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CORPORATE PARTICIPANTS

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PRESENTATION

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

Good morning. My name is Richard Glickman, and I'm the CEO of Aurinia Pharmaceuticals. And I have the pleasure of introducing myself this morning.

So -- and thank you all for actually staying and still being here. I know what the week's been like. You know for the last 2 years, I've traveled basically all over the world, and we tell our story. And the most common thing I've heard from investors and they're really good investors is that you're Aurinia, you're a 2019 story. We love you. We kind of want to own you, but you're a 2019 story. So it's 2019. And I think we're going to have a great year. And I think it's going to be an important year for patients. And if we can reproduce the data that we've generated before this year in our studies, I think it's going to be an exceptional year for patients who suffer from lupus. And consequently, then I think it'll be an exceptional year hopefully for our shareholders as well.

So always in these types of presentations, I have no idea who is familiar with our story or not. So I have to sort of tell you the whole story. And I apologize to those of you who've heard it probably numerous times.

Our company focuses primarily in the areas of nephrology and autoimmunity. The team that built this company, not the whole team now because we've grown considerably, but the initiator of this company was the same team that developed CellCept for the treatment of lupus nephritis, which of course right now is the standard of care around the world. We think we have a drug that actually, in combination with CellCept, is actually going to change the way treatment is done for these patients again and develop yet a new standard of care.

We're working with a highly differentiated calcineurin inhibitor, very different than the legacy ones. We have fast-track designation for this drug, strong intellectual property. And this drug could be used in multitude of potential indications.

We have 3 key programs, the most advanced of which, where people place most of the value, is our voclosporin oral program in lupus nephritis. And it's Phase III program. I'll be speaking to that most of my time today. We have a program in FSGS. And then we have a very different product in the treatment of dry eye. It's based on voclosporin but a completely different product, completely different formulation, completely different intellectual property.

I'll start off very briefly with an overview on lupus and lupus nephritis. So SLE is a disease that affects actually 85% women versus men, mostly individuals of childbearing age. Anywhere ranging from 0.5 million patients in the U.S. to 1.5 million, depending on where you get the data, suffer from this disease. Half of those patients develop kidney involvement. Now this is a disease that can affect many different organs of the body. It could affect the central nervous system, it could be the skin, it could be the lungs, it could be your heart, but almost half of all patients will eventually develop some involvement of their kidney. And it becomes very severe. It's easy to be able to tell in fact with these patients because they generally can be diagnosed by large amounts of protein in their urine. And if you can't get that under control, these patients will often -- eventually develop end-stage renal disease, require transplantation and in many cases, die.

There are no approved drugs in the EMEA or FDA for lupus nephritis. We're hoping this one will be the first. One of the things that people don't realize is just how severe this disease is. This is a disease that actually takes individual's lives away from them, destroys their family life, they can't have children. But when you look at death and you look at something like the standardized mortality ratio, you find that individuals with this disease that have end-stage renal disease are 60x to 70x more likely to die a premature death. It's an incredibly expensive disease. When you compare it to other autoimmune disorders, it's like 3x the cost of many of them, often in the range of \$70,000 a year per patient, not including the requirement for dialysis or even transplantation. So an expensive disease and a very difficult disease. But numbers, like they don't capture the whole story. If you look at what these patients go through, very often they're put on extremely high doses of steroids. Those of you who are familiar with steroids,



they're actually quite effective, broadly, but the side effects are really quite significant for these patients. And it really does affect their quality of life. So one of our goals is to provide an effective therapy that allows you to reduce the level of the steroids.

So this is a disease that waxes and wanes, and patients go through cycles. They flare, they're very, very ill. If we can get them into remission, they'll stay in remission for a period of time, but eventually, they often will flare again. One of the things that has been studied and is very important to us is what is the importance of looking at the reduction of proteinuria in the long-term outcome for patients. So what has been found is that if you can get a patient into remission and you can do it quickly, in 10 years' time, only 80% of those patients may require dialysis. Conversely, if you actually can't control that patient, almost all of those patients will require dialysis and transplantation. So it's so important to get patients into remission.

