Full Regular Transcription

Cassiopea SpA

Full Year 2019 Results and 2020 Outlook

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COMPANY REPRESENTATIVES

Diana Harbort – *Chief Executive Officer*

Chris Tanner - *Chief Financial Officer*

Luigi Moro - *Chief Scientific Officer*

Alessandro Mazzetti – *Chief Medical Officer*

Marco Lecchi - *Finance Director*

PRESENTATION

Operator

Ladies and Gentlemen, welcome to the Cassiopea Pharmaceuticals Full Year 2019 Results and 2020 Outlook Conference Call. I am Sandra, the Chorus Call operator. I would like to remind you that all participants will be in listen-only mode and the conference is being recorded. The presentation will be followed by a Q&A session. You can register for questions at any time by pressing * and 1 on your telephone. For operator assistance, please press * and 0. The conference must not be recorded for publication or broadcast.

At this time, it's my pleasure to handover to the management team of Cassiopea Pharmaceuticals, Ms. Diana Harbort. Please go ahead.

Diana Harbort

Thank you, operator and thanks all for joining our call today. We especially thank you for joining the call amid the coronavirus situation and we wish you and your family safety and peace during this time.

Meanwhile, activities continue at Cassiopea although we are all working for home. Today, I am joined by Chris Tanner, our CFO, Luigi Moro, our CSO, Alessandro Mazzetti, our Chief Medical Officer and Marco Lecchi, our Finance Director. Our agenda here is on Slide 3, we will be reviewing the 2019 financial results providing a product development and a commercial update, and talk a little bit about our financing plans going forward.

With that being said, I will turn it over to Chris Tanner to give you an overview of our consolidated financial results for 2019.

Chris Tanner

Thank you, Diana. Well, you know the financial numbers are still pretty simple. Our operating result is driven by expenses only since we have no revenues, went down slightly from 2018, primarily because our clinical trial expense declined because of the levels of our clinical trials in the sense that last in 2019 we had very low cost on the Clascoterone cream side, and we were completing the Phase 2 dose ranging trial for alopecia in males, and had not started the trial for females yet.

So there is a lull from that perspective, so those costs went down, but went up above the levels of the years before was the SG&A by 100% practically, primarily because of the pre-commercial activities that we undertook in the U.S., to explore the potential of Clascoterone cream 1%, and Diana will tell you more about this in greater details later on.

I think the more... if we go on to the next page, I think if you see... from the staffing perspective, we are still a very small company with 12 people and we still have a very close relationship with Cosmo, with the service agreement which continues working well. If we then move on to... basically, I can jump all the minor costs, I think it doesn't really make sense to go through these. From our perspective, if we go (unintelligible) consolidated statement of financial position, which is on Page 9... on Page 12, then you will notice that our equity declined from 14.5 million to 3.7 million, and this during the course of the year now causes... requires that we recapitalize the company, because according to Italian law, we are not allowed to have negative equity, and during the first part of the year we of course had continued expenses all the more since the Phase 2 dose ranging trial or proof-of-concept trial of the Clascoterone lotion, solution in females is ongoing.

So that brings us to the cash flow statement, on the cash flow perspective, I am now looking at Page 16. We had a slightly lower than last year cash flow from operating... or cash stream from operating activities 11.4 million Euro which as indicated before, led to the equity position that we have. Fortunately, we've had the support of Cosmo who has provided all the credit facilities that we require, so in essence there is no liquidity issue in the company, that's just from a formal perspective that we have the equity issue that we need to resolve, and I'll talk about that later on.

If we can now move on to the product development, Diana.

Diana Harbort

Thank you. Thank you, Chris. So on Slide 18, you see our pipeline depicted. Many of you are familiar with this. Just a quick overview, our Clascoterone cream 1% is in the FDA at the moment. We will talk a little bit about that further with the PDUFA date of August 27th, 2020. This is the first new mechanism of action for the treatment of acne in nearly 40 years. We also have Clascoterone in the solution form for androgenetic alopecia in males and separately in androgenetic alopecia in females, and in males we completed our Phase 2 and we are in the midst of submitting a special protocol assessment to the FDA prior to beginning our Phase 3 program and we will talk a little bit about that in the future here in the next couple of slides, and we are in the midst of Phase 2 study in androgenetic alopecia in females.

Our other 2 products which we won't spend much time on today are both novel products, one topical antibiotic for acne, the other is a novel immunomodulators for genital warts and both of these products had positive Phase 2 results and we are conducting some product development activities. We expect to move these products forward after our NDA for acne is approved.

