allows the enrollment of subjects that are either treatment naïve, as originally described in the protocol, or receiving street -- steroid treatment, oral or IV, for FSGS. Subjects taking steroids must show signs of improvements in proteinuria defined as at least a 20% improvement in UPCR from the initiation of steroids to last stability assessment prior to baseline. Subjects who have discontinued steroid treatment due to poor tolerability may also be considered for study. A total of 20 patients will be enrolled in total and we anticipate interim results in FSGS during 2020.

And lastly, no news is no news for the AURORA Phase III clinical trial for the treatment of lupus nephritis. As you recall, a total of 358 lupus nephritis patients were randomized at sites globally. AURORA is a global, double-blinded, placebo-controlled study evaluating whether the addition of voclosporin on the background of the mycophenolate mofetil or CellCept unload as steroids can increase the rate and speed up the renal response. The primary endpoint for the study is achieving to complete renal response at 52 weeks and with the study fully enrolled as of last September, we look forward to trial results by the end of this year, which if positive, will form the basis of our U.S. regulatory filing.

With that review of the clinical programs, I'll pass it over to Dennis for a review of the Q2 financial results. Dennis?

Dennis Bourgeault - *Aurinia Pharmaceuticals Inc. - CFO & Secretary*

Thanks, Neil. Thanks, everyone for joining. For the 3 months ended June 30, 2019, Aurinia reported a consolidated net loss of $15.9 million or $0.17 per common share compared to a consolidated net loss of $15.7 million or $0.19 per common share for the same period in 2018. Research and development expenses increased slightly to $11.2 million for the 3 months ended June 30, 2019, compared to $10.5 million for the 3 months ended June 30, 2018. The increase in these expenses reflect higher costs incurred for the AURORA 2 extension trial, the drug-drug interaction study, preparation costs associated with the planned NDA submission for LN and preparation costs for the Phase II/III DES clinical study.

Corporate administration and business development expenses increased to $4.9 million for the 3 months ended June 30, 2019, compared to $3.5 million for the same period in 2018. The increase was primarily due to an increase in consulting fees related to a recruitment fees and precommercial activities such as market and payer research, and higher personnel and sponsorship costs. Noncash stock compensation expense was $2 million for the second quarter ended June 30, 2019, as compared to the same number for the same period in 2018 and is included in both research and development and corporate, general and business development expenses.

Aurinia has incurred other expenses of $720,000 during the 3 months ended June 30, 2019, associated with our successful defense of a proxy contest in connection with our June 26, 2019 Annual General Meeting. There were no similar expense in the comparable period.

Aurinia also required a noncash reduction of $625,000 and the estimated fair value of derivative warrant liabilities, which reduced the loss for the second quarter ended June 30, 2019, compared to an increase of $1.9 million in the estimated fair value of derivative warrant liabilities for the same period in 2018, which increased the loss for the second quarter ended June 30, 2018. The derivative warrant liabilities will ultimately be eliminated on the exercise or forward picture of the warrants and will not result in any cash outlaid by the company.

The 6-month financial report -- results for the period ended June 30, 2019, are provided in the release issued this afternoon. As of June 30, 2019, Aurinia had cash and cash equivalents of $131.5 million compared to $144.3 million of cash, cash equivalents and short-term investments at March 31, 2019, and $125.9 million at December 31, 2018. Net cash used in operating activities was $13.3 million for the second quarter ended June 30, 2019, compared to $12.3 million for the second quarter ended June 30, 2018. Company believes that based on its current plans that it has sufficient financial resources to fund the existing lupus nephritis program, including the AURORA trial and the AURORA 2 extension trial, complete the NDA submission to the FDA for lupus nephritis, conduct the ongoing Phase II study for FSGS, initiate the AUDREY Phase II/III study and fund operations into the second half of 2020.

With that review, I will pass it back to Peter for some concluding remarks.

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

So thanks, Dennis, and thank you, everyone. So before opening up to Q&A, I just like to point out that obviously Aurinia is a truly unique opportunity. Our drug, voclosporin, has previously shown its potential in the AURORA lupus nephritis trial as well as in an exploratory Phase II dry eye syndrome study. The strategic objectives to the company remain focused on voclosporin, its clinical development programs, our precommercial and our regulatory activities. Furthermore, we're working to build additional value around the VOS dry eye syndrome program and are focused on finalizing plans to enable the start of a Phase II/III trial later this year. During the past few months and in anticipation of the AURORA Phase III results in lupus nephritis, we have been and will continue to appropriately scale the organization which, if confirmatory, sets the stage for an NDA filing during the first half of next year for voclosporin. And if approved, our projected commercial launch in 2021 as a first-line treatment in combination with the mycophenolate mofetil along with low-dose steroids.

With a strong balance sheet of $131.5 million at the end of June 2019, our priority is to maintain a robust capital position at Aurinia, especially as the company scales towards the initiation of the AUDREY Phase II/III study for dry eye syndrome as well as a potential regulatory submission and commercialization of voclosporin. We look forward to providing additional updates on our progress over the coming months.