Even partial remissions are important. There is an effect. So what are we looking for? We're looking for a drug that can control the disease, one that can do it quickly, one that could reduce steroid burden and one that's actually convenient to take. And voclosporin, our drug, actually checks the box very nicely based on the results that came in, in AURA-LV study.

The drug itself, voclosporin, is a novel calcineurin inhibitor. It has a number of advantages over the legacy CNIs, cyclosporine and tacrolimus. This particular drug has a very predictable PK/PD relationship, which means you could flat dosage and you could actually do this program without any therapeutic drug monitoring. For each of the other types of legacy drugs, you have to do therapeutic drug monitoring. It has a better glucose profile. We do not see the diabetes you see with tac with this drug. So you're treating these patients that already have lupus, the last thing you want to do is add diabetes to that. It's far more potent than cyclosporine. And it has a far better lipid profile. And why that matters is because many of these patients will die of their cardiovascular disease.

So overall, it's a very exciting novel calcineurin inhibitor. It has 2 mechanisms of action that are really relevant for the diseases we treat. First, it's an immunosuppressant, and it decreases cell-mediated immunity or immune response. Secondly, it has a direct impact on the podocyte, which is extremely important in a number of potent diuretic diseases, kidney diseases. It actually prevents the degradation of the podocyte, the foot processes and helps restore them to a healthier state. Those 2 mechanisms are extremely important.

So we have a number of studies that have been done in this area. The one I'm going to focus on providing data was the larger study that we finished 1.5 years ago. This is our large Phase II study. It's called AURA. And here we designed the study to evaluate whether voclosporin, in combination with the standard of care, which was CellCept, the previous drug, and steroids, can increase the speed of overall remission rates in the presence, once again, of those very low steroids. The study design itself was 3 arms. There's a placebo arm, a low-dose voclosporin and a high-dose voclosporin arm. All of this was done over the standard of care, which included CellCept or MMF at 2 grams a day with oral corticosteroids. The primary endpoint was at 24 weeks. The Secondary endpoint was at 48 weeks.

One of the things we did during the study was we did a very aggressive steroid taper. And by week 16, patients had to be below 10 milligrams. But our goal was 2.5 milligrams of these steroids. So virtually way, way below physiological-level steroids.

The inclusion criteria, this was probably a study that studied the sickest patients with this disease that had ever been done. Patients had to be diagnosed with SLE according to the ACR guidelines. They had to have proven -- biopsy-proven disease, Class III, IV or V. They had to have high levels of protein in their urine, greater than 1.5 and greater than 2 in the case of Class 5. All of this indicated a very, very active disease.

Now the primary outcome measure was a portion of the subjects completing a complete remission in our study and how we defined our CR rates. This was one of the toughest combination of outcome measures being studied in this disease. A CR was defined as a urinary protein creatinine ratio of less than 0.5 milligrams per milligram, with a stable-ish, we'll call it that, renal function. Renal function had to stay healthy in these patients. It had to be done in the presence of low-dose steroids. So for a fact, if you had a patient that received steroids greater than 10 milligrams for 3 days, they failed the study. And there could be no administration of any rescue medication. Secondary outcome measures, complete remission for 48 weeks, partial remission, time to remission, time to partial, durability, SLEDAI scores, et cetera. I draw your attention to the results of the study. And I point out first that this was the first global trial to ever meet its primary endpoint in this disease and virtually all of -- and almost every single relevant and secondary endpoint in very active sick patients.



In the low-dose arm in the study, which is the go-forward dose, I'll focus on that, the complete remission rate at week 24 was 33%. By week 48, the complete remission rate was 49%. Putting that in perspective, patients on CellCept were achieving historically rates in the 10% range when we initially launched that program.

The P value in this study was less than 0.001, and the odds ratio was 3.21. In terms of partial renal responses, we had 70% of the patients overall, which includes both partial and complete, respond to therapy. One of the things we've learnt in most studies done in this field is you rarely get a response, ever, of greater than about 70% of your patients having a partial or complete response.

So these were very, very significant results and probably the best results that we've seen in the treatment of this disease. Of course, the other secondary endpoints: Reduction in UPCR was significant; the reduction in anti-double-stranded DNA, showing the immunological impact of this medication, also very significant; reduction in SLEDAI scores, very important as well.

