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AUP.TO - Q2 2018 Aurinia Pharmaceuticals Inc Earnings Call

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PRESENTATION

Operator

Greetings, welcome to the Aurinia Pharmaceuticals Incorporated Q2 2018 financial results. (Operator Instructions) As a reminder, this conference is being recorded. I would now like to turn the conference over to our host, Celia Economides, Vice President of Corporate and Public Affairs. Thank you, you may begin.

Celia Economides - *Aurinia Pharmaceuticals Inc. - VP of Corporate & Public Affairs*

Thank you, operator, good afternoon, everyone, and welcome to Aurinia's Q2 2018 earnings call and general business update. With me on the call day from Aurinia are Richard Glickman, Chief Executive Officer; and Dennis Bourgeault, Chief Financial Officer.

Joining us for a Q&A session will be Michael Martin, our Chief Operating Officer; and Dr. Neil Solomons, our Chief Medical Officer.

This afternoon, we issued a press release detailing our Q2 2018 financial results and corporate update. The press release and financial statement package is available on our website at auriniapharma.com and a 6-K was filed with the SEC as well.

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 today's call.

The content of today's call is Aurinia's property, it cannot be reproduced or transcribed without our prior written consent. During the course of this call, we may make forward-looking statements based on 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 Canadian securities authorities and reports that we file on form 6-K with the U.S. Securities and Exchange Commission. All our statements are made as of today, August 9, 2018, based on information currently available to us. Except as required by law, we assume no obligation to update any such statements.

With that, let me turn the call over to Richard. Richard?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Thank you, Cilia, and thank you to everyone for joining us today, as we review our second quarter financial results and provide a general business update.

This has been an extraordinary quarter for our company and tremendous progress we've made on a number of fronts. And I'm excited to talk about the momentum our organization is developing after a period of what I would refer to as heavy lifting.

With respect to our Phase III clinical program in LN, our most advanced program, we're excited to announce the recruitment is running ahead of schedule and we foresee enrollment completion very early in Q4 this year. For me, this is an indication that the trial is progressing well. As a reminder, the primary input to this trial is at 52 weeks, after which, there is a 4-week follow-up period before a subject officially completes the trial. Thus, we expect to have data for the trial on-time and on-schedule before the end of 2019.

For a bit more granularity, we have 225 sites activated in April to enroll patients in 29 countries around the globe. As a reminder, we took a different approach in recruitment for our Phase III trial, and we opted to initiate and activated as many sites as possible from the beginning rather than activating a few at a time.

You may recall that patients that have active lupus nephritis are very ill. And our Phase II trial enrolled some of the sickest patients ever studied in this disease. Now as previously mentioned, we have implemented several additional safety parameters in our Phase III trial and I'm monitoring these very closely in a blinded manner. The DSMB also reviews all adverse events on an ongoing basis, and so far, we believe that study is progressing very well. We will continue -- we continue to have motivated patients and investigators participating in this trial and we remain very encouraged by the level of interest in the trial it has been generating around the globe. Our team is working diligently with a goal to assess the efficacy and safety of voclosporin in LN patients and are extremely determined to potentially provide the first FDA and AMA-approved therapy for these patients in desperate need.

Just to remind you that LN is a debilitating disease. It affects mostly women of child-bearing age. We are actively preparing an NDA and we expect to complete the rolling submission in Q2 2020.

During the second quarter, we also saw the first patients rollover into the AURORA 2 blinded extension study from the AURORA Phase III clinical trial. The purpose of the AURORA 2 is to assess the long-term safety and tolerability of voclosporin patients with LN. However, the study is not requirement for potential regulatory approval for voclosporin.

Long-term safety and efficacy data for our unique CNI should prove to be a great value to the medical and patient community, as we are committed to providing relevant data that could support treatment decisions in the future. That brings us to an update on new indications we are pursuing of voclosporin, the first being FSGS. Approximately 5,400 new patients are diagnosed with FSGS in the U.S. alone each year, accounting for the largest segment, almost 30% of patients with nephrotic syndrome.

