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Evofem Biosciences, Inc. Q2 Earnings Call
August 6, 2019

C: Amy Raskopf; Evofem Biosciences, Inc.; Investor Relations
C: Saundra Pelletier; Evofem Biosciences, Inc.; CEO
C: Jay File; Evofem Biosciences, Inc.; CFO
C: Kelly Culwell; Evofem Biosciences, Inc.; Chief Medical Officer
C: Russ Barrans; Evofem Biosciences, Inc.; Chief Commercial Officer

P: Randall Stanicky; RBC Capital Markets; Analyst
P: Leland Gershell; Oppenheimer & Co.; Analyst
P: Yasmeen Rahimi; ROTH Capital Partners; Analyst
P: Edward White; H.C. Wainwright & Co., LLC; Analyst
P: Carl Byrnes; Northland Capital; Analyst

+++ presentation
Operator^ Good day, ladies and gentleman and welcome to the Evofem Biosciences' Second Quarter 2019 Results Call.

(Operator Instructions)

I would now like to turn the call over to Amy Raskopf. You may begin.

Amy Raskopf^ Thanks, [Michelle]. Thank you all for participating in today's call. This is Amy Raskopf, Investor Relations for Evofem Biosciences. Please note that the press release we issued yesterday after market and the presentation that accompanies this call are available in the investors section of the Evofem website at evofem.com.

With me today from the Evofem executive team are Chief Executive Officer, Saundra Pelletier; Chief Financial Officer, Jay File; Chief Medical Officer, Kelly Culwell; and Chief Commercial Officer, Russ Barrans.

As noted on slide two, I want to highlight that during this call the Evofem team will make forward-looking statements regarding the company's future expectations, plans, and prospects that constitute forward-looking statements for the purposes of the Safe Harbor Provision under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those expressed in or implied by these forward-looking statements as a result of various important factors including those noted on slide two and described in the company's SEC filings which are available at sec.gov and through the investor section of evofem.com.

The forward-looking statements made during this call should be considered accurate only as of today, August 6, 2019. Although the company may elect to update forward-looking statements

from time-to-time in the future, we specifically disclaim any duty or obligation to do so even as new information becomes available or other events occur in the future.

And with that, I'll turn the call over to Saundra Pelletier, Evofem's CEO.

Saundra Pelletier^ Thank you, Amy. So, I'd like to say hello to everyone on the call and thank you for joining us. The first half of 2019 was significant for Evofem. To the collective efforts of our dynamic leadership team, we continue to strengthen the organization and advance the development of Amphora, our lead, Multipurpose Vaginal pH regulator or MVP-R candidate.

Amphora regulates vaginal pH in the normal 3.5 to 4.5 range, which is inhospitable to sperm and various bacterial pathogens. And it does this with no use of hormones.

Amphora was created to help empower women by providing them with a contraceptive option they can use in the moment on their terms.

To fund advancement towards Amphora's impeding regulatory approval and commercialization, we raised $80 million during the second quarter of 2019. Sixty million of the raise was a strategic investment from PDL Biopharma, a company that shares our vision and supports our mission to advance the reproductive health of women worldwide by building a premiere women's healthcare company.

The remaining $20 million came from two of our long-term institutional investors, Woodford Investment Management and Invesco Asset Management. This funding will support the execution of our growth strategy to bring our first in class MVP-R hormone-free birth control method to market in addition to developing Amphora for the potential prevention of two of the most commonly reported sexually transmitted infections in the United States, chlamydia and gonorrhea.

With that, I'll turn it over to Jay to review the second quarter results.

Jay File^ Thank you, Saundra, and good morning everyone. For the three months ended, June 30th, 2019, total operating expense decreased 49% to $11.9 million. Research and development costs decreased 56% to $5.2 million driven mainly by lower clinical trial costs in the AMPOWER trial.

