Company Name: Evofem Biosciences, Inc. (EVFM)
Event: Stifel 2019 Healthcare Conference
Date: November 20, 2019

<<Annabel Samimy, Managing Director, Specialty Pharmaceuticals, Stifel>>

All right, everyone. Good morning and welcome to the Evofem presentation. It's our pleasure to have CEO Saundra Pelletier with us today, as well as… Chief Medical Officer… Kelly Culwell.

So Evofem is developing a non-hormonal or non-systemic, on-demand contraception for women with some potential benefit in preventing the spread of chlamydia. Also the same product could potentially find utility in preventing recurrent bacterial vaginosis.

So let me step aside, I'll have Saundra provide the overview. And maybe if we have time at the end, we can open up for Q&A.

<<Saundra Pelletier, Chief Executive Officer>>

Great. Well, good morning, everybody. And it may be a little early for some of you to talk about sex and contraception, but it is never too early for me to. So, I'm excited to be here to tell you about Evofem Biosciences.

So, I want to start with sharing with you that in the United States right now, every year, half of all pregnancies are unintended. 3.6 million pregnancies are unintended. So after all the advances in technology, after all the innovations in biotech, you would think that more women would be served. And instead, what continues to happen is that women are just offered lower doses of more hormones. And so we are about to change that, and we are really excited.

So if I start with the end in mind, what you're going to hear is that everyone at Evofem is thrilled because we are going to be commercializing the first and the only non-hormonal contraceptive product for women with no systemic side effects, and women only use it when they have sex. So with that I'd like to get started.

So what makes this so exciting is that we'll have a first-in-class mechanism of action, which you'll hear a little bit more about. Non-hormonal is incredibly key. When you talk to women, there's a huge subset of women, 17 million, that say I don't have hormones in my milk, I don't have it in my meat, I don't have it in my makeup, and I don't want to put a hormone in my body sometimes for 20 and 30 years. Because oftentimes women will start their contraception in their teens and they will continue it until they choose to have children.

Also, female-controlled and on-demand is really critical. Women will say, half of all women will say, I don't want an IUD because I don't want something I can't control. And, with the age of empowerment, a lot of women say, look, I've got this. I don't have sex every day. And it doesn't make sense to me to take a medication every single day, every week, every month, year after

year after year, when market research tells you that women have sex on average twice a week. So we're really excited to offer something new and different and innovative for women.

…So who are these women? So what we did is we did market research with 3,000 women. So when we talked to you about the 17 million women, what we really wanted to ascertain is who would be the early adopters, and these are the women who, our Chief Commercial Officer says, who will stand in line and wait for the new iPhone and who are the ones that just want to wait and see and make sure. Nonetheless, all of these women are beyond hormones. And you see that it's broken up between 8.9, and the 8.9 are the ones that are ready now. These are the women who are low-hanging fruit. These are the women who have said 'I have suffered,' sometimes with very serious side effects.

The one thing we continue to say that surprises people is that not enough people understand that the side effects that women experience on hormonal contraception are incredibly real. It's weight gain, it's bloating, it's bleeding, a lot of women don't even feel like themselves. But I really want to show it to you, because some of you are visual learners and this is one of my favorite videos and it's meant to be a little humorous, but it's also meant to be quite serious. So here is the contraceptive journey for a lot of women.

> [Video Presentation: Let's talk about it. Birth Control. It can be a wild ride. Look, I know a lot about it is good – even great – but it ain't as simple as just poppin' a pill.
>
> When I first went on birth control pills, I wasn't exactly sure how they worked. My doctor said some stuff; I wasn't really listening. There could be side effects. I was ready for these life-changing little pills. And they were life changing. For instance, a pill my doctor described as 'safe' provided me with serious bouts of depression. And after eight years and five different pills, I discovered that weight gain, cystic acne, and mood swings are great birth control methods all by themselves – and especially when combined. Was I moody because I didn't have a boyfriend, or did I not have a boyfriend because I was moody? Hard to say!
>
> But it was when the pill that left my skin smooth and flawless was identified as having possibly fatal health risks, I thought 'what am I doin'?' Hey, why don't guys ever get to be the guinea pigs? Just sayin'.
>
> Anyway, I thought if chickens can be hormone free, why can't I? And since I didn't need 24/7 birth control, I stopped. And I gradually started to feel better. No more daily reminders to take a pill. No more worrying about missing a pill. And… no more pregnancy protection.
>
> So, I turned to the good old condom. Now, the truth about condoms is that no matter how many types there are, they always end up being a drag. And I found objections to using them would pop up pretty quickly. (on screen, on men's t-shirts: I love you. I'll withdrawal. It's too tight. I just got tested.) Ahhh, my favorite – how touching.

