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COMPANY REPRESENTATIVES

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PRESENTATION

Operator

Ladies and Gentlemen, welcome to the Cassiopea Pharmaceuticals Half Year Results 2020 Conference Call. I am Alessandro, 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 hand over to the Management Team of Cassiopea Pharmaceuticals. Please go ahead.

Diana Harbort

Good afternoon everybody. This is Diana Harbort, the CEO of Cassiopea, and thank you for joining our first half 2020 results call today. I am joined by Chris Tanner, our Chief Financial Officer, Luigi Moro, our Chief Scientific Officer, Alessandro Mazzetti, our Chief Medical Officer and Marco Lecchi, our Finance Director.

First of all, we hope all is well with you and your families during the pandemic times, and we're so happy you could join us today. We'll be giving you an update of course on our first half 2020 results, and giving you also an update on our product development, our commercialization update and a financing update.

First, I'll call your attention to our Safe Harbor statement on Slide 2 of the presentation, as we'll be making some forward-looking statements. So first, we'll go through the first half 2020 financial results, and I'll turn it over to Chris Tanner, our Chief Financial Officer.

Chris Tanner

Thank you very much, Diana. Well, as you can see, the net operating results of our loss declined slightly from last year as last year we have... we don't have any revenues yet. We decided not to license out any of our products prior to having an approval. So we have no revenues.

If you look at our cost, our research and development cost declined slightly, primarily because of course the Winlevi trial has been completed.

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We had an interruption of the Phase II trial in women and we haven't really... we haven't started with the Phase III trial in men yet, so we are sort of in an interregnum phase. Selling and general administrative costs increased slightly because we built up slightly the organization in the U.S., and there were some expenses there. But all-in-all, that's not spectacular.

So if we go to Page 6, you can see the details of the net operating expenses. Personnel expenses increased from 1.1 million to 1.8 million and in principle the net operating expenses, as I said before, decreased from 6.3 to 4.7 million.

If we go to the next page, you can see from a personnel perspective, we have the same number of people at the end of the year, on average it's been slightly different because we have... that's why we have slightly more expenses this year, but its 12 people that we have on our payroll.

And if we then go into Page 8, you can see how the breakdown is on the R&D expenditures. As I explained before, the very reduced cost for Clascoterone Cream which in essence is our main product, but which is awaiting of course the approval hopefully by the FDA on the 27th of August, and the other Clascoterone Solution the costs are down again because, as I said before, the clinical trials for the Phase II in women were suspended due to Corona. The service costs on the other operating expenses are primarily costs.

If you look at the next page, which is Page 9, you can see what they consist of. There were some external consultancy services primarily in conjunction with the work we're doing to establish how well the product that can be marketed in the U.S., which price, and to whom et cetera and so forth. Also the establishment of our contacts to the key people in the U.S and potentially bring you the product to market. Advertising and market expenses go in the same direction there, the rest of the expenses are really very minor.

On... you can see on Page 10 that the service agreement between Cosmo and Cassiopea continues in place with 2 different levels of charges that were made by Cosmo SpA to Cassiopea for the services that were provided both for the research and development perspective as well as for the secretarial and accounting services that were provided in the first half.

If we look at the consolidated income statement, I think we said about that, so let's move on to the changes of financial position. And there's been practically no change in tangible and intangible assets, no change in the tax receivables, so the total non-current assets are nearly identical. There is very small changes in the other receivables.

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What we have is an increase in the cash and cash equivalents because as you know, we raised... we issued 750’000 shares to our existing shareholders in June.

We used the proceeds to repay the outstanding debt that we had with Cosmo and what we have here is the remaining cash which is 8.5 million. So you can see that if you look down on the liability side, the total non-current liabilities have declined from 10.7 to nothing and the current liabilities slightly increased. This brings us, and this is important, to total equity position of 21.4 million. This is important looking forward keeping in mind that we need a positive equity from a Italian legal perspective.

So if we go to Page 13, I think we’ve run through this on an explanation basis. The change of equity position, I don’t know maybe if you have any specific details I can go and explain this later on, but I think we can move on to that. I think the important part is that we issued 750’000 shares which have a nominal value of €1 and I am now on Page 15. We had a share premium correspondingly of 30 Euro per share issued, it was 21.6 million and if you look at the expense for stock options, in the first half has amounted to 469’000 due to the stock option plan which was approved by the shareholders at the last shareholders meeting. I think this is more or less it, it completes the position.

If you look on Page 16, the consolidated cash flow statement, in essence the... to summarize the operating profit respectively, loss declined to 5.3. If we then have the cash flows from financing activities of 12 million leaving us in the end with a cash and cash equivalents position of 8.45 million, which is a substantial increase vis-à-vis of what we had at the end of June in 2019.

That completes the financing position. If you have any questions, maybe you may want to ask them right now.

Operator
We will now begin the question and answer session. Anyone, who wishes to... sir, do you wish to start the Q&A session?

Diana Harbort
I think we will go through the rest and then we have to answer the questions at the end.