General and administrative costs decreased 41% to $6.7 million in the second quarter of 2019. The key driver was a $6.2 million decrease in noncash stock-based compensation mainly associated with stock-based awards granted in March 2018 for which a significant amount of stock-based compensation was recognized during the second quarter of 2018. This was partially offset by stock-based awards granted after June 30, 2018.

The net decrease associated with noncash stock-based compensation was partially offset by a $500,000 increase in payroll-related expenses due to increase headcount, a $400,000 increase in PR and pre-commercialization, marketing-related expenses, and $300,000 rise in outside services associated with recruiting and consulting services.

Total other expense was $23.5 million in the second quarter of 2019 all related to noncash items associated with our private placement that closed during the second quarter and was discussed in detail in the 10-Q we just filed this morning. There was no total other expense in the prior year quarter.

As a result, net loss attributable to common stockholders was $35.5 million or a loss of $0.97 per share for the quarter ended, June 30, 2019, compared with the net loss of $23.2 million or a loss of $1.11 per share for the prior year quarter.

As Saundra mentioned in the second quarter of 2019, we raised $80 million from a sale of aggregate approximately 17.8 million shares of common stock to PDL Biopharma, Woodford Investment Management and Invesco Asset Management at $4.50 per share and warrants to purchase up to approximately 4.4 million shares of Evofem common stock at an exercise price of $6.38 per share.

For the remainder of 2019, we continue to expect our operating expense will average approximately $14 million per quarter. Based on our current plans, we believe that we have a sufficient funding through the anticipated approval of Amphora for hormone-free birth control in 2020.

With that, I'll turn the call back to Saundra.

Saundra Pelletier^ Through extensive market research, we've looked into the contraceptive journey for most women. What we have found is that regardless of a woman's current contraceptive use the journey is predominantly the same, emotional and frustrating.

The contraceptive journey begins, for most women, at approximately age 18 with the pill. Women oftentimes will change their methods due to unwanted side effects. They continue changing their brands or their methods throughout their reproductive life all while having to deal with method that makes their journey more complicated due to negative side effects and impacts on sexual pleasure like weight gain, mood swings.

It's really understandable that when women see the product profile of Amphora, most or somewhat or very interested at first glance because of the candidate's non-hormonal nature as well as a lubricating properties. And most importantly, the very minimal side effects expected to be associated with the ongoing use of Amphora. They like this because it can be used on an as-needed basis, in the moment. This makes women feel more in control of their sexual health.

Today, based on our latest assessment, if approved, Amphora has the potential to meet the needs of more than 25 million women who are at the greatest risk of unintended pregnancy. You have heard us consistently talk about the 16 million women who are currently sexually active and not using a contraceptive method.

But there are also 9 million women who are using barriers, rhythm or withdrawal method and they may be ready to try a new hormone-free method that they control and only use when they

need it. The bottom line is that it's time for a new innovation in birth control and that time is now.

Through our market research, we've confirmed that many women are dissatisfied with their birth control options and healthcare providers have nothing new or better to offer them. We also hear women don't want to take hormonal contraception every day. Because, on average, they're only having sex 8 to 10 times a month. We believe it's time for women to take back control of their birth control. And it's time for another choice.

We're a company that innately listens to women's needs throughout the entirety of their reproductive and sexual journey. AMPOWER is a unique clinical study that investigated Amphora for the prevention of pregnancy but it is also the first ever study to look at the effects of contraceptive candidates on sexual pleasure and sexual satisfaction for women.

With the findings of our exploratory endpoint on sexual satisfaction, we believe that if Amphora is approved by the FDA will provide an innovative healthcare solution that will also have the potential to enhance the sexual lives of women.

I'm now going to turn it over to Dr. Kelly Culwell, our Chief Medical Officer, to provide a deeper detail on the additional AMPOWER clinical findings we announced yesterday and update you on AMPREVENCE, our STI study prevention.

Kelly Culwell^ Thank you, Saundra. I'm pleased to discuss some of the additional findings from the AMPOWER clinical trial today. The AMPOWER trial was well balanced across baseline characteristics and demographics. The average age for the Amphora women in this study was 28 years old.