And with that, I'd like to turn the call back to the operator and open the line for Q&A. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Joseph Schwartz with SVB Leerink.

Unidentified Analyst

I'm [Judy] dialing in for Joe. My first question has to do with voclosporin for lupus nephritis. Class V patients haven't been shown to demonstrate benefit to treatment. And I was wondering what are you -- are you stratifying enrollment -- enrolling -- stratifying enrolling classified patients?

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

So thanks for the question. And I think the short answer is yes, but I want to give the question over to Dr. Solomons to see if he wants to just go a little bit deeper into that. Neil?

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

Yes. So I mean -- Thanks, Peter. I mean, I think -- As Peter answers, yes, we are stratifying a pure Class V versus non-Class V because there's certainly a feeling that these patients may behave differently. Actually, our previous work in lupus nephritis approved in the face of that and we showed that according to standard of care, Class V patients appear to behave exactly the same as non-Class V in the work that we did. Nevertheless, we have actually stratified between pure V and non-pure V.

Unidentified Analyst

Okay, great. And my second question has to do with biopsies. I was wondering if you could talk a little bit about baseline requirements for biopsies. And the reason is because since the inclusion criteria for Phase III has been brought into clinical patients that had biopsies within the last 24 months versus 6 months, which is required for Phase II. I was wondering how we should think about the differences in patient baseline characteristics? And how the data outcome can differ as a result?

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

Yes. So again, I'm going to pass this to Neil. But just to be clear, both in the Phase II and in the Phase III trial, there was the need to have a biopsy. It was just a time difference from biopsy to study -- to initiation into the study that differed. Neil, you want to take that?

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

Yes. I mean I think that my broad answer to that question is, we do notice that any material difference between the Phase III and Phase II studies, where we put in a little bit of leeway was just to -- in the Phase II study, we had to turn away patients who've had a biopsy even a few days after a 6-month time period, whereas, in fact, medically, there's probably no reason to do that. So what we did -- and in fact, there's publications in literature to support the fact that over a 2-year period, a diagnostic biopsy really doesn't change very much. So what we did to it, we put in some steps for patients who had a biopsy greater than 6 months to ascertain that they in fact did have active flaring disease. That these sites have to provide very detailed proteinuria measurements that have been increasing sharply up to the enrollment of the patient. I think more important from your perspective, we had relieved very, very few patients who entered on those extended criteria, and that supports my initial assertion that we expect them to be no material different from the patients coming in to Phase II versus Phase III.

Unidentified Analyst

Great. And my last question has to do with payer discussions. I was wondering what have some of your payer discussions regarding pricing has been and what the -- have you had any pushbacks on like what the upper end could be?

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

So we've not publicly disclosed any of the details of the market research that we've done up to this point in great detail, but do feel comfortable that we're pretty ahead of the curve. At least my early assessment on that work in not just doing the market research that we need to do to understand what through a basic build of a target product profile might actually look like in terms of what the potential market price is. But I think it's safe to say that it's going to be very dependent on the data and what the data shows us. And if we're able to show the types of efficacy improvements that we saw in Phase II balanced with a solid risk profile, one that's -- the balance is right there between benefit/risk that we'll be able to command decent pricing in the market. But it's so dependent on data. Right now, the only research that we've been able to do is sort of just basically building a target product profile based off the Phase II data, and we'll have to see what happens in the Phase III. I don't think we've disclosed specifically any pricing expectations. And I think that in order to do that, it would be too preemptive, really. We have to see what the Phase III trial shows us at the end of the day.

Operator

Our next question comes from the line of Ed Arce with H.C. Wainwright.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Couple here. First, on AURORA. I guess a similar line of questioning, but from a different angle, perhaps. Thinking as you surely are at this point about fine-tuning your commercial strategy for voclosporin and LN, as the data now is coming very close. Just wondering how you think about that strategy, given that these patients are very proactive. They are aware of voclosporin, they're very aware of the trials and out there and both patient and patient advocates are sort of very active? How do you think about leveraging that? And how will that impact sort of the sites that you go to first as you commercialize?

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

Well, I'll start, and then I actually have the luxury of having Dr. Randhawa with us as well, who heads up our Medical Affairs organization. He's really been sort of at the ground level thinking about that and actually talking to some of these sites. But I think the short answer is, obviously, those sites that have participated in our trials are going to be the ones that understand the drug probably the best and have a group of patients that have been on the drug. There obviously be centers that we want to tap very quickly, both from an influence standpoint, but also from a patient adoption standpoint. I can tell you as well that our commercial team, which is fairly small at this stage of the game, and our Medical Affairs group have been working with -- very closely with the patient efficacy foundations that are out there and our key opinion leader group that are out there on the early stages of not just education on voclosporin, but education on the potential for a transition in how the disease is managed. Because obviously we're adding a drug and a different treatment regimen to what currently is the standard of care and treatment for these patients. So the education efforts are there. Simrat, would you add to that?