Chris Tanner
I think that makes more sense, yes, so let’s go ahead.

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Diana Harbort

Great, great. So moving on to our product development update, I'm moving now to Slide 18. For those of you who are following along, many of you have been following the company for some time, so you may be familiar with our pipeline slide here on Slide 18. Notably our Clascoterone Cream 1% is waiting for PDUFA date that is in August of 27, so just under a month. Right behind that is Clascoterone Solution which had a positive Phase II in males and we will be moving into Phase III after we have completed the negotiation with the FDA and our special protocol assessment. Our Clascoterone Solution for androgenetic alopecia in females is currently in a Phase II proof-of-concept study. I want to give you an update on that shortly here, and of course, we have 2 earlier stage compounds, one in novel topical antibiotic and the other in novel immunomodulator both which have had positive Phase II proof-of-concept results and are in product development, for a formulation development and further CMC work before we move them into Phase II.

We will start on Slide 19 by giving you an update on Clascoterone Cream 1%. This product received conditional approval from FDA on our WinLevi trademark proprietary name. The NDA was filed last August and further was accepted by the FDA, where the FDA established August 27, 2020 as the PDUFA date.

As many have heard me say before, we've invested in an extensive medical affairs program, that has really seen a lot of success and we have increased the visibility of not only Cassiopea, but of Clascoterone and its scientific data and mechanism of action in the dermatology community. We've got 5 published papers, 23 posters and abstracts, and 24 meeting sponsorships, with over a 100 podium mentions at medical meetings by key opinion leaders. And we completed very extensive market research with peers and segmentation research with healthcare providers, which I shared with you in earlier presentations, so of course the next step is the PDUFA date here, coming up in a month.

On Slide 20, I just list for you here some of the very recent substantial medical publications that have been done for Clascoterone and I call your attention to the 2 on the left, where we... our Phase III data has been published not only in JAAD, that's the long-term extension study results there in JAAD, but also the pivotal Phase III results in JAMA dermatology. Some of these other calls or publications have received up to 20'000 downloads, of just the JAMA dermatology article alone. And so we've gotten quite a bit of interest and quite a bit of receptivity in our Clascoterone publications and we knew this would be important leading up to the PDUFA date of the product.

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I'll turn it over now to Alessandro Mazzetti, our Chief Medical Officer, who will give you an update on our Clascoterone Solution for androgenic alopecia on Slide 21.

Alessandro Mazzetti

Thanks Diana, and good afternoon to all of you. As far as concerning Clascoterone Solution in Slide 21, you can see that data, the completion of the dose raging to study in male, we identified the most effective dose for the solution and with these results, we had an end of Phase 2 meeting with FDA during either November, last November to plan all the following activity to reach the complete filing for the NDA and they agree all the full time development for the NDA filed.

In May, last May, we submitted to FDA a special protocol assessment for the Phase 3 program for the trials that should complete the clinical part of the development for the Clascoterone Solution to define the efficacy in the safety in male. This special protocol assessment would be finalized in the next months because as usual with FDA we will have an exchange of the opinion on different point of the protocol. And we think to be able to start with the Phase 3 before the end of the year.

In the meantime, an extensive Medical Affairs program also for Clascoterone Solution has been done to increase our visibility in dermatology community with 9 papers signed, several key opinion leader podium presentation. And at the end of the last year, we started also the Phase 2 program for androgenetic alopecia in females. The next step would be, as I told, to close the discussion with FDA on Phase 3 program in males and to complete the enrollment of the Phase 2 study in female.

The next slide the Slide 22, we summarize the situation of the trial in females. This trial is a multicenter double-blind trial that is ongoing in Germany on 280 subjects. The trials is planned in 4 groups, 2 groups treated or subjects treated with our solution to different concentrations 5% and 7.5% twice a day, another group with a vehicle solution and the other one with Minoxidil solution that is one of the most used solution for alopecia in female. The treatment will be of 6 months and they... the subjects will be enrolled in as planned in 7 centers in Germany. Due to the COVID situation, the enrollment was put on hold during the last 3 months, but now we restarted the enrollment. Up-to-date we have 180 subject is already increased versus this drive, it is a subject enrolled in the trial, and we do hope to able to complete the enrollment by the end of September to have the top line results within the first half of the next year.

For the clinical plan it's all, if you have some question, please.

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Diana Harbort

Yes, we can ask the questions at the end. Thank you so much. I appreciate that. Now, I think we should turn to a Clascoterone Cream 1% and some of the commercial update. First, I'll start with the U.S. acne market. The acne market is a very important market in dermatology. It's very high volume, very concentrated market with about 8’000 providers that is doctors and nurse practitioners and physician's assistant that are in derms office, accounting for almost 60% of the prescription. So it's a market that can be easily targeted by a manageable number of sales reps.

And there's a very high unmet need among healthcare providers for a novel approach especially one that targets the hormonal aspect for all acne patients. Spironolactone, which is an oral anti-androgen that's used off-label not indicated for acne. Is the third highest prescribed drug in all of dermatology regardless of indication, with over 2 million prescriptions a year and it's limited only to use in females.