Now to give you a little more detail on both Clascoterone cream and Clascoterone solution. There were a substantial amount of activities in 2019, and so I thought I'd share with you some detail in both of these programs. So I'm starting on Slide 19 here. We received conditional approval from the FDA on the WinLevi trademark, proprietary name for our Clascoterone cream for acne. We filed our NDA in August and it was subsequently accepted by FDA and the PDUFA date of August 27, 2020 was established. Importantly, we had an extensive Medical Affairs program that has substantially increased the visibility of not only the company, but importantly our drug Clascoterone in the dermatology community.

You see here, there were over 20 published papers, posters and abstracts done with this product. We sponsored over 24 meetings and there were over 55 podium mentions of Clascoterone cream 1% by key opinion leaders at major dermatology meetings. This means now that thousands and thousands of dermatologists and nurse practitioners are aware of not only Clascoterone, but the company and our clinical data. We have 2 acne advisory boards this year, and we completed some very extensive market research with payers or insurers and we've done substantial segmentation research with healthcare providers. And what I mean when I say healthcare providers that is with doctors and nurse practitioners and physician assistants who work inside dermatology offices, who write prescriptions for acne products, and I will be telling you more about that in the next coming slides. And of course the big next step for Clascoterone cream 1% is the PDUFA date here at the end of this summer.

In terms of Clascoterone solution, earlier this... well earlier of last year we announced the results of our Phase 2 dose ranging studies in male, and we identified the most effective dose which is the 7.5% BID. These 2 products had a very extensive medical affairs program that also increased the visibility of Clascoterone solution in the derm community you can see here the numbers of published papers, posters, abstracts, podium presentations. We held 3 advisory boards this year regarding this solution, certainly to help us really tease out the important aspects of our Phase 2 data, but also to design the important Phase 3 program for Clascoterone solution in males, and also to prepare for the initiation of the Phase 2 studies in females. We'll tell you more here about how that study is ongoing, but the study was initiated late last year and enrollment has been ongoing.

We also had an end of Phase 2 meeting with FDA in November to discuss the Phase 2 results for androgenetic alopecia and as we look forward to this year, we will finalize this special protocol assessment for the Phase 3 program with FDA. It's very clear to us, they have not seen a Phase 3 program for androgenetic alopecia in a couple of decades, and we think it's very important to reach agreement with FDA on the elements of the protocol. So we will be doing that prior to the initiation of that Phase 3 program. It's likely that this may take 2 rounds we're estimating, so you will see that we will initiate those activities for the Breezula Phase 3 trials in males towards the end of the year, and we think we will begin recruitment in the first quarter of 2021.

Now, I will turn it over to our Chief Medical Officer, Alessandro Mazzetti to give you an update on the Clascoterone Phase 2 clinical study for androgenetic alopecia in females on Slide 21.

Alessandro Mazzetti

Thanks, Diana. As Diana told the Phase 2 alopecia trial in women started last December. This study was planned in the moment in 6 centers in Germany, and is a double-blind, multicenter, prospective, randomized trial, in which we compare the... our Clascoterone into deeper into solutions concentration 5% and 7.5% twice a day against vehicle and Minoxidil solution 2% that is the solution approved in women for Minoxidil.

The study is planned in 280 subjects splitting in the 4 groups. So at the end, we will have 70 subjects per group, the treatment is planned for 6 months. At the moment, we had already enrolled 109 subjects and we hope to be able to complete the enrollment by the end of the second quarter by June this year to complete the clinical phase of the trial at the end of the year, of course, also for this trial... as for all the trials now ongoing in the pharma industries. The corona situation could have some impact in the enrollment of the subject. At the moment, this is the situation for this trail.

Diana Harbort

Thanks Alessandro. Now, I'll move on to giving you a commercial update for both Clascoterone cream 1% and Clascoterone solution.

On Slide 23, what you can see that we've learned some very, very key market insights about Clascoterone cream this year and also regarding its positioning in the acne marketplace. We conducted substantial market research this year, and this slide gives you what I would call the very key points when looking at Clascoterone cream 1%.

First of all, the acne market continues to be a very important market in the U.S. dermatology space. This is a very high volume, concentrated target market with just over 8’000 doctors, nurse practitioners and physicians assistants, that's what I call providers accounting for almost 60% of prescriptions. That means that with a highly targeted sales force we can cover the entire key universal providers that generate the majority of prescriptions with about 75 sales reps.