As illustrated on slide 12, study participants were diversified in race. Sixty-nine percent of women classified as white, 25.1% as African-American, and 2.5% as Asian, remaining participants classified as American-Indian or Alaska native, native Hawaiian or Pacific Islander or other.

Looking at the ethnicity breakdown, 41.3% of women reported Hispanic or Latina origin, 58.2% of women reported not Hispanic or Latina origin, and 0.6% of women did not report ethnicity. The average BMI for the study was 26.99.

As Saundra noted, a sexual satisfaction exploratory endpoint was included in the study. Participants were asked to answer unvalidated survey questions aimed at assessing the impact of their most recent contraceptive method on their life -- sex life at two time points; first, upon entering into the study; and second, after using Amphora for approximately one month.

At baseline, just 16.9% of study participants reported that their most recent contraception made their sex life a little or a lot better than before, with 7.6% of women reporting their sex life was a lot better, and 9.3% women reporting that their sex life was a little better.

However, after using at least one cycle of Amphora, 45% of women reported that their sex life was a little or a lot better. Drilling down, 16.1% of women reported that their sex life was a lot better and 28.4% reported that their sex life was a little better.

This is significant for two reasons. In the past, we have encountered some skepticism from investors that women and their partners might find Amphora disruptive. That pausing to use the product may somehow disrupt the moment. The AMPOWER data demonstrated that there was no negative impact for more than 90% of women in this trial.

Furthermore, not only it did not interrupt the moment, Amphora use had a positive impact on the sexual experience for approximately half of the women that used it, which is much greater than the number of women who reported a positive impact from their previous contraceptive method.

What these results indicate, although preliminary, is that use of Amphora increased the number of women reporting a positive impact on their sex life compared with the contraceptive methods they used before entering the AMPOWER study. This groundbreaking research has the potential to change the way women not only think about contraception but how they use contraception.

The incidence of serious adverse events in AMPOWER was low, around 1.1%. Further, none of the serious adverse events were considered definitely related to treatment with Amphora. And a discontinuation rate due to adverse event was less than 2%.

Finally, as we previously reported in the second quarter of 2019, we held a type B meeting with the FDA to discuss our planned NDA submission for Amphora for the prevention of pregnancy. As discussed from the Q1 call in May, this was a positive and constructive meeting. And we remain on track to resubmit our NDA in the fourth quarter of this year.

Shifting now to STI prevention and prevents the Phase 2B clinical trial of Amphora for the prevention of chlamydia with the secondary endpoint of prevention of gonorrhea is approaching completion. The study enrolled 860 women who had been previously diagnosed and treated for Amphora -- for chlamydia or gonorrhea in the proceeding 16 weeks. The participants were randomized to use either Amphora or a placebo vaginal gel during the duration of the four-month interventional period. Enrolment was complete at the end of March. And the last participant is expected to exit the study this month. So, we remain on track to report top line results in November.

Currently, there are no marketed products indicated for the prevention of chlamydia, which is among the most common sexually transmitted infections in the United States. If this program is successful, we expect to have the first, non-hormonal prescription contraceptive product that is also indicated for prevention of a sexually transmitted infection.

It is through these rigorous clinical studies and our steadfast commitment to improving women's sexual and reproductive health that we continue to push boundaries and empower women to make the decision to prevent pregnancy with the right option for them in the moment.

And with that, I will turn the call over to our Chief Commercial Officer, Russ Barrans.

Russ Barrans^ Thank you, Kelly. Well, as Saundra already pointed out, there's really a tremendous unmet need in contraception for those women who need or prefer a non-hormonal in-the-moment method.

Going to market for any asset, there are three criteria. It's like a three-legged stool. And the first leg is the unmet need, which Saundra described in her opening. Kelly just shared the results of the Phase 3 clinical trial in which Amphora met the pre-specified endpoints; and based on which, we believe it to be an approval product representing that second leg of the stool.

We're excited about the anticipated regulatory approval so women can have an innovation not previously available. But any stool that only has two legs can't stand. The third leg is the commercial opportunity.