In addition, we saw a stable renal function in these patients, which is something we wanted to look at when using that type of drug, a calcineurin inhibitor. And regulators were clearly important. They wanted to look very much to hypertension and what we showed was that patients' blood pressures were stable on this medication, both diastolic and systolic.

In terms of adverse events, overall, this drug has performed. We've had this drug in about 2,000 -- 2,400 patients essentially. And the drug performs like an immunosuppressant. We had very few surprises, with the exception that in 2 sites in Bangladesh and 1 site in Sri Lanka, we had a low-dose imbalance in the number of deaths. And of course, that was several years ago, and it caused a lot of grief for us. And our stock actually responded, obviously, negative to that.

As it turns out that in those sites, where they had very poor access to clinical help, that there were patients put into the trial that probably never should've made their way into trial. They were way too sick. They were -- they passed away very, very quickly, probably before even the drug had a chance to take any effect in their bodies. So that went through our DSMB, went through a number of regulators, and there were no changes made to the actual protocols for our study. However, we as a company changed the way we monitor patients. And as we went forward with our Phase III trial, we addressed that issue. And you could see that in our Phase III program right now.

So now just in summary of that study, the low-dose arm gave us the highest complete remission rates that we'd ever seen or anyone has ever seen in the field. We had higher PR rates, faster time to complete remission, a greater reduction in UPCR, a great reduction in SLEDAI scores, and the safety, for the most part, exactly as we anticipated.

That brings me to the Phase III study, which was designed to actually mimic the AURA surgery. So this is a global, once again, double-blinded, placebo-controlled trial that actually is based on the same program. This time it's randomized 1:1. Originally designed as a 324 patient study, you had background therapy of MMF 2 grams a day plus oral corticosteroids, a low dose of voclosporin on the other arm. Once again, the same steroid taper that we did in the Phase II study. So basically, the identical study. The difference is, though, the inclusion criteria. We were allowed to have a little longer to bring in patients in terms of their biopsies. Previously, it was 6 months. They had to have a biopsy before we treated them. The FDA suggested 24 months. We didn't really use 24 months, we used slightly over, in a few patients, very few patients, we used over the 6 months. If we took a patient into the study that hadn't had a biopsy in 6 months, they had to have other criteria met demonstrating very, very active disease.

The other very important point and very useful for us was that the primary endpoint was moved to week 52. The regulators wanted patients on the drug for 52 weeks. Our best data came in at 48 weeks and it was still on the curve. We were very comfortable in actually providing a 52-week endpoint. Those are the only differences in the study, with the exception that we didn't go back to Bangladesh or Sri Lanka. We did a lot more patients out of Europe and a lot more patients out of the U.S. and really followed very similarly the ethnic distribution and the geographic distribution we had previously done.

So where we're at right now? We have 358 patients. We enrolled an additional 30 patients. There was a lot of demand for the trial. We did it ahead of schedule. The trial is fully enrolled. Patients have been on the drug for quite some time. Many of them are rolling over into the continuation study, which is a 2-year continuation study because we believe this drug will be used long term on patients. And data will come this year. And



that's why I spoke about 2019 being a very important year. This is the only pivotal trial we believe we require for filing this drug. The last one with regulators was considered to be of pivotal quality. And so consequently, this is a big year for us, a big year for patients.

And looking at the commercial opportunity around this drug, there is no approved medication out there. Drugs are all used off label. Now when we developed CellCept, we were really forced to almost display cyclophosphamide as a treatment out there. In this case, we're actually just adding a drug to the current standard of care. It's an unapproved standard of care, but it's the current standard of care. We're adding voclosporin on top of CellCept. So that's a lot easier because patients flare all the time. So access into the market's quick and easy. This is an expensive disease. It's a well-established market entry into. We know where the patients are. And there's reimbursement for value because it's such an expensive disease and such a devastating disease for patients.