We also clearly understand that there is an unmet need among doctors for a novel approach for treating acne, especially targeting the hormonal aspect for all acne patients. There is no FDA approved topical product that has ever been approved for the treatment of this hormonal aspect of acne. But, doctors' use off-label and oral anti-androgen called Spironolactone, which is a potassium-sparing diuretic that's never been approved for acne and it's used off label though, for acne in females. It is the third highest prescribed drug in all of the dermatology space for any indication generating nearly 2 million prescriptions a year. The use of this drug is a very important as a piece of evidence of the importance as a novel approach for treating acne which targets this hormonal aspect.

Acne is treated with polypharmacy, in the United States per the ADD guidelines that is the doctor's use a multiple product approach of complimentary drugs to address different parts of the disease. So in the U.S., that's the reason why the average acne patient leaves the doctor's office with 2 or 3 prescriptions. And also, I'll tell you about here in just a moment, the details of our market research, but it clearly demonstrates that the potential positioning for Clascoterone cream 1%, which is around this very unique mechanism of action, and we understand clearly that doctors are predicting a significant market share update... uptake of prescriptions, especially among the high volume and high value providers.

If we move to Slide 24, some of you may be familiar with the slide I've used in the past, which depicts, in a very concise way, the acne market in the United States. There's 50 million acne sufferers and it continues to be a very relevant disease in the dermatology space. It's a 5 billion Dollars U.S. market. But, interestingly enough, treatment options are limited to therapies that were developed over 40 years ago. Most... all of the recent drugs in the last 4 decades have actually been drugs that address the same mechanisms of actions that were approved these numbers of decades ago.

And, what we understand is that the topical options tend to address only 3 of the 4 factors in acne physiology, which means there's a gap in the treatment regimen for a topical anti-androgen. And our research with payers or that means insurers in the United States continue to show that they will plan to cover acne as a medical condition.

And our research indicates that this will not change, that is our research indicates that this will still continue to be a covered or prescription marketplace. And clearly, 90% of the branded prescriptions for acne are written in the dermatology office. But, interestingly enough, dermatology physicians, assistants or nurse practitioners account for almost 1 billion of the 5 billion Dollars written in the United States and these PAs and NPs reside inside the dermatologists office.

Moving on to Slide 25, this bubble slide I have here, clearly elucidates that our market research confirms that Clascoterone can be positioned as a foundation for acne treatments. And what I mean when I say foundation is that, these doctors indicate that all acne has a hormonal component. It's just a matter of to what extent. So as you can see in the middle bubble, this dermatologist is saying if product 'x', which in this case is the Clascoterone cream treats the hormone aspect of acne, and it can work on both male and females than all patients should be on it like a retinoid.

So, clearly we are saying that our drug is a first-in-class Topical Androgen Receptor Inhibitor. And this is resonating not only with physicians, but when I get down to the payers, you'll see it also resonates with the insurers. And that all... almost all physicians surveyed agreed that there is a need for a topical treatment for acne that is triggered by hormones. And so subsequently, overall, these physicians reported a very high preference share or high use of the drug that was driven primarily by its new MOA. And 90% of the healthcare providers exposed to Clascoterone cream 1% said they would be extremely likely to prescribe the product.

Slide number 26 gives you a view of several topical acne products and what their year one prescription volume and peak prescription volume was. And our market research confirms that the interest in Clascoterone cream is similar to Epiduo and Aczone. So if you take a look at Epiduo for example and Aczone those 2 drugs generated between 369’000 prescriptions and nearly 550’000 prescriptions in its first year on the market.

And in more detail on the right side of that slide, you'll see that again, they rated Clascoterone very similar to products like Adapalene and Aczone from an efficacy perspective, because of its clinical results in both in inflammatory lesion and especially interesting they were very impressed with the long term efficacy that Clascoterone cream 1% shows especially in truncal acne.

And as far as tolerability or safety, they rated Clascoterone highest of all the products giving it... given that it has such a very positive tolerability profile and a very small rate of disconnect... discontinuation in our Phase 3 trials.

And healthcare providers also saw value of our drug in... also in moderate patients, so that they can target both the inflammation and the hormonal component of acne in these patients. And just a reminder, our NDA was submitted for acne vulgaris in the ages 9 and up, regardless of severity.

Moving on to Slide 27, it gives you a view for what the typical acne brand prices are in the United States for mostly topical and then one oral drug. And you can see that these brand prices range from 500 to 900 Dollars per month. And this is the wholesale acquisition cost of these drugs. And that the average WAC we call it for a topical acne product is 613 Dollars per month. And the newest topical brands that have been launched in the last 6 months, Aklief and Amzeeq have priced their drugs at 554 and 485 Dollars WAC per month. While Seysara, an oral antibiotic, is priced at 911 Dollars per month WAC. So that gives you a view of the market research we've done and some of the launch surrogates, as it relates to the acne market in the U.S. and the response to Clascoterone cream 1%.

