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Evofem Biosciences, Inc. (Nasdaq: EVFM)

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Jeffrey Hung
Welcome to the Morgan Stanley Global Healthcare Conference. I'm Jeff Hung, one of the biotech analysts. Before we start, please note that this webcast is for Morgan Stanley's clients and appropriate Morgan Stanley employees only. This webcast is not for members of the press. If you are a member of the press, please disconnect and reach out separately. For important disclosures, please see the Morgan Stanley Research Disclosure website at www.morganstanley.com/researchdisclosures. If you have any questions, please reach out to your Morgan Stanley sales representative.

For this session, we have from Evofem Biosciences, Saundra Pelletier, CEO; Russ Barrans, Chief Commercial Officer; and Kelly Culwell, Chief Medical Officer. Welcome everyone.

Saundra Pelletier
Thank you.

Jeffrey Hung:
So for those who may not be familiar with Evofem, can you provide a brief introduction?

Saundra Pelletier:
Sure, of course, I would love to. So, Evofem Biosciences is a biotech company that -- we are now a commercial company, because we just launched our first product, which is the only non-hormonal birth control gel that women use on demand. And why that matters is that in the US today, there are 21 million women that say they are beyond hormones. They literally will tell you that they have tried pills and patches and IUDs and they have suffered with headaches and weight gain and they just didn't feel like themselves.

And women have actually told us pervasively that because of the side effects they were experiencing from hormonal contraception, they were then put on an antidepressant, or they were put on an anti-anxiety product, or they were also put on sleeping pills. And then, once someone figured out and took the time to recognize that their body was reacting to synthetic hormones and they went off of hormonal birth control, everything seemed to settle. Their quality of life was better. They felt like themselves again.

So we're at a moment in time where Evofem is introducing the first innovation in the category in 20 years. So our product, Phexxi, we believe, is going to be absolutely game changing. It will empower these women with a prescription product approved by the FDA that they can really empower themselves. Men have had condoms for a very long time, and so women want the same opportunity. The idea to take something every day and every week and every month, year after year after year, if you're suffering, it just doesn't make any sense. Nobody would do that.

And on average, women have sex one to two times a week. So for us, we are thrilled that Phexxi really delivers an unmet need. We also know, and you're going hear from Russ, already the reaction from women has been significant.

And the healthcare providers are saying, look, we just didn't have an option. And so they're also thrilled that they have something to give these women who really were left wanting.

So the final thing I will say is that - so Evofem is absolutely committed to really revolutionizing sexual and reproductive health. And so we're going to start with this non-hormonal option that is really game changing. And then you're also going to hear that we're going to go into a Phase 3 study for chlamydia and gonorrhea where there's also no product indicated for the prevention of either of those. So, when you really talk about companies focusing on an unmet need, we are leaning into it in a significant way for the benefit of women which will benefit our shareholders. That was a long answer, Jeff, I'm sorry, but that was my...

Jeffrey Hung:
No, no, not at all. Great. Maybe let's start with the results from the AMPOWER Phase 3 study. Can you remind us what you saw?

Saundra Pelletier:
Yes, of course. I'm actually going to ask Kelly, our Chief Medical Officer to address it.

Kelly Culwell:
Sure. Thanks, Saundra. The AMPOWER study was a single arm open label trial that was conducted in 112 sites in the United States. We enrolled 1,384 women and actually enrolled those women quite rapidly over a very brief period of time really just by reaching out and asking women if they were interested in using a non-hormonal method of birth control. So it really kind of gave us a preview into the real unmet need for this product in the contraceptive landscape.

We had – our primary endpoint was a seven-cycle cumulative pregnancy rate as measured by the Kaplan-Meier methodology, and we had a pre-specified efficacy threshold with the FDA which we met comfortably. So, the seven-cycle cumulative pregnancy rate when the product was used by all comers - typical use is what we call it - was 13.7%. When the product was used consistently and correctly, that pregnancy rate was just over 6%. So, we did see a much

improved efficacy rate just by having - when women used the product every time every with every act of intercourse.