Having launched half a dozen prescription of women's health products including Mirena, I know what a successful launch looks like and that is the reason I and my entire commercial team have come to be a part of this truly iconic brand.

Our extensive market research tells us that the approximately 25 million women that make up the target segments for Amphora have high interest in Amphora if it gets approved. That same research indicate that excitement is building for Amphora among those women whose contraceptive journey is moving them away from hormones due to unwanted side effects or who are having concerns over the potential long-term safety impact of hormones.

And this isn't just for women who are seeking an alternative contraceptive method. Our market research conducted among healthcare providers has shown that when presented with a hypothetical product with attributes that are similar to Amphora, healthcare providers anticipate it would be the second most prescribed contraceptive option in their armamentarium.

And finally, our research among peers indicates that insurers will reimburse an Amphora prescription in the same way as other monthly contraception. This qualifies Amphora to be a covered contraceptive option for women under the Affordable Care Act known as ACA.

Now, some have asked me, what happens if the ACA is over turned? It's our opinion that payers have recognized significant savings through the prevention of unintended pregnancies by offering contraception at no co-pay and no deductible to women under the ACA. We believe that they would use that opportunity to reinforce that they support women and not change their current policy of contraceptive coverage even if the ACA is over turned.

So, consider this for a moment, if approximately 1 million in the United States choose Amphora representing about 3% to 5% of the identified likely interested women, the assumption being that each woman fills her prescription about seven times a year. So, at those numbers, Evofem could expect an estimated $1 billion in annual growth sales.

And with the operator, please open the call to questions.

+++ q-and-a
Operator^ (Operator Instructions) Our first question comes from Randall Stanicky of RBC Capital Markets. Your line is open.

Randall Stanicky^ On the sexual satisfaction exploratory endpoint analysis, you guys have previously called out that close to 50% of women use a lubricant regularly. So, how do you envision marketing this? Are you able to make claims of lubricant qualities? And is your expectations of those qualities could be perceived similar to other perhaps over-the-counter lubricants? Or do you have to stick closer to the specific exploratory endpoint analysis? And then, I have a follow up as well.

Saundra Pelletier^ Okay. Great. Kelly?

Kelly Culwell^ Sure. I can start. So, we do have 510(k) clearance which was previously achieved for Amphora as a lubricant. And so, we are able to note the lubricating properties of Amphora which we're hopeful we can have included in the label. And so, that will be something that can be utilized as part of the promotional aspects of the product.

In addition, we do anticipate public -- well, we will publish the results of our sexual satisfaction exploratory endpoint. And we are going to be pre-submitting the results for presentation at ACOG next year. And so, our medical science liaisons will be able to utilize that publication as part of their work directly with healthcare providers.

I'll also turn it over to Russ Barrans who can speak more about the marketing aspect.

Russ Barrans^ Yes. And Randall, the one thing that we did find in market research is that women did respond quite favorably to that. And when we looked at about 181 of the participants and their partners who are in the AMPOWER study and asked them, we literally only had one person who has suggested that the lubricating property wasn't a benefit to them. But more than 90% of both the women and the men suggested that it was a very pleasurable experience indicating that it was there. And so, we do anticipate that the opportunity to talk about that will be afforded to us through the label.

Randall Stanicky^ And presumably, this would address any questions around negative experience with the product or uncertainty around use I assume with the data in hand. Is that -- is that fair?

Russ Barrans^ Yes, that's exactly right.

Randall Stanicky^ Okay.

Kelly Culwell^ Yes. I think this in combination with our overall satisfaction data, which will also be presented this fall, I think both of those things work together.

Saundra Pelletier^ Well -- and also too Randall, if I could just add, and just for everybody on the call, I think it's important to remind everybody too that Amphora was not intended to be a libido-

enhancing product. And the irony for me is that a lot of women who do go on hormonal contraception their libido is lowered.