And acne is treated by polypharmacy. And according to the American Academy of Dermatology guidelines, doctors are instructed to use multiple complimentary drugs to address different parts of the acne pathogenesis. So this is the reason why in the United States most acne patients leave the dermatologists office with 2 or 3 prescriptions for acne. And our market research has clearly demonstrated the positioning for Clascoterone Cream 1% around its unique mechanism of action and shows significant market share uptake that's predicted among very high value providers.

Now, a little bit on the size of the acne market here on Slide 25. Acne is a disease that affects 50 million patients and continues to be a very relevant disease. It's a 5 billion Dollar U.S. market and interestingly, the treatment options are limited to old therapies that were developed over 40 years ago. The last new mechanism of action approved for the treatment of acne was in 1982 when Isotretinoin or Accutane was approved. Since that time, the drugs that have launched have been new... basically new combinations or new dosage forms of older drugs or new versions of existing mechanisms such as new topical retinoids that all have very similar mechanism of actions. And what we know is we're looking at the pathogenesis of acne, it's that topical options really only address 3 of the 4 factors in acne physiology leaving a gap in treatment regimens, and specifically there are no topical regimens that actually have an effect on the sebaceous gland function.

Now our research, our market research with payers in the United States shows that payers continue to... with a plan to continue to cover acne as a medical condition. And our research indicates that this will not change.

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And also 90% of branded prescriptions for acne are written in the office of the dermatologist. And importantly, dermatology physician's assistants and nurse practitioners account for almost 1 billion Dollars of that 5 billion Dollar market.

Now on Slide 26, I give you a brief update on some of the market research comments coming out of our studies. And it's clearly confirming that Clascoterone can be positioned as a very foundational medication for acne treatment. These doctors clearly understand that the product has clear differentiation as a first-in-class topical androgen receptor inhibitor. And almost all physicians surveyed agreed there is a need for topical treatment that targets acne that's triggered by hormones. And they go on to say that all acne has a hormone... hormonal component, and it's just a matter of what extent. And they go on to say that all patients should be on it like a retinoid. So overall, physicians are reporting a very high utilization of Clascoterone that's primarily driven by its new and unique mode of action, and 90% of healthcare providers said they would be extremely likely to prescribe the product.

So, to put this in context on Slide 27, our market research is confirming that interest in Clascoterone Cream is similar to the interest that doctors have in products such as Epiduo and Aczone. And so you can see here, that Aczone and Epiduo in their first year did 340’000 prescriptions or 542’000 prescriptions in the first year and peaked at nearly a million prescriptions or just above a million prescriptions a year. So, this is the sort of response we're getting and it looks like they're predicting this product will be of this size

And some of the comments that they've specifically make about Clascoterone cream 1% certainly are their efficacy ratings comparing it to those... to those products like Adapalene and Aczone gel 7.5%. They like the decent reduction they're seeing in inflammatory lesions and also they're very interested in the long-term efficacy that you can see by the way in our JAAD Phase 3 article. Clascoterone also had some of the highest tolerability ratings of all the products that were rated, given its very positive safety profile, and it's very small rate of discontinuation. And also, healthcare providers are seeing Winlevi could be used in moderate patients so they can target both the inflammation and the hormonal component of acne in these patients.

Now talking about price, I thought it might be helpful to list here for you what the acne brand wholesale acquisition prices are currently in the market. So if you take a look at all of these products you see here, what you see is that the average acne WAC price in the U.S. ranges from 5 to 900 Dollars and varies in pack sizes, either from 30 gram to 90 gram. So the average for a one-month supply of a topical acne product, wholesale acquisition cost is 613 Dollars.

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And the newer topical brands that have been launched recently Aklief, which is Galderma's Retinoid, its 554 Dollars and Amzeeq, a topical minocycline is 485 Dollars. While the newer systemic brand Seysara WAC price is about 911 Dollars.

Now it's important to note, and I'm sure you guys that have been covering the pharmaceutical market for some time understand that there's quite a significant deduction from WAC to net based on a couple of components, certainly the percent discounted for wholesaler distribution, but also discounts to payers and patients for market access, and this will vary over the life of a product. But this puts in context for you, what the market WAC pricing is in the United States.

Now, as I mentioned, we did a quite robust market access research, and so I thought I'd share with you some of the research coming out of very in-depth interviews that were conducted last summer with payers that represent 92 million commercial lives. Acne is a very stable and very predictable payer market. They manage these products quite consistently without major category evaluations. Acne is not a big disease on the payers list of diseases. Our market research confirms that payers will continue to treat acne as a medical disease and will provide coverage for patient acne visits and for products.

And although price is always a key driver for the decision of the level of coverage for any product, the innovation and the new mechanism of action of our product does matter. We also know the drugs that have over a 600 Dollar monthly WAC will have higher restrictions. And we are focusing on targeting Clascoterone to be in its own unique category as a first-in-class androgen receptor inhibitor, so as not to be compared to other categories.