Now, I'm going to move on to just a single slide here, on some of the key insights we have received regarding the market access or payer insights with Clascoterone cream 1%. And the expected coverage that we expect the product to have based on substantial research that was done last summer with payers that represent 92 million commercial lives in the United States.

So first of all, we start with how do payers look at this acne market generally? And what we understand clearly is that it's a very stable market for them and it's a very predictable market. It's not a market that they manage aggressively because it represents... it doesn't represent a very high Dollar volume compared to other therapeutic classes that they manage. So they tend to manage the product consistently, but without major category evaluations.

Also our market research confirms that payers will continue to treat acne as a medical disease. And will provide coverage for patient acne visits and products. So what always is important, it always comes up with any payer research that we do, and I'm sure for any therapeutic class, price is always a key driver of the decision for the level of coverage. But innovation in our new MOA does matter. We clearly understand that a price threshold of over 600 Dollars WAC per month may have higher restrictions. Of course, we are not planning to price above that. And we understand clearly that Clascoterone will be important to be classified as a first-in-class androgen receptor inhibitor, creating a new category, so we won't be price-compared against other products.

Based on our research, we are expecting that we'll have coverage, formulary coverage in at least 70% of the commercial lives in the United States without highly restrictive prior authorizations or with multiple step edits as long as we price less than 400 net prices, per month.

So this gives us a very clear indication of what the pricing and the coverage that will be expected for Clascoterone cream 1%. And of course, the market research we did with healthcare providers gives us a clear understanding of what sort of market share in prescription volume we might have.

Now, I would just to give a little commercial update on androgenetic alopecia. I thought, I will just share slides with you here. First of all, now I am on Slide 31. If you take a look at the U.S. androgenic alopecia market or AGA, what androgenetic alopecia is? Its pattern baldness in men and it's very quite common. There's 80 to 95 million Americans that suffer from androgenetic alopecia. But both men and women are impacted. That market is likely 60% men and 40% females. But interestingly enough, only a very small portion of these patients, 49 million of them are estimated to get treatment. And this is definitely thought to be caused by the lack of treatment options available for these patients. And the only 2 treatment options that are available that is Minoxidil and finasteride were approved 20 and 30 years ago.

Now, let me talk a little bit about what is androgenetic alopecia, it is actually characterized by this progressive loss of hair on the scalp in a very characteristic pattern, and it's actually caused by high concentrations of an androgen dihydrotestosterone or DHT, which at the hair follicle shortens the hair growth cycle. And so we understand very clearly that our drug has a direct impact as an androgen receptor inhibitor at the very cause of androgenetic alopecia, which is the high concentrations of DHT.

Now, there are very known psychosocial complications of AGA that include depression, low self-esteem, less frequent enjoyable social engagement, and this is clearly depicted by the number of emails that are received by us each week from patients begging to be in our trials. And we clearly understand that women are actually more likely to suffer from these psychological complications than men, clearly, because beautiful thick hair is a sign of beauty.

Now, moving on to research that was done with both doctors and patients, we understand that both these groups are excited about Clascoterone solution for AGA. Doctors were very highly receptive to the product profile and they really did tease out this novel mechanism and this impressive clinical photograph that they saw of actual patients, who had been on drug. All physicians' specialties that were tested, suggest a very high utilization with the reported adoption of over 60% of their male patients and 50% of their female patients, they would prescribe Clascoterone solution.
They also reported very high adoption rates generally and they would replace finasteride and Minoxidil equally.

You can see here a quote on the dermatologist on the site here. I'm so excited about Breezula; we haven't had anything innovative in a long time. And furthermore, I have never been able to give my female patients something that could really fix their issue. This product could give a hope... a bit of hope to female alopecia patients.

And we also tested the product profile with consumer studies with patients that had been on Rogaine. And these Rogaine patients indicated that they would at least be highly likely to request Clascoterone solution from their physician. And they would be willing to pay between 1 and 200 Dollars per month for Clascoterone solution, which is consistent with other cash pay lifestyle drugs.

So with that, I will now turn the call over to Chris Tanner, who will give you a financing update.

Chris Tanner

Thank you, Diana. As I mentioned initially, just to remind you, of course, that Cassiopea is an Italian company and Italian law doesn't allow companies to operate with negative equity. As a consequence, we need to do... what we call an equity bridge originally to be very honest; of course, we had planned when we capitalized the company prior to IPO that the money that the company had would be lasting through PDUFA. But this was 40 years ago, and there has been slippage in time here and there. So now unfortunately, we are getting close to negative equity 3 to 4 months before PDUFA, which forces us to make a small capital increase because the original plan would have been to make the next equity round after we've gotten positive news from the FDA.