FSGS is a rare disease that attacks the kidney's filtering units causing serious scarring which leads to permanent kidney damage and even failure. Similar to lupus nephritis, an early clinical response or reduction proteinuria is felt to be critical to long-term kidney health. While guidelines exist for treatment, there are no currently approved therapies for FSGS in the United States or the European Union.

After productive consultation with regulators in the first quarter, we successfully initiated our study in June. This is an open-label, proof-of-concept study in 20 treatment-naive patients with FSGS. As we are essentially enrolling newly diagnosed patients and this is a rare disease, we expect enrollment to take up to 12 months, but we intend to have planned interim data readout throughout the course of the trial in 2019.

As a company, it has been focused on lupus nephritis since its inception, expanding our scope to include other proteinuria diseases is synergistic with our current strategy and long-term vision of the company.

And one of the most exciting aspects of this trial is that we're assessing the potential of voclosporin as a first-line therapy for these patients in the complete absence of steroids.

Massive steroid doses are often given to these patients, which predictably come with multitude of well-established side effects. An approved treatment for FSGS will be a tremendous value to both patients and furthermore to our shareholders.

As I mentioned, it's been quite a fruitful quarter. We recently initiated yet another exciting program with a new drug called voclosporin ophthalmic solution or VOS for the treatment of Dry Eye Syndrome. This is a different formulation of voclosporin, which is a unique patented aqueous, preservative-free nanomicellar solution containing 0.2% voclosporin. And as you know from previous disclosures, voclosporin was found to be 3x or 4x more potent than cyclosporine A. VOS has its own separate formulation patents with exclusivity until 2013.

Dry Eye Syndrome is a chronic disease in which a lack of moisture and lubrication of the eye surface results in irritation and inflammation of the eye. Dry Eyes estimate to effect greater than 20 million people in the U.S. alone. While there are 2 FDA approved products for the treatment of Dry Eye, one of which is the calcineurin inhibitor, there is potential and need for improved effectiveness for the treatment of Dry Eye. And particularly by enhancing tolerability and the onset of action and then leading in a need for repetitive daily dosing, we believe that calcineurin inhibitors will remain a mainstay for the treatment of Dry Eye. And VOS has the potential to be the best-in-class CNI, with -- within this multibillion-dollar market.

A Phase I trial has previously been completed in 35 healthy volunteers and patients with Dry Eye. In early July, we initiated a Phase II head-to-head tolerability study of VOS versus RESTASIS and we expect to complete this trial before the end of the year. Depending on Phase II recruitment, data could be available as early as the end of the year or early 2019. This will be a 4-week study and we will be recruiting 90 patients for this trial. The goal of this program is to develop a best-in-class treatment option. And upon completion, we'll look to evaluate strategic alternate for VOS.

I believe, there is tremendous value in this asset. So that's it for our clinical programs. Aurinia is now in its substantial growth phase, transitioning from an early-stage clinical company, with one indication to a late-stage clinical company with multiple indications. We are thrilled to evolve the progress we made so far this year. And look forward to the productive second half of the year. With that, I'll turn the call over to Dennis Bourgeault, our CFO to review the Q2 financials with you. Dennis?

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

Thank you, Richard. At June 30, 2018, we had cash, cash equivalents and short-term investments of $150.2 million compared to $159.1 million at March 31, 2018, and $173.5 million at December 31, 2017.

Net cash used in operating activities was $12.3 million for the second quarter ended June 30, 2018, compared to $14 million for the second quarter ended June 30, 2017. In the second quarter ended June 30, 2018, we received proceeds of $3 million from the exercise of warrants, which were set to expire in June of 2018.

We believe, based on our current plans and activities, that we have sufficient financial resources to fund our existing LN program, including the AURORA trial and the NDA submission to the FDA, conduct the Phase II trials for FSGS and Dry Eye and fund operations into 2020.

We reported a consolidated net loss of $15.7 million or $0.19 per common share for the 3 months ended June 30, 2018, as compared to a consolidated net loss of $2.4 million or $0.03 per common share for the 3 months ended June 30, 2017. The increase in the loss for the 3 months ended June 30, 2018, compared to the same period in 2017, was primarily due to the noncash change in the estimated fair value of derivative warrant liabilities in the amount of $9.4 million. The 3 months ended June 30, 2018, reflected a $1.9 million increase in the estimated fair value of derivative warrant liabilities compared to a reduction of $7.5 million in the estimated fair value for the 3 months ended June 30, 2017. The change in the revaluation of the derivative warrant liabilities is primarily driven by the change in our share price at each period end.