Now we're expecting coverage in at least 70% of commercial lives without highly restrictive prior authorizations or multiple step edits. And we have determined what might be an acceptable net price per month in order to achieve that level of coverage.

Now, we have had our first meeting with payers, yes payer yesterday, and we have found that payers have had a very good reception and a very good willingness to meet with us for introductory calls. In fact, payers that represent greater than 75 million lives have scheduled meetings with us within the first week that we've contacted them.

Moving on to Slide 30, I've shared with you this launch approach in the past, and I thought it would be worth mentioning again, as we've adopted a very practical stepwise approach to investment and launch preparation.

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We've carefully expanded our resources commensurate with the FDA and regulatory progress of the product we have then and we are in the midst of exploring multiple M&A options to optimize the commercialization and the profitability before building our own organization.

We believe that it would be very advantageous to not have a single product sales force, but to have a multiple product sales force promoting our product. We have built a U.S. management team that has had very extensive dermatology experience in over 20 derm launches, and we built a very solid foundation for launch.

I've talked to you about the extensive medical affairs program that has really increased the awareness of not only Clascoterone, but our new mechanism of action and the clinical data in our dermatology community. And I've shared with you the market research that we've conducted where we clearly understand the positioning, the messaging, and the market segmentation of our product.

And of course, in market access, we have conducted research on the value prop, the downstream payer analysis and pricing, and we have introductory meetings with payers scheduled over the next 8 weeks. And we've identified, of course, areas of external or contract support rather than build internally. If we choose to launch this product on our own, we will likely use a contract sales organization and we would, of course, evaluate the size of that group post-COVID.

Our plan is to launch an a 2-step launch approach, where we'll be having a market access launch at PDFUA, and in order to advance our negotiations with payers in advance of the commercial sales launch in approximately March of 2021.

Now turning over a bit to the commercial side of androgenetic alopecia or Clascoterone, which is served by a Clascoterone Solution, I'm moving on here to Slide 32. Now, androgentic alopecia is a condition that is caused or influenced heavily by a dihydrotestosterone, and this dihydrotestosterone has a negative impact on the hair follicle in some patients. This DHT causes the follicle to shrink over time and causes the hair growing out of each of the follicles to become thinner and thinner until that small follicle is unable to grow new hair.

The existing treatments were developed 20 and 30 years ago, with Minoxidil being the first treatment as a topical. This brand name at the time was Rogaine, now this product is generic and over-the-counter, and also sold as an over-the-counter generic. And this is a vasodilator that is thought to bring better nutrients to the hair follicles.

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Propecia or finasteride is an oral androgen modulator, and it shows an anti-androgenic activity on the hair follicle, but because it's an oral, it has systemic ant-androgenic side effects and is in fact not indicated for women and has some very negative side effects for men. That product is also generically available, and neither of these products are promoted at all in a doctor's office.

Our drug has a direct effect on the DHTs negative effects on the hair follicle and would reduce that hair miniaturization and this dermal inflammation that also occurs. But when you think of all these treatments, all these treatments are currently cash pay treatments. Propecia is a prescription, Minoxidil is OTC, and we would expect our product to be a prescription product as well. But these products are not currently covered by healthcare insurance. These are cash paid for by the patients. And these products, whether it be Propecia, Minoxidil, or our product, Clascoterone would be used by patients to prevent the loss of hair and to grow back new hair. So they tend to be chronically used patients... .as chronically used products, sorry.

Now, if we move over to the androgenetic alopecia market, this on Slide 33, androgenic alopecia or AGA as it's often called, is also known especially in men as pattern baldness. And you can see the graphic here, it commonly appears in a certain pattern on a patient's scalp, and it's the progressive loss of terminal hairs on the scalp in this very characteristic pattern. And it's caused by high concentrations of DHT at the hair follicle, which shortens the hair growth cycle.

Now, in women, the AGA looks a bit differently. It shows up as more diffuse hair thinning. And there's very known psychosocial complications of AGA, including things such as depression, low self-esteem, et cetera. And this is clearly proved, I get... we get emails from androgenic alopecia patients around the world each week enquiring as to the status of the drug, or as to their interest in getting into our studies.

And we understand that studies have indicated that women are more likely to actually suffer from the psychosocial complications than men, likely because, of course, hair is a sign of beauty in women and hair losses is a bit less acceptable than pattern hair in women, than the pattern hair losses so common in men. But 80 to 95 million Americans suffer from androgenic alopecia and both men and women are impacted. It's thought that the market is 60% males and 40% females, but a very small portion of these patients are estimated to get treatment. And this is in the literature thought to be because they're so limited treatment options available, especially for women. And I... like I told you, treatment options are limited to these very old therapies like Finasteride and Minoxidil that were developed 20 and 30 years ago.

