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This filing relates to the proposed merger of Foamix Pharmaceuticals Ltd., a company incorporated under the laws of the State of Israel ("Foamix"), with Giants Merger Subsidiary Ltd. ("Merger Sub"), a company incorporated under the laws of the State of Israel and a direct, wholly-owned subsidiary of Menlo Therapeutics Inc., a Delaware corporation ("Menlo"), pursuant to the terms of that certain Agreement and Plan of Merger, dated as of November 10, 2019, by and among Menlo, Merger Sub and Foamix.



Foamix Pharmaceuticals Inc.

Foamix Pharmaceuticals and Menlo Therapeutics Merger Call

November 11, 2019

CORPORATE PARTICIPANTS

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CONFERENCE CALL PARTICIPANTS

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PRESENTATION

Operator:

Good morning. Welcome to the Foamix conference call to discuss the merger of Foamix Pharmaceuticals with Menlo Therapeutics. At this time, all participants are in a listen-only mode. Following the Company's opening remarks we will open the call for your questions. Please be advised that this call is being recorded at the Company's request.

I will now turn the call over to Michael Woods at LifeSci Advisors. Please go ahead.

Michael Wood:

Thank you. Good morning everyone and thank you for joining us this morning. To note, there are slides accompanying today's call. These can be viewed by logging into the webcast and the link is on the Investor's page of the Foamix corporate website under Upcoming Events. The link is also in both press releases.

Before we begin the formal remarks, let me remind you that some of the information in the news release and on this conference call may contain forward-looking statements that involve risks, uncertainties or assumptions that are difficult to predict. I would draw your attention to language on Slide 2 on the slide presentation describing those risks.

The call is being recorded and a replay will be available on each company's website. For further information related to today's announcement you may visit the Foamix website at Foamix.com and the Menlo Therapeutics website at menlotherapeutics.com.

At this time I'd like to turn the call over to Dave Domzalski, Chief Executive Officer of Foamix. Dave, please go ahead.

David Domzalski:

Thank you, Michael. Good morning everyone and welcome to the conference call.

We're very excited to be here this morning to announce the proposed merger between Foamix and Menlo Therapeutics. We issued two press releases this morning, the first announcing the intention of the two companies to merge; the second is on Foamix's earnings results for the three and nine months ending September 30, 2019. If you did not yet receive these press releases, they are available on the Investor Relations page of the Foamix website at www.Foamix.com. The merger press release is also available on the Menlo website at www.menlotherapeutics.com.

Joining me on the call today is Steve Basta, CEO of Menlo. From the Foamix team we have Dr. Ian Stuart, Chief Scientific Officer, and Matt Wiley, Chief Commercial Officer, both of whom will be available to answer questions during the Q&A session. In addition, Ilan Hadar, our Chief Financial Officer is on the call, should you have any questions regarding the financial results we are reporting today.

Let's get started. If you go to Slide 3, Slide 3 is a slide that highlights the transactions of the deal. The merger will create what we believe will be a stronger dermatology company with an enhanced pipeline, an improved balance sheet with a cash runway extended now through the first half of 2021 after the transaction close.

The late-stage asset we are gaining is serlopitant, a highly selective oral small molecule NK1 receptor antagonist, which is being developed for various pruritic or itch conditions. Menlo has already completed enrollment for two Phase 3 trials for pruritis associated with Prurigo Nodularis or PN, and results are expected in March or April of next year.

PN is an orphan like disease with approximately 200,000 patients actively seeking treatment and an estimated prevalence of approximately 500,000 to 1 million patients in the U.S. alone. Currently, there are no FDA approved treatments for this disease and dermatologists see an acute need for new therapy.

Serlopitant was granted breakthrough therapy designation for pruritis associated with PN in January of this year, which reflects a significant unmet need for treatment in this indication. Our primary focus will remain on the PN indication near term, but we have optionality to pursue other indications in the future.

In summary, we believe the combination of these two companies will create a new leader in dermatology.

We are combining a platform-based company with an indication-based company that will result in a more complete and diversified product portfolio with a pipeline to support franchise durability.

Lastly, in the merger, the top parent company will be Menlo domiciled in Delaware. So as I'll further describe, our combined company will be headquartered in the U.S. rather than in Israel, but we will still have an Israeli subsidiary.

Why did we do this deal? I am now on Slide 4. Our combination is expected to drive greater future earnings momentum with the potential for three product launches within the next 24 months, each potentially contributing well in excess of \$100 million in revenue. Combining both companies should drive the new entity to greater profitability than each as a standalone. We see clear operational synergies in this merger with the opportunity to leverage our commercial infrastructure across multiple product launches.

There is approximately an 80% overlap within our sales force alignment for healthcare providers treating acne, rosacea and PN. Leveraging our sales force and our commercial infrastructure is a key to faster revenue ramp and improved profitability for the company.

We hope to be very busy with new product launches starting with our recently approved topical foam product AMZEEQ, the first topical minocycline for treating acne, and we are planning to launch this product in January of next year. FMX103, which is a topical minocycline foam for treating moderate to severe rosacea, this drug has a PDUFA date in June of next year and assuming approval we would anticipate a launch in the fourth quarter. Serlopitant for PN, assuming positive Phase 3 results in March or April of next year, we would anticipate an NDA filing for this product in the second half of next year and a potential launch in the second half of 2021.

Lastly, we expect significant cost synergies, improved balance sheets and an extended cash runway. We anticipate savings of over \$50 million per year versus the separate companies' independent plans beginning in 2021 by eliminating or avoiding the creation of duplicate functions and infrastructure.