So this will be a small transaction, which is estimated to be around 20 million Euro. We're preparing the prospectus for a rights offering to all shareholders, which should be executed in May, because you probably know better than me that present moment is a terrible moment to be coming to the market. But we're also in discussions with potential investors who may be step-in with the exclusion of preemption rights of other shareholders in the event that the shareholders that have the pre-emption rights do not want for whatever reason to participate. So we have the choice between 2 different alternatives and these, the dependence of what we do depend on market conditions.

Importantly, Cosmo has stated that it will fully underwrite any rights issue up to 20 million and will provide additional financing needed. So from that perspective, I think we can be very comfortable and very assured that we're going to be raising the money. Question is just in which way precisely?

We are furthermore, exploring non-dilutive financing. Maybe non-dilutive financing is a financing that has an equity type component because it's results-driven.

It's normally (sub-estimated) under royalty financing with the financing party being paid in proportion of royalties. But of course, this is not equity. So there's not a dilution component. So we're talking to a number of parties about this. And depending of course on conditions, we could close on those.

Then of course, the plan is upon approval of Clascoterone cream 1%, if Cassiopeia decides to commercialize the asset by itself in absence of a strategic transaction, that we will then do a more significant equity raise to advance the pipeline and to establish the commercial organization in the U.S. and that would be happening towards the end of the year, or the very beginning of next year.

Diana Harbort

Thank you, Chris. And I'm going to jump back to Slide 29 to just describe our approach to launch of Clascoterone. I'm sure that that's a question many of you have on your mind and for those of you I've met over the years, you understand that we have adopted a very stepwise diligent approach to the launch and the investment related to the launch. And our view really is we think it makes most sense from an efficient market perspective to execute a strategic transaction, especially with a company that might have existing Derm sales and commercial infrastructure to launch Clascoterone cream 1%.

You see, we see this product, which is the first new emollient acne in nearly 40 years in our pipeline which substantially contribute to a company securing a very sustainable leadership position in the Derm space. So talks are ongoing with multiple parties that would be acquires of Cassiopeia or merger partners. But clearly, if a potential transaction is not attractive to our shareholders, then we will proceed with plans to launch Casio... or launch Clascoterone, following FDA approval.

And so on this slide gives you a sense for our thinking in this regard. We have built a U.S. management team that has extensive Derm experience in over 20 dermatology launches. We've built a very solid foundation for launch. First, our medical affairs program, which I alluded to previously, has a rapidly increased awareness of Clascoterone new mechanism of action in our clinical data in the dermatology community.

We've also conducted market research that I just went through with you where we clearly understand the positioning, the messaging and the market segmentation, which is of course the doctors that would need to be called on in order to impact the uptake of the product. We also conducted substantial market research with payers or insurers.

We understand clearly the value proposition of our product, and how they would view our product and how they would price it, or how we would price it in order to achieve attractive formulary coverage in 70% of the commercializing [ph] in United States.

And we have used our professional relations to build Cassiopeia awareness among doctors who write large numbers of acne prescriptions. We've also identified areas of what I call external or contract support rather than planning to build these internally. So we will intend if we launch this product to launch with a contract sales organization of about 75 reps. Of course, we'll refine that number as the time gets closer. That allows us to use contract sales organizations who hire more reps in the U.S. than any other company and use their operational efficiency to rapidly and efficiently build our sales force post PDUFA, so that we could be launching months later.

Well, of course, these contracts sales professionals will carry a Cassiopeia card and to the doctor and to most of the industry, it won't be apparent that they are a contract sales organization, but to be clear, they will be specifically recruited and will promote our drug and not be promoting drugs of other companies.

So our plan is to launch in a 2-step launch approach. We'll do a market access launch following the PDUFA date. That is we'll begin our contracting discussions with insurers or payers here in the U.S. to start moving through the... some of the 6-months payer blocks. And resolving as much as possible the formulary issues, so that that is taken care of as much as possible before our sales reps enter the doctor's office in approximately March of 2021. So that gives you a little bit better feel of our approach to the launch of Clascoterone cream 1%.

Now to wrap it up, I'm going to move here to Slide 35, just highlighting a few of the company milestones. As Chris mentioned, we'll be doing a capital increase here in the coming months. We'll be finalizing the special protocol assessment with FDA on the Phase 3 program for Clascoterone solution a Phase 3 in men where we'll be initiating the activities at the end of the year and likely beginning recruitment the following year. And we'll be looking forward to the Clascoterone cream 1% PDUFA date here at the end of the summer on August 27, 2020.