The other really exciting part of the AMPOWER trial is the fact that we had such an incredible safety profile. So, we had less than 2% of women who discontinued due to any adverse events, which is much different than what you would expect to see from a hormonal contraceptive study, where typically you have anywhere between 10% to 20% of women discontinue due to hormonal side effects. And we had no serious adverse events that were deemed definitively related to product use. So, we were able to comfortably meet all of the endpoints that we needed to meet for FDA approval, and that's how we got to where we are now.

Jeffrey Hung:
Great. And who do you see as the likely users of Phexxi and how many women do you estimate that to be?

Russell Barrans:
So, Saundra already mentioned that we see about 21 million women in the United States who say "I am beyond hormones". It's basically their own decision to make and they've done that. So that's who we see as the most likely candidate.

One of the things I often do say, Jeff, is that unlike other therapeutic areas where maybe you have let's just say, for example, a menopausal woman, we know that she's probably going to be somewhere between 50 and 55 years old and you have that kind of thing. In our case, anyone who is of reproductive age, what we find is it's more about the stage than the age. So although we have put these segments together, and we understand the most typical demographic, we have six different segments that were discovered out of a market research project that happened with more than 3,000 women. And we know in each one of those segments what their average age would be and they tend to be in the late 20s and early 30s as a rule. But we also see that there are women in each one of those segments that are as young as say 18 years old and maybe as old as 45 years old. And what makes them all common is that in each one of those segments they say "I am beyond hormones," and that's the commonality that happens with each one of them.

So when you start looking at our real base and I always kind of say almost every product is a niche, it's just a question of how big is your niche and what's the opportunity? And we have 21 million women of which we don't have to get a real large percentage of those to engage with us in order to have a very robust and healthy product.

Jeffrey Hung:
And one of your key components for the launch of Phexxi is the Phexxi Concierge Experience. So can you tell us about that?

Russell Barrans:

Yeah, I'm super excited about that for this reason. When we were getting ready to launch Phexxi, we were of course before COVID-19 and – but we had observed that in telemedicine there was about 15% of all scripts pre-COVID that were going through telemedicine, but contraception was one of the largest single therapeutic areas that was being used in telemedicine. So we had already determined that was going to be an important piece of the puzzle for us.

And then when we went through and we decided after COVID-19 kind of happened, that it was going to be very important for us to make sure that we leverage that. That's where this idea of the Phexxi Concierge Experience came from. And words matter, and we actually named it that very specifically.

First of all, we want this to be a little bit like a concierge when you go to a nice hotel, where you can plan that you just ask them to do your dinner for you, where you want to go, if you want to sightsee. Any of the amenities that you might want to take advantage of, that they will look after all that for you. And we do the same thing, whether it's right from the beginning, when they come in and you get a chance to have them go through the survey, then you get their information from their insurance in the background, we're able to get all that done. So, by the time they get through this process, everything that they would need to secure a prescription has been done for them. It's done seamlessly. And then, if they choose to enroll in the relationship management program that is there for women, they can get their reminders of when they're due to get their prescription refilled and they can interact with those who are also using Phexxi in chat rooms to learn about other women's experiences and be able to share their experiences with other people. So, that experience part is also very critical and that we want this to be something that, at the end, it isn't just this static thing that you go to when you get a script and you walk away, but that you engage with on an ongoing basis.

So, it's been going exceptionally well. And the data points we're getting out of there, although it's only been just a little more than a week, are very exciting.

Jeffrey Hung:
Great. And over the last couple months, you launched a pre-commercial campaign to target physicians and patients. Can you talk about your efforts there? How did those efforts go with that campaign? And are there any learnings or takeaways that you can implement in subsequent campaigns?

Russell Barrans:
Yeah. They went really exceptionally well. And as an example, we had more than 2,500 healthcare providers who had selected themselves to be put on a list that once we actually went commercial that they would receive information about that and that was just through the farming out of that effort to make sure that as many healthcare providers were aware that this was coming soon, we already had an approved asset, so unlike other coming soon campaigns that had to sort of just talk broadly about a new therapeutic category, we were able to

be more specific and talk about our indication and our name and stuff. So we had about 2,500 of those who were already in the queue waiting for information to be sent to them.