Simrat Randhawa - *Aurinia Pharmaceuticals Inc. - Senior VP of Clinical & Medical Affairs*

Yes. I don't have a whole lot more to add. What I would say, Ed, is that within the tight legal and regulatory framework that we have to operate in, in this industry, and we already looked into that, and we watch it closely. We have worked extremely closely with all the major advocacy groups over the last many -- couple of years, as a matter of fact. So I think for a company of our size, now I'd dare say, even for one that's slightly larger, we're well ahead of the curve in how we interact with advocacy groups, and we're also well ahead of the curve in understanding the realities of the market. So not just the folks who go to conferences and are speaking at conferences, but the actual prescribers, how they prescribe? What their challenges are? And what the pluses and minuses are in their minds as they treat lupus nephritis and as they consider this mechanism of action? So on all of those kinds of things, we're well ahead of the curve and the part that we're working on now is frankly deploying the right resources to leverage that knowledge. But at least from a Medical Affairs standpoint, I'm pretty confident that we're in the right place for the size of our company and where we are in the development program.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

All right. Great. That answers for that. Yes -- I'm sorry, Peter, go ahead.

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

No, no, I was just waiting to hear what the next question was. But as I said on the first call, I've been very impressed with how the team has been engrained into this and really enveloped into this community for such a small infrastructure and such a small amount of investment at this stage of the game. I think we're well ahead of the curve of where we need to be. So I'm sorry, Ed, you had another question?

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Yes. No. The other question was, I'm gratified to hear that based off of the early data from early this year that you are moving forward in dry eye with this AUDREY study. My question around that is, given, as you well know, there was somewhat of a confusing data set out of that study. And in that context, what led you to choose the Schirmer test as the primary endpoint as oppose to others and maybe sort of talk around what the potential issues are with that and the others?

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

Yes. So Ed, again, I'm going to probably key this to either, Mike or Neil, to really expand upon. But at the end of the day, at least from my own view coming into the company, early days, I didn't really -- I think, in the trial, there was a fairly clear message on efficacy across the majority of parameters on the signs and symptoms side. Unfortunately, the primary endpoint of tolerability didn't show statistically significant difference. So we really kept our decision-making criteria as to whether to move forward or not on the secondary endpoints of the trial, which were quite impressive versus the current market leader. As it pertains to the approach for the next stage of clinical development, I think a lot of that -- it really now gets positioned around the regulatory pathway for approval. And let me see if maybe Neil or Mike would want to take that one on.

Michael R. Martin - *Aurinia Pharmaceuticals Inc. - Co-Founder & COO*

You go ahead, Neil.

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

Sure. Yes, sure. Thanks. I mean, Pete, you said most of it. Ed, I would argue, assumably that the results were not confusing. I mean they're very, very clear in favor of the efficacy endpoints. So I know exactly what you mean though, this is an exploratory study and our tolerability endpoints, as Pete said, was not clear-cut. The proportion of patients from our small exploratory study, which is not how it show a difference in Schirmer Test improvement by 10 millimeters or greater, if you hit that endpoint. We're really impressively superior on a small sample size for VOS versus Restasis, where, I think 43% of VOS patients achieved a Schirmer Test of 10 millimeters -- strong Schirmer score of 10 millimeters or greater compared to, I think, 18% in the Restasis arm. This endpoint, in addition, has been one that has been used to approve calcineurin inhibitors in the treatment to dry eye in the past. And therefore, at least on that level, it is an endpoint that pressors regulatory must have. So for that -- that's why we have picked that endpoint moving forward into our Phase II/III study. So there's 2 things: one, that we were very confident because this has the very, very large treatment effect that we saw from that exploratory study; and secondly, this, we believe, is a regulatory -- for regulatory perspective, a highly relevant endpoint.

Operator

Since there are no further questions left in the queue, I would like to turn the call back over to management for any closing remarks.

Peter S. Greenleaf - *Aurinia Pharmaceuticals Inc. - CEO & Director*

Yes. Thank you, operator, and thanks to all of you for joining us on the call today. Obviously, we're really excited about what's on the horizon this year at Aurinia. And I'm excited about the potential news flow we're going to have in the fourth quarter from the AURORA Phase III trial, obviously. As we continue to grow Aurinia ahead of these results, we're also working to drive expansion of uses for voclosporin by really optimizing the FSGS clinical study and investing in AUDREY to advance VOS towards commercialization for dry eye syndrome. All the macroeconomic environment that everyone's facing aside, really, 2019 is poised to be a standout year for Aurinia.

I want to thank you all for joining us for the call today. Have yourselves a great evening.

Operator

This concludes today's teleconference. You may now disconnect your lines at this time. Thank you for your participation, and have a wonderful day.