I'm going to skip to the next program that we have, which is FSGS. This is a program of a kidney disease, which, in many ways, is very similar to lupus. However, it's a very different disease. It affects more men than women. There's about 40,000, 50,000 patients with this disease in the U.S. and about 5,400 new patients a year with this disease. Once again, you see very much similar proteinuria levels, you see very similar hyper -- lipid levels. But also, once again, you see something that's very important, which is overall a reduction in proteinuria in these patients is associated with a much better outcome and kidney survival. There are no approved drugs, once again, EMA- or FDA-approved for treating FSGS. So a very similar type of situation, very similar type of outcome measures. So generally, these patients are treated with high-dose steroids. And that time range is from 3 months to 6 months depending on the clinician but super high-dose steroids. Steroids actually work quite well for the first while. Patients then go into remission. If they are -- if they land up in remission, about half of them will do it. And then they will flare again at some point in time. And when they do, they often don't respond to the steroid therapy again. The clinicians will often then -- if a patient does respond to steroids, they'll put them on a calcineurin inhibitor. We think we have a better calcineurin inhibitor. And so what we've decided to do in this study that we're doing is we're actually doing an open-label, small study that's exploratory using voclosporin as a first-line therapy in patients not receiving any steroids. So we set it at 20 patients. The study is open. We're recruiting patients. It's a slow study to do. These are tough patients to get, especially ones that are naive to treatment. The inclusion criteria: They have to have biopsy proven, FSGS; they have to have very high levels of proteinuria, greater than 3 milligrams per milligram; corticosteroid-free; no previous exposure to steroids. The outcome measures are the proportion of subjects achieving complete or partial remission at 6 months. And a complete remission is defined as a urinary protein creatin ratio of less than 0.3 milligrams. And a PR is defined as a 50% reduction. So this study will be ongoing. We do expect that towards the end of this year that we will have an interim data readout from the study.

Our third program and the one that's actually drawing quite a bit of interest now is our dry eye program. Now as you know, dry eye is an autoimmune disease. It's associated with T-cells as well. There are somewhere between 16 million and 22 million patients out there with this disease, so it's not a rare disease. And all of the work we've done, historically, as an organization has really been in rare diseases. The number of drugs -- as you know, it's a busy space -- but nothing has really jumped out and really changing the game there in terms of opportunity. There's still a lot of opportunity. And CNIs are used very, very heavily. Of course, RESTASIS, the leader, does about \$1.4 billion. It's a CNI. It's cyclosporine in a low dose given to the eye. Lots of opportunity to improve upon dry eye therapies out there. And we think we have an opportunity to do so with voclosporin ophthalmic solution. This is very unique. It's patented aqueous, preservative-free nanomicellar solution. We've done a number of studies with dogs and rabbits, and we've done a program with Merck Animal Health. That program with Merck Animal Health has been very, very useful to us. Most people don't know that Merck Animal Health actually developed a drug called, Optimune, which was the predecessor to RESTASIS. And it actually went from basically dogs to humans and not the other way for a change. And we work with them and they've tested our drug and -- in direct comparison with their previous product, and they've made the decision to move forward to try to commercialize and approve VOS formulation that they're going to be using for their canine programs.

We had this asset sitting on the shelf. It had zone-distinct intellectual property, 2031. And we thought that it was worthwhile sort of examining whether or not this truly provided an alternative to RESTASIS that would be, I think, different clinically. And I'll explain why now.

When you give VOS, VOS as a drug or voclosporin itself is about 4x more potent than cyclosporine is. We're also able to load 4x as much drug into our vehicle than you can with RESTASIS. So consequently, you're actually delivering up to 16x the amount of calcineurin inhibition to the eye, which actually really should increase the rate at which you get your T-cell inhibition. And if T-cell inhibition appears to be and is a key player within dry eye, we should see quicker results.



Now we've seen very high concentrations achieved with this in both dogs and in rabbits. We've also demonstrated excellent tolerability in a Phase I study. So we already know in patients the drug has been well tolerated and in animals, of course, with direct, direct comparisons with RESTASIS.

And also this drug, very different than others that we've seen out there, has the potential to be treated and be used only once a day. So if you're taking -- dry eyes, your eyes are sore, having a once-a-day formulation would be an excellent advantage over current therapy.