So, I continued my Goldilocks journey to find just the right birth control pill for me, looking for a more natural and hormone-free alternative. Research led me to a non-hormonal IUD. This option only involved forcing a piece of metal and plastic into my uterus, and hoping it was only selectively toxic to sperm, but not to me. I opted out of the IUD, because I heard it could cause unmanageable bleeding, and incredible period pain. Thanks, but no thanks.

The last unexplored option was leaving my fertility up to a calendar, a thermometer, and my boyfriend's self-proclaimed ability to pull out. I didn't feel ready to explore it.

But it's not funny. Isn't it about time women have a birth control option that gives us the control over our sexual and reproductive health?]

<<Saundra Pelletier, Chief Executive Officer>>

So, we think it is about time and we are going to do something about it. And so our product, this is what it looks like, it comes in a prefilled applicator. A prescription will be a box of 12 prefilled applicators, very discreet. Women are very, very used to and comfortable using applicators like this. And you put it in, as I said, right before sex or up to an hour before.

And here's why I show it, for actually lots of reasons, not just because I like to do this show and tell. I show it so that you see that it's incredibly viscous and it's very bioadhesive. Women are not going to use something that leaks out. Also, it's incredibly lubricating. Women who have any vaginal dryness or pain with intercourse really love this attribute of the product. Now we do have 510(k) clearance as a lubricant. We did not market it that way because we wanted to get to market as a contraceptive product, but it's a really, really big benefit for women.

The other thing is it speaks to the mechanism of action. As you see, what Amphora simply does is it helps maintain normal natural pH, 3.5 to 4.5. When semen enters or chlamydia or gonorrhea, the pH rises to 6, to 7. And what Amphora does is it creates this acid buffering and helps the vagina maintain natural normal pH.

So we did our clinical study in 112 sites across the U.S. and we enrolled 1,400 women. And we are now just about, we will resubmit our NDA to the FDA actually this month, we will have a six-month review, and we anticipate launching this in June of next year. So we're really, really excited to be so close to commercialization and so close to introducing what in our opinion is the first innovation in decades in this category.

The other thing I do want you to know is that from a safety standpoint, when you look at a lot of the hormonal contraceptive trials, these side effects are 10%, 15%, 20%. For us, there was less than 2% discontinuation rate. So we feel really, really excited that not only are women going to have this innovation, they're not going to experience side effects.

This is probably my most favorite slide, and it's my most favorite slide because it's provocative on purpose. So we are the only company ever to do a contraceptive study to include an exploratory endpoint for sexual satisfaction. And why that's so exciting is that a lot of hormonal contraception lowers your libido. I say it's such a terrible trick we play on women. They have to

use contraception because they have to have sex and yet it lowers their libido and they don't want to have sex. And so for us, we're so thrilled.

You look at this chart. What you see is we asked women at baseline: the current contraception you're using does it make your sexual satisfaction worse; does it stay the same; or is it better? 16.9% said it was better. After one use of Amphora, it went up to 45.5%. Now I want to remind you, this is not a libido enhancer. This is a contraceptive product. So the fact that half of women found better sexual satisfaction is so important and so significant.

And why I say I love this slide is that all contraceptive marketing, if you really think about it, it doesn't talk about sex. And the only reason you're using contraception is because you are having sex. But all the promotion is fear-based, you don't want to get pregnant, you don't want to get pregnant, you don't want to get pregnant. So we are going to have an opportunity to really talk about the idea that not only can you have sex without these terrible side effects, not only can you have sex on demand, but you also may experience more sexual satisfaction. What a concept.

So, I just want to share with you a little bit, when I say appropriately provocative ways that we will use this to entice women.
[Video Presentation]

So if that isn't exciting enough, which if you could see, I think that's all very exciting. We actually have more, there's more.