With the additional cash available for Menlo at the estimated time of closing, which we anticipate to late first quarter or early second quarter of next year, we expect the combined entity to then have a cash runway through the first half of 2021.

This deal, the terms of which are described here now on Slide 5, has been structured as a stock-for-stock transaction such that Foamix shareholders have appropriated downside protection in the event either of the two Phase 3 clinical trials of serlopitant fail in PN, while Menlo shareholders receive a premium to their current market cap if the Phase 3 trials are successful and are able to meaningfully participate in the future potential upside of serlopitant and the Foamix programs.

The transaction structure also reflects a reverse merger where Menlo will be the technical acquirer, which will result in redomiciling Foamix to Delaware.

Each Foamix shareholder will receive Menlo shares in a ratio that is dependent on the Phase 3 results from the serlopitant trials, expected again in May or April of next year.

The base case for the deal assumes positive Phase 3 data for PN in both trials. Under this scenario, Menlo shareholders will own 41% of the combined company and Foamix shareholders will own 59% of the company. Now, if one Phase 3 trial successfully achieves its primary endpoints by the end of May while the second does not, Foamix shareholders will then receive additional shares such that Menlo shareholders are reduced to 24% ownership in the combined company and Foamix would then own 76% of the company. If both Phase 3 trials fail to meet their primary endpoints by the end of May of next year, Foamix shareholders will receive additional shares such that Menlo shareholders are reduced to 18% ownership in the combined company and Foamix would then own 82% of the company.

The cash position of the combined companies is around \$169 million as of the end of the third quarter, and again, with the additional cash available from Menlo at the estimated time of closing, we expect the combined entity to have a cash runway through the first half of 2021.

If the Phase 3 data are in before closing, or we are closing after May 31 of last year, the exchange ratio at closing will be adjusted to reflect what I just walked through. If we close before then, Foamix shareholders will receive a contingent stock rights at closing that will provide the potential to receive additional shares to reflect the potential Phase 3 outcomes I just described.

The Board of Directors of the combined company will consist of five Foamix members and two members from Menlo. Foamix will run the new merged company, which will be headquartered in New Jersey. Again, the transaction is expected to close by late first quarter or early second quarter next year.

The assets of the combined company are laid out here on Slide 6. We were extremely excited to announce on October 18th that Foamix received FDA approval for AMZEEQ, our 4% minocycline foam which is the first topical minocycline product for the treatment of moderate to severe acne. Pre-launch activities are in high gear as final preparation is taking place for our launch, again, which we anticipate at the turn of the New Year in January.

FMX103 is a 1.5% minocycline foam product. We have filed an NDA for this product for papulopustular rosacea. This NDA was also recently accepted in October and the PDUFA date has been set for June 2, 2020.

FCD105 is our combination adapalene and minocycline topical foam. We began enrolling patients in a Phase 2 study for moderate to severe acne and we expect top line results mid next year.

The addition of serlopitant means that we are strengthening our topical portfolio with a potentially innovative, high value, oral systemic drug. The lead indication, as I shared, is for the treatment of pruritis associated with Prurigo Nodularis or PN. Enrollment in two Phase 3 studies was just completed and the top line Phase 3 results are expected in March or April of next year. Menlo is also currently evaluating serlopitant for CPUO, or chronic pruritis of unknown origin in a Phase 2 study with expected results in January or February of next year. Additionally, positive Phase 2 results were also achieved for psoriasis-related pruritis.

While our commercial team focuses on the AMZEEQ launch in January, we will also obviously have a busy calendar of pipeline catalysts throughout the year.

We have presented here some background on Prurigo Nodularis or PN on Slide 7. This disease presents clinically as intensely itchy nodules typically found on the arms, legs and trunk, and results from a vicious cycle of repeated itching and scratching. The itching sensation is extreme and can lead to scratching to the point of bleeding and pain. The disease primarily affects older adults. Symptoms are commonly managed with topical agents such as steroids but with limited effectiveness. I want to stress again there are no approved treatments in the U.S. or the E.U. Serlopitant is a once daily oral NK1 small molecule receptor antagonist. The mechanistic rationale for pursuing this indication is that SP binding of the NK1 receptor has been shown to be a key mediator of sensory nerve signaling, including the itch/scratch reflex.

As I shared earlier, serlopitant has been granted breakthrough therapy designation from the FDA. Breakthrough therapy designation is granted to expedite the development and review process of drugs intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over what's currently available.

If approved, serlopitant has the potential to be the first product ever approved for the treatment of PN. Obviously, we are very excited about the prospects for another first for our company, having just received approval of the first topical minocycline for the treatment of acne.

Menlo already reported positive Phase 2 data from the 127 patient trial of serlopitant in PN. As we were giving consideration to potential merging the two companies, the data presented on Slide 8 is one of the things that got us particularly excited. Menlo's Phase 2 PN trial met its primary and multiple secondary efficacy endpoints, demonstrating significant pruritis reduction. On the primary endpoint, serlopitant demonstrated a statistically significant improvement from baseline compared to placebo at 8 weeks using the Average Itch Visual Analog Scale with statistical separation as early as the two-week time point. Importantly, the 5 milligram dose also achieved statistically significant results for the four-point responder analysis on the Worst Itch Numeric Rating Scale or NRS. This same Worst Itch NRS Responder Analysis is being used as the primary endpoint in the ongoing Phase 3 trials.