So our clinical study is a multicentered investigator mass study, randomized and with 2 groups. And we are actually directly comparing RESTASIS to VOS. We have 100 patients in the study. This study is fully enrolled. And as of roughly around December 20, this database was locked. And we expect we'll be able to release the results of this study in the next several weeks. So we thought that if we could show a drug was more tolerable and show trends towards acting quicker or even indications that would act quicker and then potentially, you could use a drug once a day, you could actually really compete, as I said, in this marketplace.

So the key inclusion criteria for this study was a patient had to have one or more eyes, diagnosis of dry eye. They had to have a symptom score of greater than 30 on the VOS scale. And a Schirmer score of greater than 5 and 10 millimeters for 5 minutes and evidence of ocular surface staining. The outcome measure was ocular tolerability versus RESTASIS. Secondaries were adverse events: OSDI, sandy, VAS, corneal staining, conjunctival staining, Schirmer tear [start]. All the things you expect to see done during one of these types of studies. So it's a 4-week study, primary endpoint. We'll have that data available for you shortly. We're quite excited. And so that'll be the next major inflection point for the company.

So what to expect this year coming forward in terms of key milestones for the company would be our dry eye program data. I hope -- we've been doing a lot of work in intellectual property. I hope we'll have some intellectual property developments to share during the year as well that I think are -- you're always looking for ways to extend the value of your programs. And also, of course, our LN pivotal data will be available before year-end as well. So this is a really big year for Aurinia.

So in summary, we have a management team that has actually worked in this area and has a lot of expertise in treating these patients. We have a very, very solid clinical dossier. We have a positive proof-of-concept Phase II study and probably the best study that's ever been done in this field and the best data that's ever been achieved. We have a very large safety database of over 2,400 patients with this drug. We've had very good interactions with regulators. Only one Phase III is required for approval. We have a rolling NDA submission opportunity to utilize as a fast-track. It's a well-defined market opportunity that is totally unserved. There's a very high pharmacoeconomic burden associated with this disease. We know how to access these patients. FSGS is synergistic. And VOS really represents a unique opportunity as a very different product that could compete potentially in the dry eye space. We have a very strong cash position. The last report was \$139 million. We did announce that we put an ATM in place for \$30 million additional. I think it's really important to try to stay strong in these companies, especially as we meet key milestones, that we're always in a position of strength to negotiate whatever might come next, whether it is inbound interest in an organization or it's being able to raise the next capital we need to drive this right through to commercialization.

So thank you very much for your attention this morning. And we have the breakout room. And we'll be available there to answer your questions. Thank you.

QUESTIONS AND ANSWERS

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

Well, good morning, and thank you for joining us. My name is Richard Glickman, I'm the Chief Executive Officer of Aurinia Pharmaceuticals. And we're having our Q&A session right now. And with me is Mike Martin, our Chief Operating Officer; and Neil, who is our Chief Medical Officer. It's Solomons so that we all know who you are. So we're here to take your questions.



Unidentified Analyst

Maybe with regards to Dry Eye, can you just maybe set the stage for what that press release could look like just in terms of the efficacy endpoints. What are the key ones that are -- that we could hear about?

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

Okay, so the question is, could we sort of provide some description as what the press release might look like? What the outcome measures might look like? And so which -- who would like to actually take that one on?

Unidentified Company Representative

I'll take it on. So the primary endpoint is tolerability on a VAS score versus RESTASIS. And so basically, as the patients come into the study, they're given a drop of REFRESH, which is a very well-tolerated ocular lubricant. And if they sting on that, and they score greater than 30 on the VAS, they're out of the study. So we don't want patients in the study that kind of are sensitive to anything going into their eyes. And so the patients will get a drop of VAS versus -- and another patient will get a drop of RESTASIS. And so we'll be looking at the change from baseline on those. That's the primary. The secondaries are corneal staining at 2 weeks and 4 weeks. And Schirmer scores at 2 weeks and 4 weeks versus baseline. And then we also have the sandy questionnaire that we're using to measure the symptoms.

Unidentified Analyst

Is there anything preclinically that makes you guys more excited about any of those? Any of those in particular?

Unidentified Company Representative

Well, in the Phase Ib study, it was a 35-patient study. It was 3 cohorts. And 30 of those patients were healthy patients. However, 5 of those patients were patients with confirmed Dry Eye. And we saw virtually no irritation upon application in the Phase Ib. So that's what gets us encouraged about potentially being able to combat RESTASIS in terms of the RESTASIS label and the irritation upon the [pack] application. So best laid plans.