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Now, we tested the product profile with both providers and patients and found that they both... both these categories are excited about Clascoterone Solution for AGA. Healthcare providers were particularly receptive to the product profile, and they emphasized the novel mechanism of action and the impressive clinical before and after photos. All the providers specialties that we did research with suggested high utilization, with the reported option in over 60% of male patients and 50% of female patients. And they reported high adoption rates that would take and replace finasteride and minoxidil, equally. You can see some of the comments that they've made on the slide here. I'm excited about Breezula; we haven't had anything innovative in a long time. I've never been able to give female patients something that could really fix their issue. This product could give a lot of hope to female AGA patients.

Now, we also tested the profile with Rogaine patients or minoxidil patients, and nearly half of these patients indicated that they will at least be highly likely to request Clascoterone solution from their physician. We also tested the cash pay potential for pricing with patients and we found that, that our product could likely be priced like other cash pay lifestyle drugs in the marketplace regardless of indication for between 100 and 200 Dollars per month.

This ends my comments here on the commercial side of the business. And now, I will turn the financial overview section over to Chris Tanner.

Chris Tanner

Thank you, Diana. I think we discussed most of it already in the past. In essence, we've raised 750’000 shares... issued 750’000 shares raising a small capital increase. We did this small because we felt it made more sense to wait until we have the approval of Winlevi before doing another transaction. At the present, we're aware that the present cash position of 8 million and the 6 million undrawn credit facility is not sufficient to finance the either an acquisition on the one hand, or the building up of the organization ourselves, but we would delay any further capital market transactions until post approval. What we're also doing is instead of... as an alternative we are considering various non-dilute financings. In the U.S., these are typically known as, royalty type financings. In essence, it is a financing that is linked, where the repayment is linked to the revenue streams of the product.

There is quite a large market and a number of players in this market. This is one of the alternatives that we may be considering for financing down the line. This of course, is all in conjunction and depending upon what is going to be happening on the static side.

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I... whether we acquired somebody or whether we merge somebody or what other strategic alternatives we finally decide to pursue individually. It doesn't make sense to do these upfront. I think we need to organize everything in such a way that we're ready to pull the trigger when we're there. So this is what we're going to be doing in the next few weeks.

Diana Harbort

Thank you, Chris. And as we wrap this up. On Slide 37, I list here some of the upcoming milestones. Of course, the most of which... the most important of which is our PDUFA date here coming up within the next month on August 27th. Followed by our launch... the launch of Clascoterone Cream, which I said would be planning a market access launch first followed by a sales launch next year.

We are working, of course from a milestone perspective to finalize the special protocol assessment with the FDA on the Phase III program for Clascoterone solution in men. And, as far as, the Clascoterone solution in females will be completing the enrollment in September and announcing the top line results for that Phase II program in the second quarter of next year.

That is the end of our prepared comments, and we look forward to receiving any questions.

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 who has a question may press * and 1 at this time.

The first question comes from Ram Selvaraju from HC Wainwright. Please go ahead.

Blair Cohen

Hi, this is Blair Cohen on for Ram. Just a couple of questions from me. First, I want to clarify something you said on the call. For the enrollment for the Phase II in females, you said the enrollment is now 180, not 165?

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Diana Harbort
Correct.

Blair Cohen
And how many in screening still?

Chris Tanner
At the moment in screening, we have other 25 subjects, that's why I told that you think by September to be able to close all the enrollment.

Blair Cohen
Okay. And for the NDA filings with all the data published in the JAAD paper included in that filing?

Diana Harbort
Yes, the NDA, of course, the clinical data is quite comprehensive, you could imagine in the new drug application, but the JAAD and the JAMA article... articles, or publications disclose the pivotal to Phase III program for the pivotal results, as well as, the JAAD article discloses the results of the open label long term safety study, that's also part of the NDA.

Blair Cohen
Okay. And have you studied (unintelligible) discussions with the FDA yet?

Diana Harbort
Yes.

Blair Cohen
Okay. And then lastly, just regarding the commercial infrastructure. Are you still waiting till after the approval to start building up this commercial infrastructure? And then as far as, you know, I know your situation with sales reps is fluid, but how are you thinking about in a post-COVID environment, you know, how are you going to hire in a situation with face to face reps... face to face commercial may not really exist. And what's the difference between the rep situation that's going to happen post approval on September versus the full commercial launch in March?

Diana Harbort
Thank you for the question. Now, certainly commencing with our launch approach. The plans, and the execution around the salesforce happen post PDUFA not before.

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And frankly, I consider us to be in a very unique, and lucky position that are our decision around commercialization... by the way, whether that be by any of our strategic alternatives, or alone, allows us to make decisions around salesforce sizing and salesforce strategy in a world that takes into account the post-COVID situation. And I find that, that we're quite lucky to be able to do that, considering had we made the assumption and hired early in the pre-COVID world, because it's very clear that many dermatologists' offices are not seeing sales reps at this time. Although, they are accepting virtual engagements or frankly meeting sales reps outside of their offices. And what we've found just in the post-COVID world is that doctors actually have more time to engage in education and in CME, and they can do so in a way that's actually even more convenient for them.