The impressive results obtained from this study demonstrated that approximately half of patients experience clinically meaningful improvement in itch when measured using a minimum 4 point improvement on the Worst Itch NRS at Week 8. In addition, the overall safety profile of serlopitant was found to be favorable to support a once daily dosing regimen.

Recently, Menlo announced completion of enrollment in two double-blind Phase 3 studies evaluating the safety and efficacy of serlopitant for the treatment of itch associated with PN. These are Studies 105 and 106. In addition, Study 107 is a 52-week open label long-term safety study running concurrently with the double-blind studies. To date, 90% of patients in the 105 and 106 trials have elected to roll into the 52-week open label study and we view that as a positive signal.

The key takeaways from the Phase 2 programs have been applied to the Phase 3 PN program to further support probability of success. For example, additional rigor has been placed on ensuring that patients enrolling in the study have sustained high levels of itch prior to enrollment. The apparent continued development of efficacy seen in the Phase 2 study is reflected now in the longer treatment duration in Phase 3. The studies are obviously also appropriately sized based on further interrogation of Menlo's completed Phase 2 study results.

We believe that these actions coupled with increased engagement with FDA afforded through the breakthrough therapy designation provides for a meaningful probability of success for the Phase 3 program.

We're excited to work with our colleagues at Menlo in completing this Phase 3 program with a view to report top line results from Studies 105 and 106 in March or April of next year. After that, assuming success, we plan to submit the corresponding NDA to the FDA in the second half of next year.

Moving now to the Foamix assets, I'll move through Slides 10 and 11.

AMZEEQ is the topical foam formulation of minocycline that was FDA approved for the treatment of moderate to severe acne in October. Our molecule stabilizing technology has allowed the company to create the first topical formulation of minocycline which provides the potential for improved tolerability in our products. Please refer to the product label for additional details on efficacy and safety.

We have been diligently working to prepare for our launch in acne. We have nearly completed the hiring of all sales colleagues and plan to host an AMZEEQ launch meeting later in January.

If we go to Slide 12, this is our first—this is a review of our efficacy results for moderate to severe acne. Slide 12 outlines one of our first two primary endpoints which is the reduction inflammatory lesion count. As you can see, in both Study 2 and Study 3, we demonstrated strong statistical significance in reducing inflammatory lesions with AMZEEQ versus our vehicle.

If you look to Slide 13, that's the second of our two-co-primary endpoints, the more subjective endpoint of IGA treatment success at Week 12. Again, we show high statistical significance and improvement of IGA success scores against vehicle. I think of particular note, this is a high bar in treatment success—to achieve treatment success. The patients were enrolled and classified on a 6-point scale, 0 being clear and 6 being very severe. Patients were enrolled as either a Grade 3 or a Grade 4 and to achieve success patients had to have at least a 2-grade point reduction after 12 weeks and achieve a score of 0 or 1. So, quite a high bar and we're obviously quite pleased with the results that we achieved.

According to our clinical trials, AMZEEQ was demonstrated to be safe and well tolerated, and for details on this I will refer you to our most recent Investor Relations presentation that can be found on our website at www.foamix.com, as well as to information on the drug's prescription label.

Moving to FMX103, again, similar strong results and two-co-primary endpoints that again were quite similar. Slide 14 reflects the first-co-primary endpoint which again is an absolute change of inflammatory lesion count at Week 12. We see once again high statistical significance and reduction of inflammatory lesions for patients with papulopustular rosacea versus vehicle.

Again, the second co-primary endpoint is IGA treatment success at Week 12. Strong statistical significance here. Of particular note, approximately half of all patients were designated as clear or almost clear at the end of once-daily treatment of FMX103 at Week 12.

With respect to tolerability, the incidence of adverse events reported for FMX103 in Phase 3 was comparable to that of vehicle. They are also working on pre-launch activities for FMX103 in rosacea ahead of our June 2, 2020 PDUFA. We'll keep you posted.

Moving now to the commercial opportunity for our products. On Slide 17 is an overview of the commercial opportunity for PN. We estimate approximately 500,000 to 1 million U.S. patients with PN of which 200,000 are treated each year. Given the high disease burden of PN and the lack of existing treatment, the market is immediately accessible and attractive for the first drug to be approved in this condition. There are approximately 5,000 dermatologists who treat approximately 75% of these patients, most of whom could be reached by our AMZEEQ sales force.

We believe the orphan-like nature of the disease creates a compelling clinical and commercial opportunity. We would also explore the opportunity for international partnering to further maximize the value of the serlopitant product.

Moving on to Slide 18, this gives you a feel for the size of the acne market. It's a very large market. We see roughly 18 million prescription on an annualized basis, roughly a 70% to 30% split generic prescriptions versus branded prescriptions, however it's the exact opposite when you look at the revenue size of the market. It's roughly a \$5 billion marketplace split 30% generic and approximately 70% branded.

Rosacea, although smaller—about a third of the size of the acne market—again, is still quite considerable and an unsatisfied marketplace with limited development efforts in this space, so we view from a commercial perspective both the acne marketplace as well as rosacea, and obviously now the PN marketplace, are quite attractive to us and underserved.

If we move to Slide 20, it gives you a feel for our targeting approach for the acne space, specifically for AMZEEQ. There are roughly 170,000 or so prescribers that treat acne in the United States over the course of a year, but of those 170,000 prescribers 3% or approximately 6,000 healthcare providers cover nearly two-thirds of all patients that suffer from acne and three-quarters of the prescription volume for acne, so this is obviously a space that we could be very efficient from a commercialization perspective.