An increase in our share price results in an increase in the estimated fair value of derivative warrant liabilities and an increase in our loss and vice versa. The derivative warrant liabilities will ultimately be eliminated on the exercise or forfeiture of the warrants and will not result in any cash outlay by the company.

The net loss before the noncash change in estimated fair value of derivative warrant liabilities was $13.8 million for the 3 months ended June 30, 2018, compared to $9.9 million for the same period in 2017, with the increased loss amount, primarily reflecting higher research and development expenses.

For the 6 months ended June 30, 2018, the consolidated net loss was $31.2 million or $0.37 per common share compared to a consolidated net loss of $54.3 million or $0.78 per common share for the comparable period in 2017. For the 6 months ended June 30, 2018, we recorded an increase of $4.6 million in the estimated fair value of derivative warrant liabilities compared to $33.3 million for the comparable period in 2017.

The net loss before the noncash change in estimated fair value of derivative warrant liabilities was $26.6 million for the 6 months ended June 30, 2018, compared to $21.1 million for the same period in 2017. The increased loss, again, primarily reflected higher research and development expenses.

Research and development expenses increased to $10.5 million for the 3 months ended June 30, 2007 -- 2018, compared to $7.1 million for the 3 months ended June 30, 2017.

We incurred research and development expenses of $19.4 million for the 6 months ended June 30, 2018, as compared to $14.4 million for the same period in 2017. The increased research and development expenses reflected higher AURORA clinical and drug-supply cost as well as startup cost for the AURORA 2 extension study and the FSGS and Dry Eye studies.

Corporate, administration and business development expenses increased to $3.5 million for the 3 months ended June 30, 2018, compared to $2.9 million for the same period in 2017. We incurred corporate, administration and business development expenses of $7.3 million for the 6 months ended June 30, 2018, compared to $6.3 million for the comparable period in 2017. The increase was primarily due to higher noncash stock compensation expense in 2018 compared to the same period in 2017.

With that, I will turn the call back over to Richard for some closing remarks. Richard?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Thank you, Dennis. And once again I'd like to thank the team for the tremendous progress we've made so far this year. We are diligently executing on our clinical programs and look forward to a very busy rest of 2018, with the completion of recruitment for our Phase III trial in LN, more patients rolling over to the AURORA 2 extension study and carrying out the FSGS and Dry Eye program successfully.

2017 was an extremely pivotal year for the company. We are now a late-stage biotech company that's diversifying its portfolio and building out its core competencies. We are a nimble and dedicated team that continue to successfully execute upon our corporate milestones. As a company, we have a drug candidate that if successful in Phase III, has the potential to be the first approved therapy for the treatment of LN. The efficacy and safety data supporting this drug is substantial. We have a clear regulatory path forward to approval. There is a large and solid intellectual property base. And we believe the market opportunity for this drug to be significant. It is with great confidence, we continue to advance voclosporin to its final development phase for LN. With that, I'd like to turn the call back to the operator and open the lines for Q&A. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Ed Arce with H.C. Wainwright.

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

Congrats on all of the progress this quarter and transitioning from 1 to 3 clinical programs. I have 3 questions. First, you had mentioned, the pivotal Phase III has appeared to accelerate recently in enrollment. Just wondering, if you could share with us your thoughts on why that might be? And if there were some particular commentary from your site PIs that you could share that could shed more light on how they see things progressing? Secondly, with AURORA 2, it sounds like, from your perspective, this is really more about communicating the long-term safety with -- ultimately with prescribing physicians and just wondering how you see that study positioned overall in the clinical program? And then lastly, you had mentioned interim readouts next year expected for your FSGS program. Just wondering, how you see the ultimate target to move forward in that? And when we could expect sort of the final readout for completion?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Okay, thank you, Ed, for the question. Before I answer your first question, I do want to point out a mistake when I kind of put some numbers around when I was talking about the IP for VOS. The actual trial program is IP is 2031, not 2013. So I apologize for that. And Neil, did you want sort of tackle that first question about enrollment and how things are progressing?