So right now for the fifth year in a row, unfortunately, STIs are on the rise. There are 1.8 million cases of chlamydia, 1.8 million every year and 500,000 cases of gonorrhea. So we are about to announce this quarter the results, top-line results, of our Phase 2b study for chlamydia and gonorrhea, and we're really excited. So the two millstones that you will – you should really expect to see delivered by our organization between now and the end of the year are the resubmission of our NDA and the top-line data from this study, and this is so important.

And so what this will be is an sNDA. So we will expand the label about a year and a half after we launch as a contraceptive product and we will add on the indication for sexually transmitted infections. And I can tell you that right now there is no product indicated. So not only is there no non-hormonal on-demand option, there are no options for chlamydia and gonorrhea. So ,we really are focused on what are these unmet needs for women, and we need to deliver on them. "Me Too" is not good enough. So we really are thrilled that we think we're doing something better.

This is the study. And at the end we'll have time for Q&A, and I'm going to ask Kelly and Russ to come up. But the bottom line is, is that we'll report our top-line results. We did 50 sites across the U.S., actually we had some sites that were both for the contraceptive study and for the STI study. And the goal was to obviously show statistical significance. And what we had talked about, if you heard some of our presentations in the past is that we thought anything statistically significant was really going to matter because there's nothing else out there. But we did say, well, perhaps we'd like to try to see if we could hit a 40% reduction. So we really thought that that was incredibly meaningful. So that's more to come, so to speak.

So reaching the Amphora woman, this is sort of a little bit of the commercial footprint, and Russ can answer questions when he comes up. But again, what we tried to do is be very specific in how we segmented this market. We joke now that from the times when, I don't want to age myself, but when I was a rep in the field, and I was a very long time ago, it was really much more challenging to get data. Now we say we can find out a woman in Topeka, Kansas who drives a minivan and has two children and know exactly what she wants.

But we've really looked at who are these 17 million women.And what you see, there are these segments. There are four segments that are the early adopters. They are literally wanting Amphora now. When we enrolled in our study, these 1,400 women, we had 500 extra women in screening that wanted to be in the study just by seeing the promotion 'do you want non-hormonal contraception'. So we actually have investigators call us and say that women are angry because they need their Amphora and when can they get it. So we are convinced that we know how to market to women. There is no question.

The second two segments are the ones that are little later adopters, still wanting, but they want to make sure that once the product gets to market, they will adopt a little later. But for us, frankly, when you look at what we feel at our target audience, out of these 17 million women, if we were to get 8 million of these women, it's almost $1 billion market opportunity.

These are the providers. Not only did we look at their prescribing habits, of course, that's what you do, but we also looked at behavior and attitudinal data so that we could see who are these prescribers that really care about innovation, who are going to adopt this. So we are going to be very, very targeted because we want to make sure our launch trajectory is really fast. So we want to go and target these providers who know that there are a huge subset of women that are left wanting.

Our Chief Medical Officer is an OB-GYN. She still practices to stay relevant. Not all the time, a couple of times a month. But I say that to you because she says these poor women come in, I give them a bag of condoms and I hope that I don't see them back here pregnant because that's the only option that I have to give them. And that's a very unsatisfying, not just for the woman. It's unsatisfying for the providers.

And the one thing that astounded me when we did this study is we had some physicians who are really actually lovely and honest. And when we started out at our… investigator meeting, some of them said to me, we're really excited to participate, but we're not really sure if we're going to have any patients. Those same people have gone from skeptics to evangelists, and I mean complete evangelists. They are so excited about the product, and I'm talking, this is 112 sites. We already have a lot of user information from these providers. So we're also convinced that when our sales force talks to these doctors, yes, we need a sales force to influence them. But once we describe who this Amphora woman is, they get it intuitively very, very quickly.

So when we talked to these providers, here's what we did. We also did research with the 1,000 providers and we basically blinded what the products were, but we gave the attributes of the products and said, could you give us a listing based on these attributes of which products you

would use in what order? Majority of providers start women out on the pill. And that's just sort of table stakes if you will. But the second product based on the attributes was Amphora. So we're really excited that once we have an opportunity to explain the attributes of the asset that we're going to be able to get a lot of traction.