So that completes our prepared remarks. If there's any questions, we'd be happy to take them.

QUESTION & ANSWER

Operator

We will now begin the Question and Answer Session. Anyone who wishes to ask a question may press * and 1 on their touchtone telephone. You will hear a tone to confirm that you have entered the queue. If you wish to remove yourself from the question queue, you may press * and 2. Participants are requested to use only handsets while asking a question. Anyone with a question may press * and 1 at this time.

The first question comes from Bob Pooler from Valuation Lab. Please go ahead.

Bob Pooler

Hi, Diana, Gentlemen, first of all, congratulations on an excellent 2019, with all the positive developments for both Winlevi and Breezula. A few questions if I may, first of all, could you provide maybe some guidance on your operating expenses in 2020? I know there's a lot of moving parts, but could you maybe provide a range for 2020?

Diana Harbort

Chris?

Chris Tanner

You're talking about a range of 2020 from a value, from a cost perspective?

Bob Pooler

From a cost perspective, yes, which is your operating expenses could to be somewhere in 2020.

Chris Tanner

Well, in principle, what you can, looking at it from a very... shooting from the hip perspective, first of all, you have to be aware that in the past, we've always driven the entire R&D based on the cash and the equity that was available. So if we raised 20 million, let's assume that we raised 20 million equity this year. And we plan then to do a second capital raising at the very end of the year or at the beginning of next year, then you can assume that the entire cost for this year is going to be in the vicinity, more or less what we had last year, maybe a bit more, because after the approval, we will be doing intensifying our pre-commercial activities. But I think our overall expenses are going to be between 15, around 15, 16, 17 million...

Diana Harbort

To be clear, Bob, remember, we... the substantial expenses that would be related to a sales force will be incurred in 2021.

Bob Pooler

Yes, because you will hire just shortly on commercial launch.

Diana Harbort

Right, so we are going to work through the payer launch first, and then those reps would be hired in the year 2021.

Bob Pooler

Yes, I mean, there are already a lot of market access programs last year, so that cost is already (unintelligible) as well. Clear, just on Breezula the Phase 3 trial, maybe a little bit more color there, I know you are in discussion on the SPA, any idea about the duration, maybe also the cost there as well and when you would expect to have results on that.

Diana Harbort

Alessandro.

Alessandro Mazzetti

Yes, for the Phase 3 alopecia trial, our plan is to start the operational activities by the end of this year. While for the enrolment for the clinical trial activities we plan to have them during the 2021 and 2022, because FDA during the end of Phase 2 meeting asked to have one part of the trial as double blind that has part the first 6 months, and afterwards 6 months follow-up for safety reason. So we do hope to complete all the trial before the end of 2022.

As far as concerning the cost, at the moment, we can plan a cost ranging between 20-25 millions overall, because as, you know, FDA is requiring 2 Phase 3 trials. So all of them should be cost roughly between 20 million and 25 million.

Bob Pooler

Okay. Thank you. Very clear. Just on the COVID-19, are there any constraints for your side, in terms of manufacturing, supply constraints for the studies or is it more external factors that would lead to delay... potential delays?

Alessandro Mazzetti

Sorry, do you mean the delay for the...

Bob Pooler

Well, just on the coronavirus, are there any potential delays from your side, so you know with the enrollment this year was (unintelligible) not for Europe, that's outside Europe, but let's say from a manufacturing you have some (not audible) clinical trials every year from your side will not be affected.

Alessandro Mazzetti

For the Phase 3, I think we will not have any delay for the manufacturing and for the trial because the plan is to start for the clinical part at the beginning of the next year, so I don't think for that moment we can still have something the problems related to coronavirus.

Bob Pooler

Okay. And then just a final on, you stated there that Cosmo will fully underwrite the rights issue up to 20 million, provide additional something if needed. Are there any restrictions on the Cosmo side? They would increase the share... again as on Cosmo side, I think it's looking at the value of the company and also you know close to an approval (unintelligible), quite high too, I understand that you were also willing fully underwrite it as well. So anything there on restriction still from Cosmo side or...

Chris Tanner

No, Cosmo said... Cosmo announced 45%, and we are talking about, right, a small transaction, right, it depends of course on what the share price is. But if you would... we would be lucky enough or whatever they have share price going back up normal and 20 million can be raised you know, with 500'000, 600'000 shares and that is... even if we would be the sole underwriter or writer it would be to the tune of 5% to 6%, right, but Cosmo is willing to underwrite the entire exercise or will... it is not willing, it will.

Bob Pooler

It will, yes, will.