And then, this could be a testament of the work we did ahead of time with some of our social influencers. What we mean by that is we've contracted with women who have significant followings on social media because they had themselves already indicated through personal experience a desire to be non-hormonal. And so they started talking about Phexxi. Again, it was already an approved product, started talking about it coming out to market. So in that first four days of launch, we had 12,000 visitors to our www.phexxi.com website, which would allow them to get information there, but then also that's where they get to click into the Phexxi Concierge Experience. So we feel like the success of that was really done well and has achieved a very rapid interest on both HCPs and on women's parts as a result.

Jeffrey Hung:
Great. And you're planning a consumer push in January. Can you talk about what we should expect for that campaign and how might those efforts differ from other campaigns targeting consumers that you might be running now?

Russell Barrans:
Yeah. Saundra already kind of alluded to that, I think earlier, that typically OPDP which is the division from the FDA that reviews promotional materials once and requires although the length of time isn't absolutely stated, but they require you to make sure that you have adequate awareness in the healthcare provider community before you go out to DTC commercials and online video assets.

So typically most products will feel like they have to wait six months to make that happen. We believe that our vaginal pH modulator story is easy enough to communicate that we can reach that healthcare provider community in a more rapid fashion by the end of the year. So, we will launch our assets both for over the air which is just another way of saying things like Hulu and YouTube TV and places like that. So that's the over the air campaign, as well as we're evaluating which of the cable networks we would want to go on, and that will launch in January.

I think the thing that you should expect to see is that we're going to be probably a little more cutting edge, if you will, and what I mean by that is if you go back and look at history of all contraception advertising, it's almost all fear based. In other words, it's just about ‘don't get pregnant’ or ‘you've got other things in life that are more important right now than having a baby’, but it's almost as though there's this ignoring of where babies do come from. They come from sex.

So we're actually going to bring back into the notion that the reason you need to use Phexxi because you're in a relationship of which you're having sexual interactions with someone and your desire at this point is not to have hormones and not to have a baby. So you're going to see this hopefully shake things up just a little bit where people have kind of recognized that for the

first time women are in control of their own contraception. They're not dependent upon a man to wear a condom if they choose to try to push back on a woman. But she has a chance to say 'I'm only using it when I need it, and I am in control of it myself, and there are no hormones entering my body' and you're going to see these come out in a real playful kind of way that that we address the fact that it's the relationship between a man and a woman that is the need for having sex in the first place.

Saundra Pelletier:
And Jeff, can I just add a finer point to that really quickly?

Jeffrey Hung:
Sure.

Saundra Pelletier:
Okay. So we have been asked by a variety of different investors why we aren't on every television show, why we are – why you don't see us every time you turn on your computer or turn on your television. We recognize that DTC and consumer outreach is critical. It is a critical success factor to making sure that every woman has access to Phexxi. However, to Russ' point, it would be a suicide mission if we drove women into offices and doctors had no idea what Phexxi was. They didn't know who the Phexxi woman was. They didn't know who – how to prescribe it? How does it work? How to counsel their patient? And the reason we care so much about that is we want to make sure that these women not only love Phexxi, but they're long-term users of it.

So educating the physicians was critical. That's why we have this footprint of 70 people on the ground. And it's not that we weren't ready. It's not that we don't think it's important. It's not that we don't have a provocative campaign that we believe is going to be so exciting. It's that we wanted to be appropriate and give the right time to educate the physicians first.

Now we are doing some of it with social media influencers, but I just wanted to say that at this moment in time, women are more empowered than ever, but they have abandoned hormones, not their doctors. They are still seeing their doctors one to two times a year. They haven't abandoned them. So we just wanted to make sure we're creating the right relationships with the providers first. And I just wanted to say it expressly, so that the investors and the shareholders recognize that - that it is coming and it is forthcoming, but we needed to take this right step first because we're a prescription product.