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

Yes. I'm answering. Ed, good question and we've obviously had a lot of very, very close contact with our PIs throughout the world. They continue to be extremely enthusiastic about this study. That's about what we got and not results and then continuing to enroll patients. They also, obviously, highlight the unmet medical need in the very, very severe patients that we're recruiting. Obviously, the physicians themselves are blinded. They have no way of knowing what therapy these patients are assigned to. However, they will clearly -- they see the patients overall benefiting from entering this study. And I think that's probably what we can say about this at the moment, Ed.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Yes, I will say the rest. As we recruit patients, we are very focused on trying to make sure we get the right patients in the trial, the right balance of ethnicity. We haven't rushed it. It sort of naturally sort of habitual momentum. With that, we still turn away a lot of patients that are probably not appropriate for this study. So we're pleased with our progress, particularly in light of the fact we've been very picky on how we like to treat at the trial. Your Second question related to the long-term use of the drug and ARORA 2 study. And I can just quickly comment that when you're on a calcineurin inhibitor, whether you're honored for transplantation, but when you look at drug voclosporin and you look at these patients, we generally believe, the patients will be on for a fairly substantial period of time. And anything we can do to add to the safety database from the long-term use of this drug, is going to be very informative for clinicians in making their decision. So it's a natural thing to do with several year follow-up extension. I think it's going to be very valuable for us because I really do believe that when decision is made as to which drug to remove the patients from, whether it's complete removal of steroids or whether it's reduction of CellCept with having this long-term data will be very, very useful. I think it also becomes useful as well when you start looking at registries and when you start looking at other things such as patient pregnancies, et cetera where many of the drugs that are being used today are actually quite an issue when it comes to pregnancy. When you look at CNIs, they have a fair history about their usage during pregnancy. So any long-term type data we generate on this drug is going to be very valuable. In terms of your third question related to FSGS, we're relatively new in this disease or very new in this disease and we're looking at patients that are naïve. But we think it's really important. Physicians have been really demanding and patients are demanding an alternative to high-dose steroids. The current therapies are 6 months versus extremely high-dose therapies. I think the -- that the nature of the way this drug works, its impact on the pulse rate, its impact on the immune system makes it an ideal candidate. And we really don't know what the next step looks like. I think until we really take a look at our actual data that we generate and if generated consistent with what we expect this drug to perform, then we'll have more granularity about what the Phase III program would look like. And Neil, do you want to add anything to that?

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

No, I think you said most of it. I think the key points about this is, nobody has ever done naive steroid-free therapy before. But it's the very fact that everybody thinks it's a great idea. I think it is key to us, and I think we're going to see the benefits of this particular therapy. And then, we performed -- this study done in the rigorous fashion than any other method we tend to these studies. I think people are very excited about that. In terms of timing and what we report when, I think when we get enough data that gives us enough of a signal, then we will be obliged to release some kind of results and then we'll move quickly on to discussing further development, when we get the adequate amounts of data, I think -- yes.

Operator

Our next question comes from Joseph Schwartz with Leerink Partners .

Joseph Patrick Schwartz - *Leerink Partners LLC, Research Division - MD, Biotechnology*

So I wanted to ask question about Dry Eye program as well as the FSGS program. You mentioned that the Dry Eye program is a tolerability study. It's very large and I would imagine potential partners would be interested in the clinical profile as it pertains to efficacy. So how well suited is the Phase II program to demonstrate or to be able to detect the potential positive attributes of the product? You mentioned that you thought that it would be better tolerated, but also maybe have improvements in signs and symptoms as well as time to onset.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Neil, did you want to address that? I -- and....