So, they're taking a productive so that they can have sex because you wouldn't take contraception unless you were going to have sex but then their libido is lowered. So, the idea that half of the women liked or like it lot, the sexual pleasure component, and then the other half had no change. So, there was no negativity and half of them had improvement.

To your point, we think is really significant and really important as we talk about sexual pleasure because we think it's appropriate and a little bit provocative but we think it's time for that in this category.

Randall Stanicky^ Well -- and I guess the other part of this too, can you maybe update us on timelines for STI and ultimately pathway for that to get into the label? And then, I've got one last quick one for Russ.

Saundra Pelletier^ Okay. Will you go ahead.

Kelly Culwell^ Sure. As I noted in the call, we will have our top line results from AMPREVENCE by the end of this year -- in November of this year. And that will set us up to have an end of Phase 2 meeting with the FDA. And we have previously discussed with the FDA that should we meet our primary endpoints for the study that we can try to include this as one of two pivotal trials which means that our second confirmatory Phase 3 would start in the middle of 2020. And that will lead us to resubmitting or to submitting the sNDA at the end of 2021.

And because we have fast-track status for chlamydia, we anticipated six months review for that sNDA. And so, we should be able to add that into the label in 2022.

Randall Stanicky^ Okay. That's great. And then, for Russ or maybe even Jay, you guys have talked previously about moving forward on OUS. I think you had mentioned Asia-Pac moving forward with some binding offers. And you're about to kick off EU. I believe that was last quarter you talked about that. Maybe I missed it. But where are we on those potential announcements? Are those 2019 events?

Saundra Pelletier^ Russ?

Russ Barrans^ Yes. Those are actually ongoing and you're right. We had in fact kicked off the European process and we're currently in due diligence process with three of our companies out of the EU. So, that process is ongoing where non-binding offers will be expected later this year -- later -- excuse me -- this month which would then put us in a position where we believe we can close that by the end of the year in terms of the EU.

And in APAC, we're in a similar situation where those due diligence are ongoing. So, they're both actually pretty close to be in the same time track right now. So, we anticipate that in one or both of those areas, we would be able to get a licensing deal done before the end of the year.

Randall Stanicky^ So, FTI data before year end November, NDA filing before year end, and potential OUS announcements before year end as well?

Saundra Pelletier^ Correct.

Russ Barrans^ That's correct.

Operator^ Our next question comes from Leland Gershell of Oppenheimer & Co. Your line is open.

Leland Gershell^ Thanks for taking my question. Great progress. A couple of questions, first, actually on the point about the ACA reimbursement, want to sort of drill down a bit. Since Amphora I think will be defining a novel class of contraception product, I wanted to ask and see if that would have that positions reimbursement either pro or against given that there are multiple classes out there each with I think multiple products on a prescription basis.

I believe under ACA, the requirement is to reimbursement at least one of the products in each class. So, given the new category, presumably that would be a support for Amphora?

Russ Barrans^ That's correct, Leland. And we have actually spoken with payers who represent about 70% of the covered commercial lives in the United States. And the indication by them was that in fact there isn't anything in that category that we would be in. So, therefore, we would likely be the covered benefit.

The one thing I will say is that is not an automatic. So, we have put together a very experienced team of market access people who will be calling on payers before we actually are commercialized in order to make sure they're aware of what's coming and so we can get those onto those formularies as quick as possible.

Leland Gershell^ Okay. Great. And then, given that Amphora is really an entirely new type of product in this overall category, what can you do as a company without treading into who -- any sort of compliance, FDA-type issues, ahead of the launch, ahead of approval perhaps in a non-branded fashion that could make the public aware of Amphora and garner interest in this novel profile?

Russ Barrans^ Well, we're doing two things right now. One is we already have our medical scientific liaisons who are able to have a scientific conversation with healthcare providers and also with payers in that community together with our market access people. So, that will be ongoing.

We will also be able to start doing some non-branded public relations in the third quarter or excuse me, in the first quarter of next year as we anticipate the approval. And those will be non-branded. So, of course not specific to Amphora but letting people be aware of the fact that there is a -- there are options available to them in a non-hormonal fashion.