The sales force will be 125 sales reps. And for those of you that understand commercialization, in the OB-GYN space, 125 sales reps covers 100% of the contraceptive prescriptions, and 99% of the contraceptive prescriptions are written by OB-GYNs. So we are actually – we're actually in the process now of hiring the management team and we'll hire the sales force in the April-May timeframe.

The other interesting thing is that unfortunately some companies have stepped away from women's health. And so for us we have amazing, amazing sales and marketing people that are contacting us all the time, because once people really love women's health they're very committed to it, incredibly loyal. So we feel like we're going to be able to hire half of our sales force without even using recruiters, which is really exciting.

And then this is to say, direct-to-consumer advertising is critical, and women are absolutely ready for this. And we obviously would take DTC seriously, but this is the kind of product that we saw in our own enrollment that is so promotion sensitive. So we are going to be very, very focused. We're actually going to start non-branded promotion now, to talk about the fact that it's been decades since something new has come to market. And then six months after we launched to the doctors, we're going to launch our very focused direct-to-consumer advertising.

The reason it's six months is we want to make sure -- the last thing you want is to have a woman go into a doctor's office and the doctor never heard of it, because that's not going to be a recipe for success. So six months after we launch to the doctors, we'll launch our direct-to-consumer advertising.

So these are the milestones that you should expect from us. As I said, but I want to say again, we will resubmit our NDA. We will release top-line data on our STI study, and we have already accelerated and started our pre-commercialization activities, which we're thrilled about.

The team, is a team of people that have spent their careers in women's health, not just good marketers, good sales people, not just doctors, but people who have focused on the mindset of the woman from puberty to menopause. When she does want to get pregnant, when she wants to space her pregnancies and when she doesn't want to get pregnant. And we thought that that was really, really, really critical. I would be candid. Of course I would say this, but I really mean it. I think you would be hard pressed to find a team that has more expertise. They've launched the biggest assets in the category: Mirena, Plan B, Paragard. There's not an asset that you can name in women's health that our team has not touched. So we understand execution and we understand launch.

And the time is now, and I can tell you that when we go out and talk to anyone, whether we talk to payers, whether we talk to women and whether we talk to providers, everyone is excited that we are going to have a first-in-class product. Everyone is excited that this is going to be on the

market next year and it's not enough just to have the right asset. You have to have the right asset, the timing is critical, and you have to have the right team. And we have all of that for our recipe for success.

So I want to thank you for your time. If you have questions, we'd love to answer them. And I'd like Kelly and Russ to come up and join me for the Q&A, if that's okay.

Q&A

<A – Saundra Pelletier>: Oh, thank you. Any questions?

<Q – Annabel Samimy>: If I may.

<A – Saundra Pelletier>: Yeah, please.

<Q>: So I just want to touch on the NDA resubmission. Can you just explain what happened there? Was it held up? Was there something missing from the application? And it's clearly a six-month review if you're planning on getting approval in June?

<A – Saundra Pelletier>: Yes, Kelly, do you want to take that?

<A – Kelly Culwell>: Sure. Are you asking why...

<Q – Annabel Samimy>: Yeah. Can you give us a little bit of a regulatory background?

<A – Kelly Culwell>: Yeah. So this submission is based on our recently completed Phase 3 contraceptive trial. That trial was our second confirmatory trial for efficacy. The initial trial was done between 2011 and 2014. It was a very large Phase 3 comparative contraceptive trial However, about 20% of the subjects were from Russia in that initial trial and ultimately their data was deemed not generalizable to the U.S. population. And so we worked with the FDA to do a second confirmatory trial in U.S. population only. And so that's why this is a resubmission. And, yes, it is a six-month review because it's a Class 2 resubmission.

<A – Saundra Pelletier>: Okay. And can I just add to that? And the other thing is that when we went to the FDA and they said the Russian data was not generalizable to the U.S. population, they – we extracted the Russian data. We still met our endpoints after extracting the Russian data. So we went back to the FDA and they said, you know what, we actually agree, however, your analysis is considered *post hoc.* And if we accept this, we're going to be setting a precedent that we cannot set, so we need you to do one more, but it's just going to be Amphora alone, half the patients, much quicker.