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

Yes, I'm at to see that. So, Joe, it's -- again, it's always a challenge with these relatively limited-size proof-of-concept studies in what you're going to see, what you hope to see and what you expect to see. So we know -- so certainly, the way we've designed the study and the assessment that we're doing the efficacy assessment, that we're doing, for example, the Schirmer's test, we -- there is a dramatic early effect. The study is certainly designed to show that. So, for example, it's a short study. If we do see early separation in some of the efficacy then the study design failed to see that. But of course, again, I think we have to caution in fact that from a statistical perspective, we don't see it, it doesn't mean it's not -- the fact is not there. It's -- that's way we designed these proof-of-concept studies that if we do see early differences, they will show up in the results. But to me, I think we just have to caveat and caution of the difference. If study results are not seen it doesn't mean that the drug is not doing its job. And I think that's probably the best important thing Joe, for me from the eye perspective.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

I think -- clearly, from the tolerability perspective, I think that one is really important. I think we need to take a look at one of the biggest issues people facing using RESTASIS is the tolerability issue and I think that several -- there will be really several benefits of this program. I think one is that this is maybe easier on the eye. Certainly, historically, when we did the Phase I, it turned out to be that way. And then second, if you keep in mind, this drug is 3x or 4x more potent but you're also delivering almost 4x as much drug to the eye as you are with RESTASIS. That means you're delivering somewhere between 12x and 16x the amount of drug. When you do look at animal experiments in this area, you do see fairly rapid impact of the drug. And we would hope that we see that carry through in the human clinical side. Certainly, in the limited Phase I experience that was seen with this drug. We did see early signs and trends. This is a much larger population who is on. So I think we've got a fair shot, although, I take the caution that's been expressed. But I do think we have a fair shot of seeing some trending at least early, early efficacy with this molecule.

Joseph Patrick Schwartz - *Leerink Partners LLC, Research Division - MD, Biotechnology*

Okay, great, that's helpful. And then on the FSGS program in Phase II, it's looks like you're targeting patients with more than -- or very vulnerable to 3 mg/mg of urine protein-to-creatinine ratio that seems like it's a lot higher than certainly your lupus nephritis inclusion criteria and some other FSGS inclusion criteria that we've seen, which is like 1 to 2 mg/mg. So I was just wondering if there's specific reason behind that? And are you purposely targeting sicker patients here? And then FSGS is a pretty catchall classification of patients with a lot of different diseases. So I think this is relatively small study to think that, that could found the results in any way, given the wide variability in presentation that people with FSGS have.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Neil, could you?

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

Yes, yes, again, one of the things that we're really trying to find out and there is a huge amount of interest in the renal community, is the effects of specifically, calcineurin inhibitors as well as other drugs on the podocyte disorders. Now, sometimes we don't see this disorder podocyte effacement in patients with lower levels of proteinuria. So in some ways what we're doing is, we're trying to enrich the population of FSGS patients to those who we believe are most going to benefit from the drug. And this is certainly conceivable as we move into Phase III we may be able to go into lower levels of proteinuria and hence patients with less disordered kidney biopsies. But I really think that these are the patients we're going to see the benefits in, these are the patients that the physicians are currently incredibly interested in treating with our FSGS present therapy. And the nephrotic syndrome, not spoken a bit, hypoalbuminemia, hyperlipidemia still represents the great unmet need. These are patients that do the worse. These are the patients that we believe that our drug could do great benefit, Joe.

Operator

Our next question comes from Elemer Piros with Cantor Fitzgerald.

Elemer Piros - *Cantor Fitzgerald & Co., Research Division - Analyst*

What I'd like to understand is, if you could tell us a little bit more about AURORA 2. What is the duration of the trial? What is extension phase? And what was the rationale to keep it in a blinded fashion?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Neil, you get a lot of questions today.

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

Yes, they're all good questions. You've said the rationale or the -- I think first question was the duration. So we're heading 2 further years so that we hope to get a -- in total, I guess, 3 years of comparative data. And that's what the comparative data, answers the second part of your question. The only way we can get good -- the best way of getting good quality safety data, is to have comparative. Certainly, companies with other drugs have gone into sort of open-label continuation studies. And that is definitely a way of doing it. We believe, it's much more powerful and continues to allow our comparison of both safety processing and the efficacy data as well by continuing patients in a blinded fashion. The other thing that would -- the other big piece apart from the long-term safety data, long-term renal function effects on other aspects of lupus, is potentially assessment of readouts. As we know, lupus nephritis is relapsing, remitting disease, even though we're getting patients intermission, but we wish to sort them going back into disease flare again. And these are some of the things that we're going to see in our continuation study. We're also going to look at extrarenal parameters and where these patients normally note lupus flares. And again, that could also trigger further clinical work in the extrarenal