Jeffrey Hung:
That's helpful. So you officially launched Phexxi launched last week. I know it's early, but what has the feedback been like so far from physicians and customers? Is there any feedback on whether patients are facing any challenges obtaining prescriptions or getting prescriptions filled?

Russell Barrans:
Yeah. Listen, this is, Jeff, one of those times when after having launched multiple drugs across the – in my career that I've got to say, I probably never had a more exciting time than we're having right now.

A couple of statistical things that I'll just share with you is when we drive women from the www.phexxi.com website to the portal for telemedicine, once they sort of start that that survey, we're able to then start counting them as people who have at least initiated into the telemedicine portal. We had originally forecast that we would have about a 22% conversion rate out of that – and that was based upon working with all of the telemedicine people and their experience in the past on how many people convert. And in that first four days, our conversion rate was 57%, which is substantially higher. Not to suggest that that trend is going to continue, because it is just a week of data. So I'm cautious to kind of make sure that people don't hear me say that that's going to be the final number, but it's been very exciting to come out of the gate that way.

A couple of things that -- anecdotally that we're hearing from the field is that while there's a challenge around COVID-19 in getting to see some offices, having an opportunity to make appointments ahead of time, because we had some time before we launched, they've been able to get in and see, in the first four days, a thousand different offices that they were able to get in and see. And the exciting part is that in those offices, you've got a lot of excitement that has built. Multiple reps have indicated that even the staff have asked their OB/GYNs that they are working with to write them a prescription for Phexxi.

And as we started watching this go through, a couple of things that were really exciting is that we had at launch 55% of all lives were already covered under insurance. So as a result, we haven't had that same kind of thing that I've experienced in the past where when you come out of the gate, you have no insurance coverage and you're trying to find a way through co-pay cards and other manners to get women covered and a lot of them just had to pay out of pocket cash. In our case, what we've seen is virtually almost everybody that has submitted for coverage with their insurance has had coverage of some sort. So that's been very good.

We haven't had to provide the co-pay card assistance for anywhere near the number that we had originally forecast we would because of the fact that we have so many plans that have put it on at zero co-pay and zero deductible, which, as they interpret the ACA contraceptive carve out, they understand that because it has a unique mechanism of action as a vaginal pH modulator that they feel like it should be one of the ones that are covered at zero co-pay and zero deductible. So consequently, we've had some really great things.

Now, there's always a few little nits and nats that happen here and there. We discovered in particularly one of the channels that there was no box to check that said ‘my shipping address and my billing address are the same’. So we had a couple of rejections that had to be fixed, but that was done within minutes once that was discovered. So there's always those little kind of

things that happen. But overall, it's been going exceptionally well. And the reception both from women and from HCPs has been fantastic to date.

Jeffrey Hung:
And one of the main areas of pushback that I've heard from physicians has been the pregnancy rate versus some other options. I guess, how do you address that and is that something that you think physicians will shift their views on with education? Or is the focus more that there's still plenty of women who may not be on any contraceptives so that they still have a greater benefit with Phexxi?

Russell Barrans:
Yeah. So there's two things, Jeff, and I'd say part of it is one of the things you just said at the end is true. So, once we've had this discussion with a lot of healthcare providers, sometimes they'll then immediately go and say, 'yeah, but an IUD is 99% effective' and you have to remind them that we're not talking about the woman who will accept hormonal methods or will accept an invasive thing like an IUD or a rod in their arm.

So, once we've done that, you say, 'but let's talk about the 21 million women, that's who we're really talking to doctor. We're not trying to convert your hormone-using patients over to non-hormonal.' That's been a big thing, Jeff, to get healthcare providers to realize we're there to help assist them in their armamentarium of offering something to women that currently is not available to those women who won't and can't use hormones.