<Q – Annabel Samimy>: Where were the 80% of patients from?

<A – Saundra Pelletier>: The U.S.

<Q – Annabel Samimy>: They were all U.S.

<A – Saundra Pelletier>: Yes.

<Q – Annabel Samimy>: Okay. And then I also wanted to touch on the STI prevention, because I think that's an important aspect of the product. Can you maybe share with us some of the data that you have? I gave you some idea that there was some kind of prevention aspect to it.

<A – Saundra Pelletier>: Kelly?

<A – Kelly Culwell>: Yeah. So we actually went straight into human studies based on *in vitro* and animal data, because we had an extensive database, safety database from our contraceptive programs. The Agency was comfortable with that. So the product itself has very high efficacy in animal studies in preventing chlamydia and gonorrhea as well as several other STIs as well. and very kind of impressive kill time data. And really the background as to why we really felt in addition to that is its mechanism of action. There's been a lot of studies to show that chlamydia and gonorrhea just cannot survive in an acidic environment, and particularly one of our active ingredients has also been shown to have direct impact against chlamydia and gonorrhea.

So sort of all of that data taken together led us to feel very confident that we would see a positive outcome in a contraceptive trial, and so confident that, really this was our first human study, but we powered it to be a pivotal trial. So it's really a Phase 2b/3. And we've had conversations with the Agency that, should we meet our endpoints with this trial that we really needed to do one additional confirmatory pivotal study in order to get approval.

<Q>: Just one additional.

<A – Kelly Culwell>: One additional. Yeah.

<Q>: Yeah. So there is no other preventive treatment for here for STI. So what were the specific endpoints that the FDA needed to meet? You're essentially blazing a trail with this a little bit.

<A – Kelly Culwell>: Exactly. Yeah. So we did – we had a lot of discussions with the FDA about what type of study they'd want to see. They wanted to see a placebo-controlled trial. And so we did in fact do that. We enrolled women who were at high risk for chlamydia or gonorrhea infection during the study period. So these are women who had had a previous infection with chlamydia or gonorrhea in the prior four months and that puts them at up to a 30% risk of getting a subsequent re-infection. And so we purposely enrolled a very high risk population for this first-in-human study.

The Agency was not particularly – they didn't tell us what percent reduction we needed to see. We worked with some colleagues at NIH to develop the protocol. And as Saundra mentioned, we originally powered the study on a 40% risk reduction. I'm thinking that that would be a pretty impressive reduction in risk. However, given that there isn't any other product as you mentioned, any statistically significant reduction would be a vast improvement on where we are now, particularly given that this product is primarily a contraceptive and this is an add-on benefit.

<Q>: Okay.

<A – Saundra Pelletier>: Anyone from the audience have a question before I hog all the questions? Go ahead.

<Q>: Duration of IP?

<A – Saundra Pelletier>: 2033.

<Q>: [Question Inaudible]

<A – Saundra Pelletier>: Russ, do you want to take it?

<A – Russ Barrans>: So we talked to payers that represent about 70% of the commercially covered lives in the United States and we've asked them the question that you just did. What they basically told us is they expect it because there is nothing that is like us, that we would be a covered benefit. Where we would go inside of those categories - at this point there's a difference of opinion. Most see us going into a category that currently is made up of just OTC products that we would fit into. So there's nothing that's covered in that category. So the indication was that we would be covered. We then have taken the second step, which is we've already engaged with a law firm to start the process of establishing that 19th category as a Vaginal pH regulator category because our unique mechanism of action would put us into that category.

At that point, we would hope that by the time we get to the STI indication we would then be put into that category allowing us to have just better clarity where we fit. But let's be clear that what we heard was that 50% of payers right away said they expect that we would be a covered benefit under ACA, which means no co-pay, no deductible, no matter what kind of a plan a woman is on. So even if she's relatively healthy and is in a high deductible plan where it's $2,000 or $3,000, she still doesn't have to pay that deductible for her birth control and we would be one of those benefits.

And then we found that, among the remaining 50%, half of those just are not sure exactly where it fits, but they anticipate that we would be covered. And then as is normal, you have about 25%, you get to push uphill. But we've done this before and expect that we'll be able to move a lot of those payers as well.