Slide 21 gives you a sense for where these patients are. This is a heat map. The green shows you where the bulk of the patient population is, and the grey shading outlines the field territory structures that we have or we'll be planning to deploy once we launch the drug the beginning of next year. So, again, we capture where the patients are residing.

Slide 22 speaks to the high percentage overlap of patient coverage across acne, rosacea and PN. The same sales footprint we will deploy to launch AMZEEQ will be leveraged to launch FMX103 in rosacea later in 2020, assuming an approval, as well as serlopitant in 2021, again, assuming an approval. Our market research suggests an approximately 80% sales force coverage overlap between AMZEEQ and FMX103 and PN.

If we move to Slide 23, we believe the entire Foamix team and its commercial and scientific infrastructure can be leveraged across all of these products, creating increased operational efficiency, which should drive higher profitability over time.

Slide 24 lays out the expected news flow over the next 12 months. It's quite a busy calendar over the next year beginning with the planned commercial launch of AMZEEQ in January and serlopitant Phase 2 data readout in CPUO about a month or so after that, in January or February. Then serlopitant Phase 3 data readout in PN in March or April, and then the FMX103 PDUFA for rosacea which is scheduled for June 2 of next year. We also anticipate Phase 2 data readout from FCD105 in moderate to severe acne around the midpoint of next year. Assuming approved, the launch of FMX103 in rosacea then towards the fourth quarter of next year as well as the NDA filing of serlopitant in pruritis associated with PN during the second half of 2020, assuming positive Phase 3 results.

To conclude, and I'm now on Slide 25, we are incredibly enthusiastic about what we view as a transformational deal that will create a scaled dermatology company with an enhanced financial profile. Serlopitant is an innovative Phase 3 asset with a near-term data readout. The drug has breakthrough therapy designation and has the potential to address a highly underserved market.

We believe the merger has sound strategic and financial rationale as it creates opportunities to leverage both our commercial and scientific infrastructure as well as extends our cash runway now through the first half of 2021.

As we examine the dermatology landscape, subscale companies with limited product offerings and pipeline have struggled and the sector will likely face increased consolidation. Foamix is excited to be taking a leadership position here. Following the merger, Foamix will have one differentiated commercial stage product in acne and the opportunity to launch two additional drugs over the next 24 months, therefore creating increased operational leverage for the company.

Additionally, this transaction diversifies our 505(b)2 focused development approach towards increased innovation as serlopitant is a new chemical entity that has not been approved for any other indications.

All of this, we believe, can provide significant long-term value to our shareholders.

That concludes my prepared remarks. We're ready to open up the call to Q&A now. I expect that most of your questions will be regarding the transaction we're announcing, but as I said, if you have any questions to ask about the Foamix's third quarter financials or about other recent developments, we'd be happy to take those also. I'll turn it back to the Operator to coordinate any questions.

Operator:

Thank you. If you would like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Our first question is from Louise Chen of Cantor Fitzgerald. Please proceed.

Louise Chen:

Hi. Congratulations on the deal. Thanks for taking my questions here. I had a few. The first question I had is can you talk about the build-up of your joint commercial infrastructure? How many sales reps there will be, the marketing costs, the ad campaign. Then the second question I had was on AMZEEQ, your expectations for uptake, reimbursement, patient co-pay assistance, anything along those lines. The last question I had here was on the CPUO study, the Phase 2 data that's coming up. Since that has been, based on our diligence, a very large indication potentially and maybe even larger than PN, just curious if that turns out to be positive if there's any renegotiation of the deal terms or what's in the agreement for that. Thank you.

David Domzalski:

Thanks, Louise. Let's talk about the commercial buildout. I should turn it over to Matt Wiley, our Chief Commercial Officer. Matt?

Matt Wiley:

Yes, thanks David and thanks Louise. We have better than 90% of our sales infrastructure now in place. We expect the balance of that to be ready prior to launch. That team has kicked off its home study and training beginning last week. It will be training through the balance of this year.

As Dave said in the prepared remarks, we are going to have our launch meeting in early January and then the sales team will be out promoting AMZEEQ.

Regarding the question about market access and co-pay, we haven't guided on uptake for AMZEEQ. Our Market Access team was active at the AMCP meeting a couple of weeks ago and engaging with payers. We expect our compendia load later this month which will also disclose our final pricing from a wholesale acquisition cost perspective and then that typically starts the clock for how payers then put products in the queue for review, but we do have ongoing meetings and negotiations with plans today.

David Domzalski:

Thanks. I'll offer a few comments on the upcoming CPUO study and then I'll turn it over to Steve. Obviously we look forward to the results at the turn of the year. We're obviously bullish on the prospects of that being a successful study outcome. I'll reiterate near-term focus will be on PN as it is really the most advanced product. What we'll be focusing on is keeping R&D spend locked in on the PN indication and, quite frankly, most of that spend is winding down, so we couple that with our R&D spend that's basically complete for FMX103. We're going to focus as we move forward all prepared commercially for AMZEEQ, FMX103 and all the dominant work for PN.

I think this goes to the core tenet of the deal which is leveraging our existing infrastructure for AMZEEQ for three potential launches over the course of the next 24 months. Clearly we believe there's a lot of inherent strategic value for other indications for serlopitant and we will obviously be thoughtful about timing and spend in the near term in light of the significant revenue opportunities that we view for AMZEEQ, 103 and a PN indication.