In the comfort of their homes, they can participate in a virtual education forum, that allows them to get CME without taking substantial time away from their practice, flights, costs for hotels et cetera to attend some of these meetings. And what we found is, because our scientific data and this new MOA is so compelling and interesting to healthcare providers. They are predicting... we have had several advisory boards recently over Zoom with you know, 15 dermatologists at time talking about the data and their views of the product and in fact, their market environments. And they find our data compelling, so is that they would be very interested in virtual engagement as well. So I'll just sum this up by saying, I think it's... we are in a very lucky and unique position to be making commercialization decisions, taking into account the COVID world.

Now, you asked about the difference between a market access launch and a sales launch, and I thought... I think it's worth mentioning. A market access launch involves much different group than a sales launch, so a market access launch involves meetings with payers by contract national account managers who are me... who are... we have hired on our behalf to meet with payers to introduce the product. We can have those introductory clinical meetings now through PDUFA, and we'll continue to have them like I said over the next 2 months we've got many, many of these scheduled, where the focus is on the clinical data. So a medical review and a medical presentation of the clinical data. And we're able to engage these payers, because they're so interested in the MOA.

Now, contract negotiations would happen in the last quarter of this year, so that's what I mean by a market access launch which has done by a very different group, and a very small group versus a sales launch, which would be engagements with healthcare providers and doctors.

Blair Cohen

Okay. Thank you very much.

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Diana Harbort
You're welcome.

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

Philippa Gardner
Hi, there. I have a couple of questions, if I could, please. First of all, I just wanted to come to your comment on your fluid interactions with the FDA on Winlevi. I wanted to ask, has there been anything unexpected in any of those interactions that you've had with them. And then my second question was just a clarification point, some comments from Alessandro regarding the start of the Phase III trial in males of Breezula. I think, you said on your last call that you're expecting a first patients in first quarter, and I think earlier Alessandro said the trial to start at the end of this year. So when you talk about the trial starting at the end of this year, is that getting sites up and ready to receive patients or is that first patient in by the end of this year? Thank you.

Diana Harbort
You are welcome. You are welcome. So yes, we've had fluid interaction with the FDA, quite normal and customary, and we have not had anything unexpected. As far as the clarification around the Phase 3 in males, this is highly dependent on reaching agreement with the FDA on the special protocol assessment. So it is not going to be easy for us to give you a specific date until we have reached agreement with FDA on the SPA, and I just want to remind everybody in the context of the market, I explained to you that Finasteride and Minoxidil were approved 20 and 30 years ago.

So putting that into context, the FDA has not seen a Phase 3 program in androgenetic alopecia since iterations of those products were approved. And because of that, we think it's very wise reach agreement with that... with the FDA on our Phase 3 program before we embark on the trials. So we will... as soon we reach agreement with the FDA on the SPA, we will announce what our plans are, more specifically what the trial will look like and when we will enroll et cetera. That’s the reason why we can’t give you a precise date on when these trials will start because they will involve interaction with FDA.

Philippa Gardner
And can I just follow-up to that please, Diana, because you kind of sort of preempted my question, but I guess what is the main sort of point of discussion on the trial design? Is it the length of the end point or what is the main thing that needs to get sort of locked down still.

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Diana Harbort

Well, in reality in a special protocol assessment, many, many, many attributes are locked down with the FDA as you call it. So it's the typical... it's the typical... actually reveal the entire protocol length, number of patients, what are the end points, what's the... what is the active portion, what's the long-term follow up portion et cetera. So it's... it's basically the entire Phase 3 protocol, but please remember, there isn't quite as... I mean, if we go to and we compare this to acne, right, there is... and this is a very different case. FDA has seen numerous Phase 3 programs for acne over the years, whether they be of old products with new dosage form, size, strength and et cetera, but there has been a number of acne products, right, and so the Phase 3 protocol isn't so exotic, right. It is well worn path by many, many companies and many products. That is not true here because Minoxidil and Finasteride were approved quite a long time ago. And we think it's highly important as for a small company to de-risk our Phase 3 program by getting absolute clarity with the FDA on what they will require.

So we look forward once we have completed this negotiation with FDA and it could take a couple of rounds to share with you what our plans are just as soon as we have more specifics to share with you.

Philippa Gardner

That's great. Thank you very much.

Diana Harbort

You're welcome.

Operator

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

Bob Pooler

Hi Diana, few questions from me. Just following up on Breezula. On that Phase 3 program, do you have an estimated cost for that Phase 3 trial now?

Diana Harbort

Of course, we have you know looked at what the cost would be given our current assumptions and of course given as we blew out the financing needs of the company, but we won't be disclosing that at this time. We think it would be best to of course give an indication of that in the context of having made an agreement with the FDA on the protocol itself.

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Bob Pooler

Yes, that makes sense. Just on the... just on the finances there, could you provide some signs on the operating expense this year and also your current cash reach?

Diana Harbort

Can you repeat the first part of your question?