<Q – Annabel Samimy>: So I just have another question with regard to the category that you fit in and not so much for the FDA classification. But technically the women that you're targeting had an option of using a spermicide or any of the over-the-counter treatments that they're available. So my job is to always be a naysayer first. So what is going to shift those women to a product like this as opposed to just having gone to use a spermicide over-the-counter and having full access to that, but not reaching for that access?

<A – Saundra Pelletier>: Do you want – I mean that you want to start and I'll add?

<A – Russ Barrans>: Why don't you start from a medical side and then I'll add the market research.

<A – Kelly Culwell>: Yeah. So currently all available spermicides all contain nonoxynol-9 which is a surfactant. And I'm speaking to the – from the point of - there are no doctors that are talking to their patients about using spermicides because this surfactant, the detergent of the nonoxynol-9, has actually been shown to increase women's risk for HIV with frequent use. And so it actually has a black box warning in the FDA. It's actually not available for use in a lot of countries in the world because of this increased risk. And so, because healthcare providers aren't talking to their patients about it, it's currently certainly not being marketed, but just sort of sits there on the shelf and there's very, very little knowledge of that kind of option for women because of the fact that it has so many negative side effects.

<Q – Annabel Samimy>: Okay.

<A – Russ Barrans>: And then, further to that, when we did market research, what we really discovered was a couple of things was that women are looking for an FDA approval. So when I brought Mirena to the market back in 2001, everyone kept telling me, women don't want IUDs. They're not going –you're not going to get a woman to use IUDs. And today that franchise for Bayer's going to be about $1.4 billion.

And the reason that I bring that up is to simply say we met that same challenge before where we were told that this isn't going to happen, but when you understand what women really are looking for, which I did back in 2000 and understood that there was an opportunity there, we're in the same position today, I think, as Saundra illustrated, with a vast number of women who are looking for another option.

<Q – Annabel Samimy>: Okay. So just really mindful of the time. So I just want to make sure, I'm asking too many questions here, but so one of the things that you had up on the screen was the, I guess the percentage of physicians who use different types of contraceptions. So oral contraception seems to be still pretty high up, and then goes to Amphora, then there is a multiple other options like IUDs or rings now. Where do you see the trends going? Because it seems like a lot of the markets has been moving more and more to long acting contraception, whether it be copper IUD, non-hormonal IUD or hormonal IUD. How do you change that last bit of behavior? I'm just – I was surprised to see that oral contraception is so high up there when there's all these different options.

<A – Saundra Pelletier>: Yeah. Russ, go ahead. Yeah, go ahead.

<A – Russ Barrans>: Well, one of the things that I often say is that this contraceptive journey is a little bit like a river. You jump in and it's moving and it's flowing already. And almost every young woman who goes in to get contraception will initially be offered a pill. And that's simply for the reason that it's sort of become the go-to thing that most OB-GYNs will assume that they're here, that they're going to take a pill, they're going to try to explain that to them.

So if you look at that whole total, before we introduced Amphora, 74% of the time, they're getting a hormonal method, afterwards it was 62% of the time. And while it's true that definitely there's been this move towards the LARCs, or the long acting methods. They have sort of found themselves in a nice little niche, and they pick up around in total about 15% of the population because half of women won't even consider taking an IUD. They'll say, no, I'm not interested. I don't care what the benefits are.

So what we've found is that the doctors indicated to us that there's this big gap, and they don't really know what to do once they've moved through their options, whether it's modality or whether it's different progestins. Where do I go next? And what that 15% represented to us was an indication that doctors have said, when you presented this to me, I get it, there are these women in my practice who are right now unmet.

<Q – Annabel Samimy>: Okay.

<A – Saundra Pelletier>: So the final thing, and I know we are out of time is that, what we also found was when we introduced it to women, women say, look, I don't have to suffer anymore. I don't have to. If I choose not to, I don't have to do that. And so when we give women that option too, they say it's about time that I can have sex on demand. Men have had condoms forever. I should have something that I only use when I need it, which is exciting.

<< Annabel Samimy>>

Great. Thank you so much. That was wonderful.

<<Saundra Pelletier, Chief Executive Officer>>

Thank you.