Chris Tanner

That's a back stop of the event that other parties don't participate, I would hope that other investors consider the current price to be highly attractive as well, and that they would participate in the transaction equally.

Bob Pooler

Yes, seems to me like an opportunity. Well, thank you for answering questions. Stay safe and healthy and fingers crossed for your first part approval in 2020.

Diana Harbort

Thanks, Bob.

Bob Pooler

Thank you.

Operator

The next question comes from Raghuram Selvaraju from HC Wainwright. Please go ahead.

Edward Marks

Good afternoon. This is Edward Marks on from Ram. I appreciate you guys taking the questions. I just have a few based on the status... the NDA status. Just wondering what the status currently is and really around have you received any unusual requests for additional information from the FDA since the original submission?

Diana Harbort

Alessandro...

Alessandro Mazzetti

Yes. No, at the moment, all the requested to be received from FDA are... I can say the standard one are just some additional requests on manufacturing CMC or technical data, but absolutely no particular request. And I would like to underline that during the mid-cycle meeting that we had on February 12th, no substantial issues came out in any of the... in any part of the dossier, no substantial issue in CMC, nor in the clinical... nor in clinical part of the dossier. So at the moment we are quite confident that no major issue, there are in our dossier, and we are waiting for the light cycle meeting at the end of April for the confirmation of this... of our (unintelligible).

Edward Marks

Okay. That's good to hear. And it looks like you did a lot of commercial outlining in this presentation as well. I am just wondering if you have advanced into labeling discussion with the FDA as well.

Diana Harbort

We have not.

Alessandro Mazzetti

No, we have not. The labeling discussion will start at the beginning of May according with the time line that FDA gave us at the beginning and that was confirmed during the mid-cycle meeting.

Edward Marks

Okay. Perfect, good to hear. Thank you guys for answering all the questions. I appreciate it.

Alessandro Mazzetti

Thank you.

Operator

The next question comes from Philippa Gardner from Jefferies. Please go ahead.

Philippa Gardner

Hi there, I have 2 questions, if I could, please. Just on Winlevi and the FDA review. So firstly, I was wondering, do you yet know if you are likely to have an Advisory Committee Meeting? And then secondly I noticed in the Annual Report that the manufacturing inspection that we expect in March has been delayed because of the restriction. So do you have any sort of idea as to when that might take place? Do you think that will still happen within the timely manner to stick to the original PDUFA date? Thank you.

Diana Harbort

Alessandro.

Alessandro Mazzetti

Yes, for the inspection to the manufacturing plant, now is planned the first week of May. They postponed from the end of the February to the first week of May.

And for the... the other question concerning the Advisory Board Meeting... during the mid-cycle meeting they said that at the moment there are no reasons for having such kind of meeting, no reason to have deep re-discussion on specific issue and particularly no reason to have specific discussion concerning the safety profile of the drug.

Philippa Gardner
Great. Thank you.

Diana Harbort
Thank you.

Operator
The next question comes from the Nicholas Gordon of Logistable Limited. Please go ahead.

Nicholas Gordon
Hi, good afternoon, everyone. Thanks for such an extensive presentation. Just 2 questions from me, the first one is, obviously we've got a pretty difficult time at the moment in terms of not only financial markets? But, you've got to do this raising by May, it seems. Do you have an idea when you probably have more details, is it s a couple of days or couple of weeks, pre-Easter. And then, the second question is around the potential for a strategic partner that you've outlined, that you would have to consider that versus is it is a good deal for shareholders. Having you got some basic line in the sands of where you feel that a deal will not be in a shareholder's interest vis-à-vis a price range, I don't want a specific sort of number. But, where do you think you would certainly walk away if someone offered a certain price? Thank you very much.

Chris Tanner
Diana, should I take those? Or do you want to?

Diana Harbort
You can take the raising by May. I will take the strategic partner question.

Chris Tanner
Okay. On the raising side, as I mentioned briefly is, we are currently writing the prospectus. And want to have the prospectus finalized in such a way that we can then basically wait upon the occurrence of the...of the market more or less to be where it should be.

But, we are targeting... in order to be cautious, we are targeting it towards the very end of May and we will be announcing basically according to Italian law, you know, there is the ordinary shareholder's meeting and the extraordinary shareholder's meeting and these will be a month apart more or less with the extraordinary shareholder's meeting plan to be taking place towards the end of May and that will then be approving the "capital increase" or recapitalization purposes as an extraordinary event. So, this would mean that the transaction would be happening in the first 2 weeks or something like that of June

And we would hope that by then the market's will have somehow stabilized. But, even if they don't, we will do the transaction, right, but yes, from Cosmo's perspective, if necessary Cosmo would be the only... the only underwriter... the only subscriber if nobody else want to participate.