I think to answer your question is there ability to change the structure of the deal, the short answer to that is no. The deal has been well thought out to provide meaningful upside potential to Menlo shareholders assuming a positive Phase 3 readout in PN, but additionally there's protection for Foamix shareholders to the downside in the case that there happens to be mixed results or negative results.

Certainly how we view it, collectively as management teams, we're certainly planning for success. We feel quite good about the probability of success for obviously the PN indication and CPUO indication. I'll turn it over to Steve for any additional thoughts or comments.

Steve Basta:

Yes, Louise. Thank you, Dave. Louise, one of the things you've correctly observed is the CPUO market opportunity I think is a really significant market opportunity relative to the PN opportunity is a really significant market opportunity. PN is the nearer-term commercialization event and so clearly as the commercial (inaudible) thinking about the indication launches, thinking about acne and thinking about rosacea and thinking about PN as the near-term launches, that's sort of the core commercial focus to how we get to profitability. CPUO provides one of the longer-term growth opportunities and I think creates really significant upside.

How we thought about it from the Menlo perspective in terms of the value creation that the CPUO Phase 2 data brings is really embedded in the premium that already exists in the transaction. We are, A, getting a premium to the current market cap relative ratio and that's sort of the embedded value of the program including the upside potential for the multiple additional indications, and we're going to own 41% of the company going forward, so if there is value to be created from the multiple additional indications then Menlo shareholders participate in a really meaningful way in the context of the upside from those programs, while being in a structure that because of the leverage of having multiple products can achieve profitability both sooner and to a greater degree than the companies could separately and therefore there's future opportunity to pursue the upside opportunity in some future products and future indications without having to experience the dilution that it would take for us to finance all of those individually as separate companies. So there's already an embedded premium that captures the value of the program and there is significant upside to be shared by the Menlo shareholders because we're going to own a significant stake in the combined company.

Louise Chen:

Okay, great. Thank you and congrats again.

Steve Basta:

Thank you.

Operator:

Our next question is from David Amsellem with Piper Jaffray. Please proceed.

David Amsellem:

Thanks. Just have a couple and this is for either Dave or for Steve. There's multiple indications, obviously, for serlopitant, so, longer term, how do you think about the potential expansion of the sales infrastructure for, say, an indication like psoriasis where there may be some primary care targets in the overall physician audience? That's number one.

Number two is as it relates to pricing of serlopitant—this is a question for you, Dave, and I know maybe I'm putting you on the spot here, but the company, Menlo, recently had an Investor Day and they talked about pricing, so I was wondering to get your thoughts, pick your brain on your thoughts about the molecule and how you think about appropriate pricing. Thanks.

David Domzalski:

Sure. Thanks, David. In terms of the commercial infrastructure, again, that's one of the key tenets to this deal is that we've got a sales force that we'll be launching with AMZEEQ, about 50 representatives or so. We've already talked that there's about an 80% overlap for the patients, the targets for PN as well as for rosacea, so we really envision significant cost synergies and operational efficiency as we would look to launch these products over the next couple of years.

I think as Steve alluded to, then we start thinking what's coming behind and that's one of the beauties of the deal is that we've got immediate or certainly in the near term pretty significant product launches, and then we've got durability of each franchise through other potential indications such as CPUO and the like.

We'll certainly cross that bridge as we move down the line and what that looks like in terms of a commercial infrastructure. As you rightly outline, there's potential to move into the larger mass market and we'll have to consider how best to do that when we get to that point. One of the key things, though, is that we'll be launching these products—assuming they're approved—over the next three years and by leveraging the infrastructure we have we can move towards profitability we think much more quickly than trying to do this as individual standalone companies.

I don't know, Steve, if you have anything to add.

Steve Basta:

Thanks, David. One additional thought in the context of the synergy of the call points, you may recall from our Investor Day presentation, David, that the core call point for CPUO is in fact in the dermatology channel, so while it is a broader population of patients, they are still primarily being referred to dermatologists, so the same sales call point that is happening for the Foamix product and for the PN product, as expand into CPUO or psoriasis or other future indications, there's still the commonality of the core call point being dermatology as the leverageable revenue opportunity that takes advantage of the existing commercial infrastructure that is being put in place.

David Domzalski:

Then, David, the other one that you inquired about, price, I'll turn it over to Matt. Obviously, we've put a lot of thought and we've obviously listened in on the Investor Day presentation and we spend a lot of time talking with the team at Menlo, so I'll turn it to Matt to offer some thoughts on pricing.

Matt Wiley:

Thanks, David. I think it's still a bit premature to put a pin in the map on price. I think Karen Smith did a really nice job during their R&D Day explaining for those products with unmet needs how a population of the patient size can drive the price and I think we're aligned with that thinking.

David Domzalski:

It's clearly a very motivated patient base and I think that allows us to have a lot of flexibility in how (inaudible) the product is priced and I think because of that and I think because of the structure here is that this product can be quite profitable and meaningful to the overall bottom line of the company.

David Amsellem:

Thanks. Appreciate the insights.

Male Speaker:

You got it.

Male Speaker:

Thanks, David.

Operator:

Our next question is from Ken Cacciatore with Cowen & Company. Please proceed.

Ken Cacciatore:

Hey guys, congratulations on this transaction. I have first a couple of simple questions, just to make sure I have this right. I'm probably that not good at math compared to everyone else, but as I read this, in success, if Menlo has success, it seems as if at the current trading price for Foamix you'd be paying \$165 million essentially for the asset, understanding that the Menlo shareholders get to participate in the whole company. Just trying to understand, put some valuation parameters around it. Then, in failure, it's roughly \$55 million. Just any help in kind of confirming the way I'm looking at it.