Leland Gershell^ And then one last one which maybe more for Jay. Just as you look toward becoming a commercial company, I know you're not giving guidance for next year at this point. But just how should we think about overall organization expansion and build out toward at least U.S. commercialization of Amphora for Evofem?

Jay File^ Sure. Yes, you're right. Obviously, the big focus right now is on pre-commercialization activities as well as getting the NDA file and wrapping up AMPREVENCE, the Phase 2B. So, really, the majority of the hires, we're at just over 35 employees now. We'll probably be close to 50 by the end of the year based on current headcount needs. A lot of those are going to continue to be building up the sales and marketing, the commercialization team. And then starting in last Q1, you'll start seeing Russ really building out his sales force and prepping for potential PDUFA date and the commercial launch in 2020.

So, G&A will remain relatively stable as far as headcount and growth goes. And you really start seeing the sales and marketing to continue to expand through the end of the year and really come into its own starting in 2020.

Leland Gershell^ Okay. And have you -- I know you're going to employ multiple strategies for marketing and detailing. Have you defined a sales force organization size at this point? Or is that still kind of an indetermination at this point?

Jay File^ I'll let Russ take that.

Russ Barrans^ Yes. We'll have 125 representatives, about 12 managers that cover them. That will give us a footprint that literally covers all of the highest prescribers in contraception.

Operator^ Our next question comes from Yasmeen Rahimi of Roth Capital Partners. Your line is open.

Yasmeen Rahimi^ Congrats in the continued progress. So, three questions for you. Question one is the following, so Russ, can you give me a little bit more color in regards to your market research? Which segment of the market is going to be likely to adopt Amphora the greatest? So, specifically, which group of women would want to switch? And so, if you could build out the market segmentation a little bit more in detail for me?

Question number two is also directed for you, Russ, which is what are key lessons that you would have learned in regards to commercialization in regards to contraception that you find are sort of the most effective way to drive strong adoption? And then, I have a follow up.

Russ Barrans^ Thanks, Yasmeen. So, when we looked at market research, what we found was, interestingly, that across almost all ages there is high interest in a non-hormonal method. So, it didn't matter if you're a millennial or if you were someone who is closer to the peri-menopausal age. There was people across all sectors that were quite interested.

We also found that there was a group of people who are currently using hormonal contraception that indicated that their concerns over their future ability to become pregnant or their side effect

profile that they were currently experiencing would make this a very interesting product for them.

The highest group of interest came from those women who we would say have already sort of abandoned their contraceptive method because of the fact that they just couldn't find one that fit them and healthcare providers acknowledge that pretty actively as well by indicating that this would be the second most used product in their portfolio showing that they do have a relatively large number of women who have abandoned using some form of prescription contraception because of the side effect profile.

So, the segments that seemed to be the lowest hanging fruit, if I can use that terminology, would be those women who are currently not using anything because they've already made the choice that hormonal contraception is not for them of which there is about 25 million.

And then when you start looking at the 17 million that are currently using some form of hormonal contraception, we found that numbers range from about 1.5% to 2.5% of each one of those groups wherein what we call the transition stage and would be quite interested in considering making that move to Amphora if it gets approved.

Yasmeen, I'm sorry. Can you remind of the second part of your question?

Yasmeen Rahimi^ Yes. Actually, before we get to the second part, I have a follow up on the comment you just made. How did you actually determine the number of women that aren't taking anything? Did you just look at the number of women that aren't in reproductive age but then subtracted out women that are not taking?

I guess the question I'm trying to get at is -- if women aren't taking any contraception, are they willing to admit that to their OB-GYN that they're not on anything? So, where is that number actually coming from so that these women are already in the clinic but aren't taking anything? Does that make sense?

Russ Barrans^ Yes. And that's a great question. Because there's approximately 43 million in the United States who are reproductive age and we certainly didn't go out and talk to all of them. So, that data comes from the CDC and it is self-reported on their part.