space further down the line. So the rationale, I would say, is twofold. I think it's always good to have more safety data, even though, it's not requirement to have all the safety data. The regulators certainly look favorably when it comes to the NDA approval on the companies to have extra additional safety data to be able to strengthen the case. But also you know we're going to be looking at the potentially expanding the label in lupus nephritis but also in SLE with some of the extra data that we get. And we believe that being in a comparative, continued blinded adds both statistically but also clinical power to our arguments.

Elemer Piros - *Cantor Fitzgerald & Co., Research Division - Analyst*

Yes, maybe just a follow-up, Neil. I understand. Is there maybe just a small concern that over a year period, it's relatively easier to keep the patients who are in the trial to experience a modest or minor response then -- but when you pave this out to 3 years, it's -- wouldn't it -- more likely that you would lose those patients. So the comparison between these 2 aren't -- may not be as balanced?

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

Right, not exactly sure. I understand the -- certainly, over the prolonged 3-year period, what you are fighting is-- what we know from the arms trial that we -- that team also performed is that over a 3-year period, even on standard of care, patients do continue to go into remission after 3 years of therapy. I think it's important to have a comparator to make sure that what we're seeing is not just a -- the sort of background quiescence of the disease over time. I'm not exactly sure if I've answered your question, but ...

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

I guess I know our first thinking is -- certainly, we're not using AURORA 2 for part of our approval process. We should -- clearly, it's our belief we'll get approval if we're successful on clinical programs on the basis of the data generated in the actual Phase III trial. Having that additional data, I think it's beneficial. I think you're right there is a risk over time, you're going to lose patients. The tendency though is for these patients just to stay on drug and to look for durable response. If you take a look at the Phase II trial, it was very curious that every single patient in the active arm of our trial in the Phase II they went into complete remission state and remained in remission for the duration of the trial. It's my expectation that we will see, and my hope first that we'll see the similar results in the phase -- in the follow-up extension study. I think that's really important because you will be showing really long-term stability in those patients. And I think at the end of the day, it will impact how physicians decide to treat. So I think having that data is going to be valuable. I think you're right, there's a risk that over time, you could lose patients. I think you more likely lose patients and end up actually following out of remission. It's my expectation and my hope that the patients are on the combined therapy right now would actually like to stay in the study because they are doing better. So time will show us that answer, but important thing is, it doesn't put our other trial at risk.

Operator

Our next question comes from Doug Miehm with RBC Capital Markets.

Douglas Miehm - *RBC Capital Markets, LLC, Research Division - Analyst*

Seems fairly simple questions. Number 1, in terms of the patients that you're going to end up pass in this trial, how many will have been recruited by sites that were used in your previous trials, roughly?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Interesting question, Neil, I don't.

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

Yes, we're -- obviously, we've not finished recruiting yet. There is some overlap, one of the things that we've learned both from the oral trial but also actually we've got someone back to arms trial. It's 2 things. One is, sites that's good recruiters that manage their patients well, but also the flip-side is there is that, perhaps haven't recruited well and more difficult to cooperate with. So it's kind of venn diagram in some ways and in some sense that we cherry-picked some of the better-performing sites from recruitment perspective, but also from compliance perspective. But also, we've got some new sites on-board, new countries on-board that we didn't use before for a variety of reasons. So we have -- I think we've mentioned before on calls that we've attempted to get more patients in the U.S. and Europe in the study to try and get a kind of more representative population for the markets in which we plan to launch this drug in. Other than that, I think it's probably a moving target at the moment and we'll have more information when recruitment is complete.

Douglas Miehm - *RBC Capital Markets, LLC, Research Division - Analyst*

Yes, of course. So -- but you will have more patients enrolled from the U.S., and -- of course?

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

Yes.