Then also, Dave, as you talk about the launch and now we have more cash, which is fantastic, but can you just talk about some of the things that you've observed and learned since you've last commercialized a product and watching other folks take products to market within the derm space and outside of it, some of the things that maybe you're learning and observing that you all are applying to your launch to do it a bit differently.

Then, lastly, just if Steve would talk about his diligence on the Foamix assets, obviously making a bit of a bet on you also and I'm sure he's going to say lovely and nice things, but would just like to hear the work that he did and his thoughts behind Foamix's programs.

David Domzalski:

Steve, why don't you go first. Why don't you take that first?

Steve Basta:

Certainly. Let me take the last point, and actually I think both Dave and I might chat a little bit about how we're thinking about transaction value because on that point I don't think we're thinking about dollar value.

David Domzalski:

Right.

Steve Basta:

We're really thinking that both of our companies are undervalued and it's really about relative ownership, because I think that the value accretion that gets created, when you think forward about the revenue that gets generated from these multiple products being applied against a single company cost structure rather than two company cost structures, the profitability that comes out of the same programs is significantly greater and so what we really have thought about is the relative ratio of valuation, not the nominal price because we don't think that our market values today reflect the significant opportunities that exist and the even greater profitability opportunity that comes in the combined company. We've really been thinking about the relative ratios, not specifically a nominal price as you're describing.

In terms of how we thought about the Foamix products, we actually got really quite enthusiastic through the course of the diligence process. We have the good fortune within the Menlo team—and this is sort of cheating a bit in terms of knowledge about the space—that three members of our senior management team were former executives with Medicis who launched Solodyn and developed and launched Solodyn. So, our knowledge about the space, our knowledge about the use of minocycline in the treatment of acne and their focus for many years was how do we create a topical minocycline product in order to manage the adverse events associated with the oral form made it a relatively straightforward and easy diligence process for us to get really quite enthusiastic about the upside of the Foamix opportunities.

We think this is just a really natural switch. Oral minocycline is a core product in the treatment of acne today and at the same time the physicians are prescribing that on a daily basis, they are anxious about the side effect profile associated with oral minocycline.

The ability to detail the first topical minocycline product and to convert those scripts is really going to be quite straightforward and so among our team, our chief medical officer, our head of commercial development, our head of Medical Affairs all had significant experience and background in that space, had a depth of knowledge and history in terms of their work with physicians in the oral minocycline space and to a person everyone of them said, 'Absolutely, a topical ought to replace to replace oral.' This is absolutely the right way for the market to go and it's what physicians have been waiting for.

Our enthusiasm for the upside opportunity in the acne space as the first launch is really high, and then equally so rosacea is just characterized by inadequate treatments today. Either treatments that have too many side effects and are really difficult for patients to use or just don't have enough clarity and efficacy and the opportunity of a new mechanism of action product to be launched in the rosacea space I think creates really meaningful upside opportunity in that as well.

We're really quite bullish on the prospects for both of the products, which gets back to my earlier comment about valuation. That's why we weren't really focused about nominal value. It's not about where the stocks are today.

David Domzalski:

Right.

Steve Basta:

The entire derm sector has been under pressure and has been under pressure for the last couple of years, most notably because launch costs for single products are really high. It is hard and expensive to build an infrastructure for a single product launch and get to profitability quickly. The opportunity here is if you've got three products being launched within one organization, the path to profitability is faster and clearer and the profitability that gets generated, if you've got the same revenue from the product within one company with only one infrastructure versus that same revenue being split among two companies with two core commercial infrastructures and two G&A infrastructures, the overall EBIT generated from the one company is so much greater than the EBIT generated from the two companies and added together, that the value to be created is much more substantial.

In addition, (inaudible) the product launches, we honestly think that the serlopitant launch will go better and faster by coming through a sales organization that has already recently launched two products that are innovative first-in-class products. Those sales reps have then terrific credibility with physicians. They solve the problems that the physicians have. They have established relationships. Their ability to bring a third product to market should make the launch faster than if we were launching it de novo in a new organization. We think that the leverage synergies, the cost savings associated with putting the companies together and the ability to accelerate the launch and each launch helps the other product by virtue of the novelty of what the sales reps are bringing. I think it sets us up really nicely to create significant value.

I don't think about a nominal value number; I think about owning 41% of a leading dermatology company in the future as being a very significant upside opportunity for our shareholders.

David Domzalski:

Thanks, Steve. I think Steve absolutely covered that quite well. I like to keep things pretty simple and when we look at this transaction, and as actually alluded to in the deck, this is one of those 1 plus 1 equals 3 in the way that Steve and I have talked about it quite a bit since the beginning. It's not as if we would be having an organization with a product base that we have to create an entirely new infrastructure, whether it's within the derm segment or otherwise. The synergies here make a ton of sense for us.

Then, when we think through the value of the deal, we again think through the upside for shareholders on both sides of the coin here, for Menlo and Foamix shareholders, and the chance to really unlock the value of this company.

To get to your question about what's happened in the marketplace when it comes to launches, Ken, the biggest thing I would say that I've seen over the course of the last several years is that what used to be, call it an arms race, as to how much money you can throw at a launch, how big can you make your organization and try to overpower the competition, for these type of marketplaces, that doesn't necessarily work. I've been actually saying that since the beginning. It's a lot more about precision and targeting and data utilization and I think we've talked about that for the upcoming launch of AMZEEQ for the last several quarters that when we take a look at where the patients reside, we can efficiently deploy our infrastructure to get to the patients and get to the prescribers that we know actually treat the condition and we know those prescriptions will get adjudicated.