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

And I think, further to that was sort of some of the issues around activity. This is a small study. And I don't think people should have expectations in a 100-patient study that you can actually create statistical significance on all the parameters. What we are really looking at here is it's an investigational study to give us direction as to where we want to go. But we want a good case for it. The case ideally would be, yes, we're more tolerable but we're faster acting, which is a real critical issue. It often takes patients quite a few months before they see the activity of some of these drugs, and particularly RESTASIS. This, we believe, based on the animal data we've seen today, it has the potential to act faster. You're delivering much more significant amount of calcineurin inhibition to the eye than you would with some of the other products that are available today or will shortly be available. And so in theory, if that's relevant, we should actually see that. We do see it in animal models. The question is, will we see it in the human? That's what we're going to find out in the roughly 2 weeks' time.

Unidentified Analyst

Okay. The RESTASIS on, what are you assuming there for the primary endpoint?

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

Do you want to answer that one?

Unidentified Company Representative

So we're basically assuming a clinically meaningful difference is a 15-millimeter difference. And so we're powered to show that. And that's kind of a measure that's approximately relevant to a patient that's clinically meaningful. So it's 15 millimeter difference.

Unidentified Analyst

And the RESTASIS arm that, what are you assuming is the tolerability score there?

Unidentified Company Representative

You know the only data that we have to go on is the irritation rate in the label. If you talk to a RESTASIS patient, they say, it stings like -- people that I've talked to, over half of them say it stings. So that's really all we have to go on. So we're kind of shooting blind a bit. No one's ever done this with a VAS score at 1 minute. Of course, we have that at 1 minute and 5 minutes every time they visit the clinic. But that's kind of what we're dealing with.

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

And I think that irritation tolerability issue has been like well understood. It's probably the reason why only 3% of patients actually repeat their prescription. Still that said, they do \$1.4 billion a year with the drug. So I think that when you look at the label versus real life, I think the numbers seemed to be a bit higher in terms of irritability in actual use. The label is around 17% in terms of people finding it fairly intolerable as well. I think we were powered against that. But the reality is, like I said, this has not been done before. No one's actually done a head-to-head before. But we felt that -- sometimes, you need to do an experiment to decide whether or not it's worth the real investment. And people often avoid doing that. They take the easier route. We could've done other things. And yes, we could create some value in doing so. But the reality is if you really want to differentiate a product, if you really want to compete in that space, we need to show certain differences that will make this product unique in that treatment population. So we did the tough experiment.

Unidentified Analyst

And if it is successful, what would be the go-forward plan with RESTASIS?

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

So this is where it gets interesting. I think there's a variety of things. One is that, historically, this company has been viewed as very binary, that our future is based on LN. And that's great, there's a huge market for LN. For a lot of investors, and ourselves, no one just likes binary. We like to have multiple product opportunities. One way or another, we're going to further develop this organization. This is an asset we owned. Now we have 2 very distinct programs. The dry eye product, if it actually works it's actually a significant market opportunity in itself. So if we're successful now, we become a company that really has 2 very distinct pathways to go down to. And it's no longer just a binary company based on the performance of voclosporin in lupus nephritis. And so that's the real benefit. Now where we go from here is, if the market and if the data is strong and the market responds well, that's great. It allows us to further leverage and build our business, which is what we're hoping for. And so basically, the decision as to whether we partner out right away or whether we hang on to it, which is really the question a lot of people ask these days, management's position on that right now is, let's look at the data. Two, we know the players out there in the field. And we know because when we designed the trial, we asked the question to those players, what would it take for you to be excited about data coming out of this program? So that being said, we asked our customers what they might want. We developed our program around that. So we have an opportunity to certainly out-license it. And at one point, it will happen. Because you're not going to keep the nephrology and the ocular the same. However, why do you want to do it now? You finish your Phase IIa, it's not expensive to run a Phase IIb. And that Phase IIb could be designed large enough to really be a registrational