Douglas Miehm - *RBC Capital Markets, LLC, Research Division - Analyst*

Okay, good. Second question has to do with the sort of makeup. I know you made one slight revision, just with respect to the time from biopsy. Maybe you can just give us a little more detail on that if you can in terms of patients that are being recruited right now?

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

Yes. I think the first thing to say is that, in terms of the patients that are going into study, there is -- overall, there will be very, very little difference. So in the AURA trial, we required that to be a biopsy within 6 months of entering into study. We still expect the large majority of patients coming to study to have a biopsy, not only within 6 months but actually most of them were actually within weeks of coming into study. That's the operation that we're allowing. What we found in the AURA trial, was that some patients, especially, patients from the United States, who would have a recent biopsy, say, 7 or 7.5 months ago, decided not to enter the study because they didn't wish to have another repeat biopsy, which was not going to change their management, and which the physicians did not think was medically necessary for them. And -- so what we did, we put in some very, very strict criteria to permit, under very certain circumstances, patients with the biopsy of greater than 6 months to enter the study as long as they could demonstrate that the elevated proteinuria coming in to study was actually of very recent origin so that at that time it represented a flare in active -- very recent flare in activity rather than kind of chronic leakage of protein. I can't give the exact numbers, we have those again but like recruitment numbers, it's a moving target. But what we do know is that it's a very small minority of patients coming to the trial.

Operator

(Operator Instructions) Our next question comes from David Martin with Bloom Burton.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

I got a couple of questions. At one point, I think there will be the discussion that there may be a separate study or a sub-study within the larger study, with before and after biopsies. I'm wondering, if that is happening or if it's planned?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Okay, Neil, do you want to deal with that question as well?

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

Sorry, a separate study form before and after biopsies. We haven't any plans to do that. But we certainly -- some physicians will be doing because their ongoing clinical practice is to repeat biopsies. They do that in anyway and we're certainly interested in the outcomes of any of those.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

If so, you will have access to that data as well?

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

We will do, should they be performed. It's not certainly, their practice everywhere to do so. It's obviously, an invasive procedure.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

Okay. And then there have been plans to do some preclinical work, looking at the effect of voclosporin on TGF-beta levels and inhibition of calcineurin A alpha and A beta. When might we see those results?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

So, those are ongoing. We have initiated several those and there is some additional ones planned. I don't have a very tight timeline. On the list of priorities, for us, the clinical work has been the highest priority for us as well. And given all the new programs, we have been funding those through academic operations. So I don't have, but I will get you through a better timeframe on when we expect those. But I imagine, some of them probably by mid-next year. We're also doing studies looking at the podocyte now as well in terms of mechanisms, et cetera. So those things have become very important to us to have a sort of just additional knowledge of mechanism, how this drug works. So fair question, I don't have an accurate answer. I don't want to -- I will get you an accurate answer on the timeframe for those studies.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

Okay. Last question, you referred to the small Phase I, up from -- VOS study that was done previously. And, I guess, they were helping volunteers as well as some patients with Dry Eye. The signs of efficacy that you saw, was that are endpoints that were subjective or objective?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Fair enough. Mike?

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

Yes, they were both on signs and symptoms, Dave.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

Okay, if patients -- it was a patient assessment with their own systems? Or did the physician measure things like cure amount and that type of thing?

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

Yes, Schirmer's test scores were used on the physician side and also -- so that's on the signs side and the symptoms side, the patients, and the physicians filled out an OSDI questionnaire, ocular symptom disease severity score questionnaire, which is standard in the field.

Operator

Thank you, ladies and gentlemen, there are no further questions at this time. I'll turn it back to management for closing remarks.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Well, thank you, operator. Once again, thanks, for all of you attending, thank you for your questions. It really has been an exciting quarter. When we set out at the beginning of the year to deliver a number of clinical programs and to execute the ones that -- particularly lupus nephritis program and I can't be more thrilled with how the company has performed, how we delivered against our milestones, but also I'm now really excited, as you know, we're getting close. And it's a very exciting time for our employees. I think it is a very exciting time for our patients too. And so, look forward to the rest of this year and of course, next year we'll actually have our data. So thank you, all for being on today's call. Once again, thank you.

Operator

Thank you. This concludes today's call. All parties may disconnect. Have a great day.