Nicholas Gordon
Okay. Understood.

Diana Harbort
Alright. And then, as it relates to strategic partner, we understand very clearly the value of our drugs. We've had done substantial amount of market research that I tried to share with you today, that elucidates not only the... the potential prescription volume over time, but also the market access or the payer landscape and coverage and pricing for our drug. So, that allows us to have a very clear understanding of the primary value driver of the company and it is under you know... and we understand clearly what the cost would be for, and the opportunity would be for us to launch the product on our own. So, we would review any opportunity or any valuation for a strategic partnership with that in mind. So, that's kind of how we look at it. I am certainly not going to be giving any Dollar value range in this call or publicly. But, we clearly understand what is likely to be the value of Winlevi and Breezula certainly.

Nicholas Gordon
And will that be the main driver when it comes to strategic versus internal, if you can't get the right value?

Diana Harbort
Well the... you know, there are a lots considerations as they are always is in transactions. But, that is a main... well; value tends to be a main driver.

Nicholas Gordon

Thanks.

Operator

The next question comes from Paul Verbraeken from Research Partners. Please go ahead.

Paul Verbraeken

Hi, good afternoon. Just one financial question, you have a cash plan of about 1 million per month or a bit more, does that mean that you've already drawn a bit more than the Cosmo facility in the first half? And if so, how much do you think?

Chris Tanner

Marco, do you want to make the statement on that, on the details?

Marco Lecchi

Yes, yes. At the end of the year, we've drawn 10 million Euro. And now, in the first 3 months 2.5 million Euro from the facility.

Paul Verbraeken

Okay. And that means that you'd probably draw some more in Q2 or is that, that's going to be it?

Marco Lecchi

No, we are going to draw until we make the capital raise.

Paul Verbraeken

Okay, got it. Thank you.

Operator

The next question comes from Barbora Blaha from Credit Suisse. Please go ahead.

Barbora Blaha

Hello, thanks for taking my question. I have one question to clarify the patent life, because I thought that the patent loss of exclusivity is in 2030, but I saw in the Annual Report that the patent expires in 2028, could you give some clarity on this issue, please?

Chris Tanner

Luigi, can you make a comment on that?

Luigi Moro

Yes, the patent cover in the cream, the Winlevi cream is expiring in 2028, but some term adjustment are awaited for the patent topics. Of course, these don't change radically the situation but could adjust. But, for the solution, we have a much more... much longer life in terms of exclusivity. It is, if I remember well, is over 2030.

Barbora Blaha

Okay. Thank you. And then a quick other question on the second round of financing, does this depend on the... whether you do this strategic transaction for Winlevi or whether you go on the market by yourself?

Chris Tanner

Of course in principle from a practical perspective, the... the... I think the critical... one of the critical events proposed for both, any potential strategic as well as for a fund raising is going to be the approval of the drug. And we will then see right where we stand, if there is no satisfactory strategic transaction, then we will proceed with preparations for the second capital raise.

Barbora Blaha

Okay. And the capital raise, this will be on equity markets or like with royalty banks?

Chris Tanner

No, no, no, that will be on the equity markets or potentially it could be a mixture. But, it depends but...

Barbora Blaha

Okay, okay fine. Thank you.

Operator

Next question comes from Boyadjian Rupen from Finanz und Wirtschaft. Please go ahead.

Boyadjian Rupen

Hi, thank you for having my questions. Can you give us some indication about the size of this backend offering tips you will go ahead?

Chris Tanner

That is very, you know, that is, if we look at what is... what is we have the authorization to issue to 3 million shares, right, from our shareholders. And if we issue 750’000 shares now or more or less, to that tune or a bit less, then we have 2.2 million shares left. And then, theoretically... but that’s of course, there is a lot of ifs and buts and when, but if the share price hopefully will be substantially better than it is now, then that would give us the opportunity of raising to the tune of the 100 million, meaning...

Boyadjen Rupen

Okay.

Chris Tanner

... the remaining shares that are authorized.

Boyadjen Rupen

Okay. Thanks a lot.

Operator

For any further question please * and 1. And then Gentlemen, so far there are no more questions.

Diana Harbort

Okay. Well, thanks, all for participating in our call today. We appreciate your interest and support of Cassiopea. And we wish you again you and your families safety and peace during these tumultuous times. Thank you very much.

Operator

Ladies and Gentlemen, the Conference is now over. Thank you for choosing Chorus Call and thank you for participating in the Conference. You may now disconnect your lines. Goodbye.

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