self-study. And then you have your Phase III. Point being is a lot of value could be created for relatively little money relatively quickly in this program. It's not like our rare disease programs that are very slow. So I'm not in a rush for us to out-license this really quickly. What I want to do is really assess it. See what the value proposition is. See what the clinical program would look like. We have a designed clinical program but we can modify it based on the actual data. And then go back to our board and get the wherewithal in which to actually proceed, hanging on to this asset a little longer. And that's more likely than not if the data is really positive. At some point in time, I think a proper transaction. And that proper transaction could really make a difference when you're looking at our need to commercialize, funding any gap that you would have between the time you actually have your data, by the time you filed and the time you actually launch your drug. It can be very valuable to us at that point in time to have nondilutive financing strategy. So that's overall the strategy.

Unidentified Analyst

So for the LN study this year, will you give any metrics on, say, the percentage of patients that are rolling over to the open-label or anything? What else are we going to hear about from here?

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

We have been giving some guidance early on, on rolling over patients. It's actually -- quite a number of patients are rolling over. I guess we'll have to decide in the future, going forward, how often we will give guidance on that as well. But we had publicly presented when we initially started it that there was a significant number of patients that were rolling over. But we haven't been updating on that recently. But it's still -- it's very healthy. We have a very, very significant rollover occurring here. I only expect...

Unidentified Company Representative

I wanted to add just also one point. It's a double-blind continuation. It's not open label.

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

Yes, that's a good point, yes. Other than that on the LN program, though it's really about the execution. Our attention has gone from recruiting patients now to making sure that we maintain those patients. And that they're well looked after and compliant as well. So that's where our energy is going. And I don't expect we will have a lot to offer between now and then, other than some intellectual property that relates to the program potentially that could change, I think, the -- going from the October 2027 date to a significant future date, if we're successful in some of our actions that we have taken over the last several years. My expectation is this year we will actually have a pretty clear picture on that. And that we will share that when we have it.

Unidentified Analyst

Any competitive updates that are out there now? And last year, something failed if I remember it?

Unidentified Company Representative

Yes. I think every year something -- a number of things fail. I think we are expecting the -- and I guess, the Benlysta results will be available at some point, probably this year. But also, I think, the anti-CD20 from Roche will have some Phase II data, at least early Phase II data probably this year as well. But other than that, we -- everything else is in much earlier phase, and it's very difficult to see what's coming online.

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

I think what's important is really understanding that the nature of the drug that we are developing, where its role is in therapy, is really very complementary to those types of biological programs. And so I'm not threatened by them at all. In fact, I want these patients to have access to excellent medicines. The tendency of all the biologicals is very slow-acting. And we know from our experience that voclosporin therapy, you could see a very, very, very rapid activity of the drug and clinical benefit to the drug. So we think that combination in the long run is going to be very helpful to patients. You actually would treat them fairly quickly with this drug. And maybe over time, these very slow-acting mediocre efficacy, so far to be quite frank, in some of these biologicals, will have a role to play. But they do show good safety, which is important. But they're very slow to act and they don't work in a lot of patients.

Unidentified Analyst

What is the peak sales you think now and what kind of markets?

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

I always get in trouble for this type of question. Any guidance from my IR person? How do you -- peak sales is a question we have. It's like -- look, I think there's a couple of things here that we kind of talk about. One is, what does the therapy look like, valued at, and there's a range. We went out and we publicly stated that between [50,000 and 80,000 of all our payers] per year is probably a range that is reasonable. And we haven't had a lot of pushback in our discussions with payers for this program. You look at the number of patients out there. And you say to yourself, you know that 50% of all patients with lupus will have this. And you look at just U.S. sales alone, and you do the math. And you take a look, it was about 200,000 patients in that ballpark, maybe it's a little larger depending who you believe, but you go relatively conservatively. And then you run the numbers and you look at a disease which is cycling through. And from that, you can get a little bit of a sense of what peak could look like. It's substantial. And so as -- even as a stand-alone product, it is a very -- I think very exciting commercial opportunity. So you could run your numbers.

Thank you for your questions. It's good to have someone asking them. Anyone else have a question before we leave JP Morgan for 2019? Hearing no more questions, we're going to adjourn today. Thank you very much for attending.

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