And then there's another thing that's really important for us that we start sharing with them. When you look at the AMPOWER trial - and it's in our interactive visual aid that they're sharing - the efficacy when used as directed was 93%. Well then, one of the things that our reps are saying to them is, if you think about the oral contraception, it is 98% with perfect use. But then why do you call it perfect use? Because nobody's perfect, and when you start looking and you ask, almost all women report missing one or two pills every month. And then once you've missed a pill, you have a different protocol to follow, and if you missed two pills you have another protocol to follow and if you miss three pills, you actually scrap the whole thing and you start all over for that month. That's why the typical use of the pill is what's most commonly referred to as what you expect and that typical use is about 92%, which is virtually about the same as what we see with our use as directed.

And then when the healthcare provider kind of pushes back and says, 'yeah, but you're using your perfect use.' And what we say to them is 'but there's a big difference between - here's how our use as directed. Use it before you have sex. You can use it immediately before, as a part of the play, or up to an hour ahead of time, discretely if you want to put it in while you're in the bathroom or you're preparing.

We stop, because that's it.

And then you say, so there's nothing really about that that makes it perfect, that you have to do things perfect. And Kelly already mentioned that in a clinical trial, you have to count all those people who didn't use your product but got pregnant.

And then we walk through the fact with them to say, look the majority of women who didn't – who got pregnant didn't use it as directed and what does that mean? Well, it means that they might have had sex at 9:00 at night and they use Phexxi. And then at 10:30, they had sex again and maybe didn't even leave the bedroom, but they didn't use Phexxi. Well, what we liken it to when we say to the healthcare providers that's a little bit like using a condom at 9 o'clock and then using nothing at 10:30, and expecting the condom you used at 9 o'clock to protect you for sex at 10:30, and we usually get a smile out of them and they kind of chuckle and say, but it's the same thing. You have to use it with each and every act of sex.

Therefore, if women use it as directed, it's not complicated, it's not – there's nothing that makes this where you would say well perfect use, well it's pretty simple. Just use it and use it before you have sex, and use it within that hour, and you can expect the same kind of efficacy that you typically get with the pill. So we don't really think that women who are using Phexxi are making a big tradeoff in terms of efficacy because they're getting that similar experience as the women who typically are using the pill.

Saundra Pelletier:
And Jeff, I wanted to say ACOG says repeatedly that the most effective method of contraception is the one that a women will use consistently. So, if she is beyond hormones, there's nothing out there that she's going to use consistently, if she doesn't want to have a copper IUD inserted that she can't control.

And the other quick thing I want to say is that, look, when we recruited Russ to come to this organization to lead this launch, it was because when he launched Mirena, it was suggested that that was going to be a $75 million product. Last year, it did $1.4 billion, because it was a moment in time. Women were tired of having to remember to take a pill every day. They wanted a fit and forget method. That moment in time is now repeating itself because women are saying ‘we are over hormones’ and there is no prescription product that exists.

So we were in a moment when in telemedicine the most receptive therapeutic category is contraception. Women are home more now with COVID, assessing their quality of life. They have a chance to breathe for once to say ‘how do I really feel? What about my longevity here?’

So, even though, yes, we're targeting this 21 million, I want you to hear that I've talked to providers myself who've said to me we believe that there are some of our hormone users that, now that this is available and out there, that's just icing on the cake by the way, we've not included that any of our projections, but I believe we're also going to get some women who leave hormones to come on Phexxi as well.

So we're excited because we think the moment is now. So going back to your efficacy point is that if women are doing nothing right now because they are beyond hormones, I can tell you that not having any option to use as a form of contraception is much, much, much riskier. So for us that's why we don't think there's a tradeoff at all, and the providers that we're talking to have said, look, women used to leave our office with a bag of condoms. Well that didn't satisfy the women or us. And now we finally have something that women can use and is as effective as the typical use of the pill.

Jeffrey Hung:
Great. That's helpful. So let me ask I guess looking forward on the 3Q call, what should we expect to hear with regards to sales or launch metrics?

Russell Barrans:
Well, I think the key, Jeff, is going to be we're only going to have three weeks of script data when we get to that call – official script data through IQVIA. So I don't expect that that's necessarily going to be the thing that makes everybody jump up and down with excitement, because there'll be such a small sampling of what we expect.