So, I think it's probably easier for women to report in a fashion that's not necessarily with their OB-GYN, although the OB-GYNs readily admit that many of these women will discontinue taking anything and then not tell them and they don't learn of this maybe for another year until they see them again for an annual. So, that data comes from the CDC.

Yasmeen Rahimi^ Thank you. And then the question I had was sort of key lessons that are most effective in regards to commercialization that you want to point out that are probably not obvious to us.

Russ Barrans^ Yes and I'll be quick on this. One of things as really key is we've kind of found that there tends to be, if you will, a perfect synergy that happens when you do three things. First

of all, you put a sales force in that experience and knows what they're doing in women's health. Secondly is you supplement that with some good DTC that reaches to the women that are key in.

One of the key lessons we've already learned over the years, so from 10 years ago as an example where you would have to always do commercials on TV is today we can be very pinpointed with digital marketing and get to where those women are currently consuming their information be it on the internet or social media or places like that. So, we're able to use that very targeted method to do that.

And then the last thing we really do I think is something that we've done effectively over the years and now in different companies with different products is to segment out positions not just upon their behavioral segmentation which is looking at back what they did previously in terms of contraception but also on attitudinal behavioral -- attitudinal segmentation and layering those two together.

So, we can see exactly what the attitudes look like and what the tendencies are. And then we put together an algorithm that allows us to be very specific at looking at the position and understanding exactly which segment that they fall into and making sure we put our efforts where it's most likely to get good benefit.

Operator^ (Operator Instructions) Our next question comes from Raghuram Selvaraju of H.C. Wainwright. Your line is open.

Edward White^ This is Edward White for Ram. I appreciate you taking the questions.

So, in regard to the new AMPOWER study, it sounds like it's going to be a great advancement for a lot of women. I was just wondering how significant this is in terms of the label claims that you might be able to make with the FDA?

Kelly Culwell^ Yes. So, I assume that you're asking about the sexual satisfaction endpoint. And so while this was an exploratory endpoint and so we don't anticipate at this point that it will be in the label. However, we have multiple ways that we can talk about this with healthcare providers in particular. So, we are going to be publishing this data. We are going to be submitting the data for presentation next year at the American College of OB-GYN. And so, that will allow us and allow our medical science liaisons to talk to healthcare providers about this data.

We're also including the same endpoint that's been included in our AMPREVENCE study. And so, should we see consistent results from this work then we have a stronger argument to get this potentially in the label in the future. But for now, we'll be utilizing the data as part of a publication strategy through our medical science liaisons.

Edward White^ Okay. That makes sense.

Russ Barrans^ And then Ram, let me just add that the one thing we'll also do post approval is we will do some additional marketing survey research that once we can demonstrate again post

approval that in the real world experience women are having the same level of sexual satisfaction then OPDP will permit you if you grab more than one source to replicate the same results to put that into your promotional materials even if it's not in the label.

Edward White^ I see. Okay. And moving onto the MPT gel just the Phase 2B trial, I was just wondering about the timing of that whether that's either 2019, 2020, or if you're going to wait until a lot of the things are wrapped with the NDA submission before you start jumping into other trials?

Kelly Culwell^ Right. Yes. We are going to wait until we have approval for Amphora as a contraceptive before launching any additional trials including the Phase 3 trial, confirmatory trial, for the STI indication.

Edward White^ Okay. Thanks. And just one final question on more financial matters, just looking at a lot of these noncash items, they're a little more difficult to kind of predict the model as we go forward. Just wondering if you're looking at any more noncash items to hit the P&L in any of the future quarters that you can at least currently predict?

Jay File^ Yes. No, that's a fair question. Everything related to the private placement was effectively recognized during the second quarter. It was rather self contained during April and June.

Through the remainder of the year, it will really just be that associated with the noncash, stock-based compensation of which there'll be about $500,000 associated with R&D and about [3.5] associated with G&A which includes our sales and marketing aspect for the time being as well until we're commercial. So, in total about -- and additional $4 million will be recognized through the end of the year barring any additional grants; but currently, that's not anticipated.