It's not about as much any more how many representatives that you can put out there or how much A&P spend that you can crank up. It's about are you going to the right people with the right data behind that.

I would also say that consumer engagement is different and again you need to be much more efficient in getting to consumers. We think there's significant opportunities for obviously AMZEEQ in the near term and without doing multimillion dollar mass media campaigns to do that, that are just mass articulated in the past. This is Generation Z. They get their data on that handheld device that we all walk around with every day and they're not necessarily watching all this on television, and to be able to mobilize patients through those types of resources are very efficient and relatively low in terms of cost.

I'd say the last key thing is really around payer partnering. I think to be successful in this business from a commercial perspective you have to approach the payers as a partner to make sure it makes sense, not just to get access but also to have an appropriate gross to net, and that's the approach that we've taken. We've seen a lot of launches, certainly in this category but in others, that have price points that we believe are actually quite egregious and that actually gets the hair up on the back of the payers and that puts you in really tough positions when it comes to getting access.

We've partnered with the payers since the beginning. That's been to me one of the biggest changes in commercializing products, so we've gone into this with a partnering approach. I think that's sort of the (inaudible) in the initial negotiations that we've had.

I'll turn it to Matt to see if he has any additional comments or color.

Matt Wiley:

The one last point I would make on that, Ken, for your benefit here is the market—as there are entrants that have come in over the last couple of years or are coming in, we observe that there's a lot of similar type of positioning and branding elements in the space, so we look at that and say a significant opportunity for us to disrupt through how we position the product. Of course, we thought about positioning with the existing products on the market but also pipeline products, so we believe that we're going to have a market position that's durable and branding elements that are unique in the space.

Ken Cacciatore:

Great. Thanks so much. Really thoughtful transaction. Very happy for all of you.

David Domzalski:

Thanks, Ken.

Operator:

Our next question is from Balaji Prasad with Barclays. Please proceed.

Balaji Prasad:

Hi. Good morning everyone. David, I just (inaudible) saying that I had to remove myself from the queue owing to an advisory, so I'll follow up with you later.

David Domzalski:

Okay.

Balaji Prasad:

Congratulations on the deal.

Male Speaker:

Thanks, Balaji.

Operator:

Our next question is now from Jason Gerberry with Bank of America. Please proceed.

Jason Gerberry:

Good morning and thanks for taking my questions. Dave, just for you, can you talk a little bit about how the deal might have been motivated to have multiple products, a portfolio of products to go to payers and have potentially stronger point of leverage by having a portfolio approach as opposed to just the minocycline based product or products that you'd be having.

Then secondly, just on the IP assumptions for the target asset, are you modeling in or are you assuming 2030 for composition of matter or were you assuming 2034 on the method of use IP? Just provide clarity on how you're thinking about duration of asset exclusivity.

David Domzalski:

Sure. Regarding how we thought about the transaction itself, just strategically this just makes for us a ton of sense. We've been a 505(b)2 company with our two products that are topical minocycline based and obviously can address significant marketplaces, but the opportunity to join forces with Menlo and have an asset like serlopitant that has a ton of durability—this is a new chemical entity—certainly, strategically makes a lot of sense. We've become a much more sophisticated organization and that creates leverage across the spectrum. Certainly payers it provides leverage and having multiple products now to go to them, it creates leverage for really all partners.

If you're looking at a company like us in the derm category or otherwise, look at a company like this combined saying, 'All right, they've got scale. They're a strong organization.' That gives us again sophistication and a strategic presence that I think each company as a standalone had not as much of.

We really are quite bullish about the prospects of having us together and what that means, not just with the payer base, with our partners. I think when we look at the access to capital markets, it just gives us a lot more leverage as we build the business.

When it comes to the IP, we've obviously looked at it in conservative terms, through 2030, but the other way to look at it is we think that the durability for this product line can certainly go much further beyond that.

I don't know if Steve has any additional comments on it.

Steve Basta:

Yes. I think that just on the IP you've captured the two timelines that are important. Our view on exclusivity for serlopitant actually goes out to 2033. We have issued methods of use claims to protect the use claims that protects the use of serlopitant for the treatment of pruritis that are really quite broad, already issued in the U.S. and should provide exclusivity through the 2033 date, so pretty confident with that timeline. But, as you observed, the composition of matter goes out to 2030, so provides additional protection in that process and that's with actual (inaudible) extension, so I think that provides a significant protection and runway.

As for the deal motivation, we've talked about a number of the parameters but just to sort of synthesize it, there is enormous revenue upside I think associated with one sales organization selling three profoundly novel products for acne, for rosacea and for Prurigo Nodularis. Obviously, a breakthrough designation for PN, so really it does open up a whole new conversation with physicians about a problem that they have that is significant and gets through to have access and that access then accrues to the benefit of the other products, so the access they're getting on acne will accrue to the benefit of the PN launch; the access the rep gets to talk about PN will accrue to the benefit of the acne product. There is real leverageable commercial synergy associated with having three very significant products that are launched.

The other very clear synergy is we've estimated that the savings by putting the companies together and launching through one commercial organization is greater than \$50 million a year versus the cost of having two separate infrastructures and that just accrues to the bottom line for our combined shareholders. Our shareholders get the benefit of that \$50 million a year savings collectively in the aggregate for the combined company and that's shared among the parties for both companies that there's just significant earnings momentum that gets driven by virtue of taking the duplicate costs out.