Bob Pooler

Yes, just guidance for this year on your operating expenses, so for the second half of the total year and also how is your cash reach?

Diana Harbort

So what I will say is that and before I turn it over to Chris, is that our operating expenses in the fourth quarter of this year will be highly dependent on our commercialization alternatives and we are advancing a number of these and we will later announce them after PDUFA, once we solidify them. So of course, the operating expenses in the fourth quarter of this year will be highly dependent on our commercialization strategy. So therefore, we can't issue a guidance on that. But just know that we have 8 million in cash and we also have a 6 million Dollar ability in loans in open line of credit, so we think of the available cash that the company has for the combination of the cash on hand plus our credit facility that is still open with Cosmo that would equal a total of then 8 plus 6 equals 14 million.

Bob Pooler

Okay. And then just on Winlevi, are you in discussion with consumer you were having discussions also with some of the major dermatology players. How are they going with those potential players and again, when would you expect to announce an agreement if it does happen. And of course, that’s post-Winlevi approval, but do you expect to announce that this year, or will be likely more in the early next year, if it happens?

Diana Harbort

Well, like I just mentioned, we have... we are advancing in number of alternatives simultaneously right now. And I would expect that we will have clarity and we will be able to update you after we have decided which route we will take. And I am hoping that that in fact will be this year.

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Bob Pooler

Okay. And then just one final question on Winlevi. On US approval, how fast could you actually start in the EU and also other countries.

Diana Harbort

Well, we have been concentrating in the first priority on the U.S. and that is because of the pricing in the U.S. compared to the pricing for acne products in other territories. So we have not been prioritizing in EU filing though it is possible we could pursue that. And that's specifically because of the low pricing for acne products in the EU as to make it not a huge priority for us at the time, more our company needs to be focused on the absolute most important value drivers to its shareholders.

Bob Pooler

Okay. Thank you. That’s clear and fingers crossed for U.S. approval Winlevi at the end of August.

Diana Harbort

Thank you.

Operator

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

Barbora Blaha

Hi, thank you for taking my question. I have 2 quick questions. One is, has the facility in Milan already being inspected by the FDA or if not, when do you expect this inspection?

Diana Harbort

Is there another question too?

Barbora Blaha

Yes, then it is a follow-up on the cash because Chris said that you paid back the loan to Cosmo but then you said that you are... you have only 6 million available from the loan, so could you theoretically use the 20 million, the entire original amount or do you have the 6 million left because you paid back?

Diana Harbort

Thank you. So on the facility in Milan, we... actually the FDA had an inspection scheduled in May and they cancelled the inspection because of COVID.

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They have instead requested documentation in lieu of or in advance of a preapproval inspection. We have had multiple back and forth with the FDA on the documents, normal and customary, and then it's looking to us at this time that they may not inspect the Cosmo facility. And just to give you a background that Cosmo facility has been manufacturing pharmaceutical products for several countries around the world for some time, and has in fact had regulatory inspections by multiple regulatory bodies including the U.S. FDA. So it is not a new facility. I mean it is not an unknown facility to either the FDA or other regulatory authorities.

And Chris, I will turn the direction to you over to answer some cash question on the available standing loan facility with Cosmo.

Chris Tanner

Yes, I think Barbora, we have to look at the ability of Cosmo to provide financing sort of like a backstop facility, right. We are at the present time considering the financing, as I said before, longer term royalty type financings respectively in conjunction with strategic transactions going to the capital markets and we... as a consequence, that is what we are going to be relying on if we need financing down the line and not on the Cosmo facilities. All the more since if we would be having both, we have to be aware, if we would be having a royalty financing then the Cosmo facility would be subordinated to this and then we would... it would need to be cancelled anyway, right. Because most of the royalty type financings require that they have a first lien on revenue streams and this of course would make having an additional classical corporate banking facility very difficult. So we are just moving this ahead, and more or less in parallel we know that in the case of need. Cosmo is there to provide additional funds, but in principle what we have right now is what you can see and what we have announced to you.

Barbora Blaha

Okay, thanks.

Operator

The next question comes from the Zain Kazi from Minteiliar Corporation. Please go ahead.

Zain Kazi

Hi, there. Just a quick question in relation to the clascoterone cream 1% launched timing. With market access plans to Quarter 4 in 2020, and sales launch in March 2021. Question was in relation to revenue and when you anticipate the product generating revenue. And secondly, at what point in that process will medical professionals be able to actually prescribe that product?

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Diana Harbort

So, in the lunch time I described to you which is the market access launch first followed by the sales launch in March, in that situation the revenue would not be occurring until March.

Zain Kazi

And in terms of the dermatologists having the ability to prescribe the drugs that you are saying that would be post-March? Is that correct or?

Diana Harbort

Correct, yes.

Zain Kazi

Yes, okay. Thank you. Thanks for answering.

Diana Harbort

You're welcome.

Operator

As a reminder, if you wish to register for a question. Please press * and 1. The next question comes from Wilbur Elliot from Raymond James. Please go ahead.