Operator^ Our next question comes from Carl Byrnes of Northland Capital. Your line is open.

Carl Byrnes^ Congratulations on your progress. Are you able to provide any guidance on R&D spend for the second half of the year and also for 2020 given that we've seen some drops but also considering the planned trials that you have in place? Thanks.

Jay File^ Sure. Yes, we haven't given too much guidance on this but I can basically outline it for you. We do anticipate that overall R&D expense will basically obviously decrease compared to the prior year.

For the remainder of the year, we've basically recognized everything that we anticipate to through June 30 on the AMPOWER trial. Any expenses associated with that will just continue to be related to the NDA submission and not CRO or trial related.

AMPREVENCE with the last patient out forecasted for this month that, again, that's basically playing catch up with the invoices coming in and recognizing the last expenses, probably another maybe $7 million to $8 million in expenses associated with that trial.

As Kelly had just noted for 2020, the focus really is on commercialization and getting the approval for Amphora. As such, we don't anticipate kicking off the confirmatory Phase 3 for STI until after approval so you really see the first half of the year being relatively low in R&D and then we'll see that trial kick off as anticipated starting as early as July.

We'll reach out again to CRO, engage, then you'll see that start to increase. They relatively start off somewhat slow so it won't be a huge number compared to what we've incurred in the prior year. So, I would anticipate overall R&D expense will be even lower in 2020 than it was in 2019.

Operator^ There are no further questions. I'd like to turn the call back over to Saundra Pelletier for any closing remarks.

Saundra Pelletier^ Great. So, I want to thank everybody for joining us today. We are thrilled to share with you the additional findings from AMPOWER. There's a few things that I want to reiterate, we've been asked repeatedly about the age of the Amphora women. And as you heard today from Kelly, she is 28 years old.

I also want to reiterate that after at least one cycle of Amphora, 45% of women reported their sex life was somewhat or a lot better in our exploratory sexual satisfaction endpoint. The idea that a contraceptive product can actually enhance your satisfaction is so important and so significant.

This company is made up of people that have spent years in women's health. I, myself, have spent 30 years in women's health, not to date myself. But as a women, these kinds of findings make you so optimistic about your sexual experience. And so, we're really excited about this.

Also, Amphora was very well tolerated with fewer than 2% of women discontinuing AMPOWER due to adverse events. If you study this category and you look at what's happening with side effects, hormone-related side effects, I can tell you that less than 2% is incredible. So, we're very excited about the safety profile of this asset.

We've also made a lot of progress this year and we look forward to achieving our near-term milestones. For AMPREVENCE, we anticipate the last patient visit will occur later this month. We're looking forward to reporting our top line data in November. Our next step for the prevention of pregnancy is to resubmit the NDA in the fourth quarter and to launch in 2020.

The time for innovation and birth control is now. It's no secret that women make sacrifices. Some of you on the phone have even said to me that as you talk to your partners and your significant others and your daughters, you recognize that these side effects are real. They're just not talked about because women are asked to just deal with it if you will. It's been a bit of a dirty little secret really.

So, whether it's daily dosing, medical procedures, lack of control, headaches, lessened libido, women have accepted the current contraceptive choices as status quo. But that time is soon to be over because Amphora will change that.

The fact is that 25 million women are no longer using hormonal contraception because their journeys have been emotional and they've been frustrating. Here, at Evofem, we're preparing to potentially change the lives of these women who could soon become the Amphora woman. That's why we believe that Amphora represents a tremendous commercial opportunity as a revolutionary advancement in women's health.

So, this concludes our Q2 earnings call. On behalf of everyone here at Evofem, we want to thank you for your ongoing support of our mission to develop and provide innovative solutions that will empower women to take control of their sexual and reproductive health.

So, have a great day. Thank you again.

Operator^ Ladies and gentleman, thank you for participating in today's conference. This does conclude the program and you may all disconnect. Everyone, have a great day.