Jason Gerberry:

Got it. Thank you.

Operator:

As a reminder, it is star, one on your telephone keypad if you would like to ask a question.

Our next question is from Patrick Dolezal at LifeSci Capital. Please proceed.

Patrick Dolezal:

Hi. Thanks for taking my questions and congratulations on the transaction. I have a few questions for me. The first one was just on the timing. I'm curious what the driving forces were behind pushing you to complete this transaction now versus waiting for Menlo to get Phase 3 data out of the way. Second question, could you just characterize the mechanism of serlopitant and speak to its rationale in PN as well as some of the other targeted indications. Then the third is just on the launch potential of AMZEEQ. An obvious comparator that comes to mind is sarecycline and I was just curious how you think about similarities and differences of AMZEEQ versus sarecycline and is sarecycline a reasonable launch surrogate.

David Domzalski:

Sure, Patrick. Thanks. I'll take the first one and I'll turn it over to Steve and obviously ask Matt to follow-up with some comments on the launch potential.

Yes, I think that it makes a lot of sense to do this sooner than later. I think with each week and month that goes by the cost of operating businesses as a standalone becomes more challenging. Think again, you get the most cost synergy by doing this now. As you move to the potential readouts, not knowing what the reactions are to share price, etc., the cost of capital becomes more challenging. So, from our perspective, we looked at to do this now is the most sense, the most efficient way for us to create the synergies that Steve and I have been talking about. Then allows with reduced future dilution to our shareholders as opposed to finding financing on our own.

Steve Basta:

I would echo that sentiment. Dave and I are probably getting many of the same questions from investors as we've had many of these conversations. It's clear that our entire sector has been under pressure because of financing overhang and we get the question often how much money are you going to have to raise associated with building out a commercial organization and how are you going to be able to build out a commercial organization, so the opportunity to mitigate that financing overhang because the combined company is going to have sufficient assets to be able to run through the launch of both the first and the

second product and get to the NDA filing and review for the third product that provides a significant run rate, mitigates the financing overhang and creates the significant earnings leverage and the revenue ramp leverage. You create an organization that is just much more efficient at launching multiple products, requires less capital because we're able to aggregate the capital from the combined company, and all of those advantages accrue better if we do this transaction sooner rather than later after we've built up duplicate organizations and then it's really inefficient to try to do so, so it made more sense to do so before we started duplicating capabilities and it allows us to accelerate the launches of these multiple products.

Specifically on your second question regarding the mechanism of serlopitant, serlopitant is an oral NK1 receptor antagonist. By blocking NK1 which is the receptor for substance P which has been known to be associated with signal transduction associated with itch, we can block the CNS signaling of the itch irritation process and so we have a once daily oral NK1 receptor antagonist that is systemically available. By virtue of being an oral agent it becomes really easy for patients to use on a once-daily basis. That helps with patient compliance and it allows an easy to use therapy to manage what is the most troublesome and most complained about condition associated with Prurigo Nodularis patients and that is their itch. It's actually their itch that is causing them to scratch to develop the PN lesions. If you can manage the itch you can significantly alleviate the primary complaints that PN patients have and then from the perspective of the questions that we got earlier, it also broadens the opportunities to the future pipeline indications, so chronic pruritis of unknown origin, pruritis associated with psoriasis and a number of indications to be follow-on, PN becoming the near-term commercial opportunity but the combined company will have the leverage of having those pipeline opportunities to be able to build out in the future.

Matt Wiley:

Patrick, this is Matt. On your question regarding sarecycline, I think the uptake of Seysara has been really encouraging, 160,000 prescriptions year-to-date through September. We look at sarecycline as an oral—as a different value proposition than what we have with AMZEEQ and so as it relates to surrogate benchmarking I think it's encouraging that the market still finds new products interesting and that there's still a significant unmet need but we believe that the value propositions for the two drugs are very different.

David Domzalski:

I think to the last point too, Patrick, the (inaudible) waiting, we are quite bullish about the prospects of these indications for serlopitant and that's clearly a signal that we are sending is that instead of waiting it's a message of strength. We view that there's significant upside potential for serlopitant as it's in the bag with the products that we will have, so that's clearly the message that we're looking to send to our shareholders and to the market is we view significant upside potential, obviously for AMZEEQ, for FMX103, but for serlopitant and getting through the clinical programs as well as the opportunity to leverage the cost infrastructure, leverage the operational infrastructure, get good cost synergies going into the launches of these products.

If you think about it, again, three potential launches with significant revenue and profitability opportunity over a 24-hour month period leveraging one infrastructure with minimal additional spend beyond just your normal A&P for brands, you don't see that very often. That alone I think makes a lot of sense to try to do a deal like this.

Patrick Dolezal:

Great. Thanks a lot for that and congrats again.

David Domzalski:

Thanks.

Operator:

We have reached the end of the our question-and-answer session. I would like to turn the call back over to management for closing remarks.

David Domzalski:

Thank you very much, Operator. I want to thank everybody for taking time out of their day here on Veteran's Day, to jump on this call first thing in the morning. I want to thank Steve and the rest of the team for joining and we look forward to speaking with you soon and providing an update on the progress of our activities here. Thanks again and we'll speak soon.

Operator:

Thank you. This concludes today's conference. You may disconnect your lines at this time and thank you for your participation.