Wilbur Elliot

Hi, good morning or good afternoon. Hi, Diana, how are you? I want to ask about some of the data you provided with respect to previous launch analogs, I think it was Slide 27, of the deck. Any one of those in particular you think stands out has been a better competitor for clascoterone, upon launch just thinking about Aczone and Epiduo, both of those products generated relatively high numbers in the first year versus their peak, and I would expect, you know, your launch to encounter a little bit slower built kind of given the uniqueness of the product and for the new MOA, but just want to get your thoughts around that?

Diana Harbort

So, what's interesting about Aczone in the Epiduo is there launch has occurred in a situation where market access was quite different at the time. And specifically as it relates to the net sales the gross to net on those products during the years... the early years of launch, would likely be different than the more aggressive growth to net that are seen in the early launch period for most any product in the U.S., market.

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But, to be clear, as it relates to the overall interests and the overall reception that we are getting from healthcare providers when they predicted their use, the market share that they appeared to be willing to give Winlevi quite quickly is so large that we are slicing it by 60%, because it's so large.

And we think, of course, that's driven by... this is a first new MOA in a long time they know acne is hormonally driven. And they have not had a product that could be used in such a topical way, meaning a way that could be used in both males and females. And we also know just to be clear to put this in context Spironolactone does over 2 million prescriptions a year. So if I would have put that on this slide for peak sales. That would work the size of this products, and that's an off label oral anti-androgen use for acne. So to be clear, perhaps in the beginning the update could be slower Aczone or Epiduo clearly. We haven't the launched the product yet. We don't have our salesforce yet. But, what we can tell you is that the reception is so overwhelming positive that's its predicting a product of the size for Epiduo and Aczone.

Wilbur Elliot
Okay. Thank you. If I could just follow up with respect to Spironolactone other than just cost and coverage issues, any other impediments in terms of (unintelligible) to covert from that oral to the topical?

Diana Harbort
Well, I'm glad you mentioned that, because I just want to be more clear, because it brings up the point about what we are... how we are positioning the product. Oral Spironolactone is used in females for what is so-called hormonal acne, which is actually a misnomer because all acne has a hormonal trigger, and if you actually look at the pathogenesis of acne you see that these... that androgens have a major effect on the sebaceous gland, causing increase seam production and in increase inflammation. And we can see with our mechanism of action that we have a very powerful MOA in affecting that sebaceous gland function in both the production of lipids as also in... as an anti-inflammatory and you can actually see by our Phase 3 data. But to be clear, we are positioning as our doctors have told us that Winlevi should be positioned for both males and females for the treatment of acne.

So, just to put that in context, also just understanding that there has been quite a bit of antibiotics stewardship that is an interest by the specialty, by all... by doctors in general regardless of disease to use less antibiotics. And this, of course, has positively benefitted Oral Spironolactone, where instead of patients to moving oral antibiotics that is the female to oral antibiotics are being moved to oral Spironolactone.

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But, to be clear we are not targeting just the conversion of Spironolactone patients to Winlevi, we think that is actually not the most relevant and not the most broad positioning. I mean, we have been encouraged by doctors to position our oral anti-androgen receptor inhibitor for both males and females.

Wilbur Elliot

Got it. And just one last follow-up if I may. You had mentioned and touched upon the, you know, current list price dynamics in the derms space and relatively high growth in that deductions out there currently guess as you are beginning to have conversations with payers and thinking about ultimately net price of the product. Any thought that this could actually command somewhat of a premium on ASP or net basis versus currently market products just given the novelty of the MOA?

Diana Harbort

So we of course will have those sort of conversations publicly after we are launching the product and announcing our WAC and then talking about what we are expecting in gross to net after we have had negotiations with payers. But, what is clear and we've been very careful in our labeling with FDA that this is the first in class. And so, that from a compendia standpoint it will standalone as an androgen receptor inhibitor. And we think that's importance so that it's not referenced price to other drugs and because its own unique class. So we've been mindful of this dynamics from the very beginning as we began the drafting of the label itself. And we will look forward to updating you publicly once, of course, we have launched and have more information to share in this regard.

But, to be clear, our market... it's very important we understand that it's one thing to generate prescriptions, it's another thing to make sure these prescriptions get filled. And so, we are clearly understanding as we are meeting with payers now, what their requirements are, and we are also of course establishing patient access programs et cetera that are also important components of gross to net, but are also very important to make sure that when a prescription is generated that it actually gets filled. But, as you know, this is a process that takes some time, and also reflects in gross to net improvements overtime. That's the reason why we are beginning our launch first with the market excellence launch, followed by the sales launch.

Wilbur Elliot

Thank you.

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Diana Harbort

You're welcome.

Operator

Once again, to ask a question, please press * and 1. There are no further questions at this time.

Diana Harbort

Well, thank you everybody. We appreciate your ongoing interests in Cassiopea. And we again continue to wish you and your family and your organizations good health in these times. And we look forward to interacting again hopefully on or about August 27th. 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.

- END -

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