But what we are looking at is what are these key metrics that are driving behaviors and if we can start – we'll start to match all those up as close as we can to say when you see this number of conversions happening at a telemedicine portal, what does that convert to in the physician's office, and can we find some parallels. What's the click through rates look like? What are the engagements that happen at the social media site?

So as an example, one of our social media influencers is someone who was on the Bachelor, has almost 700,000 followers. And one of the key things about being in social media which sort of gets lost on me a little bit - and I guess that makes me old - is that the 'likes' and the 'shares' are so important for these media people, these YouTubers and such; that's how they build their business, that's how they get paid.

Well, for every one of these people who 'like' or 'share' it that have themselves 500, 1,000, 2,000 people, and that multiplication factor, that goes on - you can have literally 1 million people who potentially could hear your message just through one of these social media influencers putting it out there. So we'll try to start tracking some of these metrics. We'll look at the metrics of the numbers of times that these have happened and then try to look at draw those correlations between all of that.

So I think in our first call, we can expect to see a little bit more of what I'm going to refer to as the soft data that would be more leading indicators of where we're at with what some early data from the uptake. We'll probably start getting an idea just at the very beginning what the abandonment rate was around prescriptions that were written and -- but again that will be a pretty small snapshot. Probably not enough that I would suggest to people we've got a trend, but we can at least share that data with them. But the more important data I think in that first call will be those other things around what's happening digitally.

Jeffrey Hung:
Great. And in the last couple minutes, I do want to ask you about EVO100, but we are getting a lot of questions from the audience. A lot of people are interested how you're thinking about partnerships for Phexxi outside the US and preparations or Europe or other parts of the world. So maybe you can talk about that quickly and then talk about EVO100 -- both highlights of the program and an update of where you are with that? Thanks.

Saundra Pelletier:
Yeah. So super quickly, I'll start and maybe Russ you can add or Kelly you can add. So the bottom line is that we have had very serious and significant outreach from companies that have a footprint in women's health outside of the US. These are companies that have launched very successful assets. So what we're doing now is – so the short answer is we're very focused on it. We have our Head of Business Development, that's what he does all day long every day. And so what we're assessing though, to be candid, is that as we move forward in the perfect transition with chlamydia and gonorrhea, what we're looking at is that is it smarter and better to partner with a company that both wants the non-hormonal contraceptive product as well as the chlamydia and gonorrhea prevention.

So we did a little pause, did a little hold, if you will, to just make sure we're getting the best cost of capital, right. We know that this is going to be payments that will be non-dilutive. It will help our balance sheet clearly. But we also want to create access. So the short answer is we are very assertively talking to a variety of different partners all over the world, there is serious interest in Asia and Europe and also Latin America actually. So we think that by the end of next year -- we're giving ourselves a little more time so that we can get the best opportunity for shareholders and for access -- but we are in active and engaged discussions.

The final thing I want to say too is that in some of these markets you have to do an additional clinical study. So our regulatory team is meeting with all of these regulatory authorities like the FDA in these other countries to find out what's really going to be required, so that can be part of the discussion and negotiation with these partners. Will they do the clinical study that's necessary? So obviously that's a cost and that's a timeline issue. So we are very focused on it.

And then Kelly, you want to talk about the program?

Kelly Culwell:
Sure. Absolutely. So we are moving forward to have our first patient enrolled before the end of this year. We had a Type C meeting with the agency a few weeks ago which gave us a very clear path forward and it was very productive. And so we are – we have finalized our protocol amendment based on that feedback. We are in the process of site recruitment. We have submitted the protocols to the IRB. We are full speed ahead to get that first patient enrolled before the end of the year. And that will give us a top line data in 2022. So everything is full speed ahead on that.

Jeffrey Hung:
Great. Well, looks like we'll have to leave it there. Thank you all so much for your time.

Saundra Pelletier:
Great. Thank you very much, Jeff.

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