Evofem Biosciences, Inc. (NASDAQ: EVFM)
Q2 2020 Earnings Conference Call
August 4, 2020 11:00 AM ET

Company Participants

- Amy Raskopf – Head of IR
- Saundra Pelletier - President, CEO & Director
- Justin File – Chief Financial Officer
- Russell Barrans - Chief Commercial Officer
- Kelly Culwell - Chief Medical Officer

Conference Call Participants

- David Amsellem - Piper Sandler & Co.
- Leland Gershell - Oppenheimer
- Raghuram Selvaraju - H.C. Wainwright & Co.

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Evofem Biosciences Second Quarter 2020 Financial Results Conference Call. [Operator Instructions].

I would now like to hand the conference over to your speaker today, Ms. Amy Raskopf, Evofem Biosciences' Head of Investor Relations. Ma'am, please go ahead.

Amy Raskopf

Thank you, and good morning, everyone. Welcome to the Evofem Biosciences Q2 conference call. If you haven't done so already, I encourage you to access the Q2 2020 presentation and the press release we issued earlier today, both of which are at evofem.com under the Investors tab.

Before we begin, I would like to remind you that remarks on this call will contain forward-looking statements, which are made only as of today,

August 4, 2020. For a more detailed description of important risk factors that could cause our actual results to differ materially, please refer to our annual report on Form 10-K, our most recently filed 10-Q, and our current report on Form 8-K filed with the SEC on June 2, 2020.

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

Saundra Pelletier

Thank you, Amy. Hello, and thank you all for joining us today. The second quarter marked yet another period of relentless execution. We have checked every box. We delivered on every single milestone that we promised that we would achieve.

- We said we would secure capital to get us through our PDUFA date, and we did. Despite the significant fundraising challenges posed by COVID, we secured $25 million from a private placement of convertible notes and warrants.
- We said Phexxi was an approvable asset based on our successful Phase III results, and we were right. The FDA approved Phexxi on May 22, ahead of the PDUFA date.
- We were candid with our expense and cash burn guidance and transparent that we needed to raise $100 million to support the successful launch of Phexxi and initiate the Phase III STI trial. Once again, we exceeded expectations, with an oversubscribed underwritten public offering of common stock that brought in approximately $111 million, including the green shoe.

As you might imagine, I am thrilled with the dedication and the effort of this team and our singular focus on execution. Our ability to secure an FDA approval and critical capital in the middle of the COVID pandemic testifies to the experience, strength, discipline and focus of the entire Evofem team. During a time when many companies were unfortunately not able to weather the pandemic, we have executed and we have excelled.

Let me put an even finer point on these accomplishments.

Number one, less than 14% of products receive FDA approval. I want to say that again - 14%. So think about all of the time, all of the effort, all of the energy, all of the money and only 14% of products are actually approved.

Number two, the $136 million we raised this quarter was made even more difficult by a changing investor landscape because on May 21, the day before the FDA approval of Phexxi, PDL BioPharma, our largest shareholder at the time, distributed 13.3 million shares of Evofem as a dividend to its shareholders. This was done following PDL's decision last December to liquidate and monetize all of its assets to return proceeds to its shareholders.

Then on June 4, which was right on the heels of our fundraising close, Link Fund Solutions sold 19 health care assets from a fund formerly run by Woodford, which included 9.1 million shares of Evofem, to an institutional investor. Similar to PDL, the portfolio sale was unrelated to Evofem's business activities. So in the course of just 2 weeks, the market absorbed 22.4 million shares of Evofem, in addition to the 31.7 million shares we sold in the June financing, which, unfortunately, put downward pressure on our stock price.

But today, these overhangs and these distractions are gone. Our balance sheet is the strongest that it has ever been. We have a fantastic new group of investors who believe in our story, they believe in our mission and they believe in our team's ability to execute. We are preparing to launch a disruptive new technology that women have been waiting for.

We are very, very pleased that you are with us today, and that you've joined us on the journey. Russ Barrans, our Chief Commercial Officer, is going to talk more in a minute about the precommercial activities and the launch plans that will serve as the foundation for Phexxi's success. But first, I'd like to ask our CFO, Jay File, to review the results of our second quarter. Jay?

Jay File

Thank you, Saundra. For the second quarter ended June 30, 2020, total operating expenses were $22.4 million compared to $11.9 million for the quarter ended June 30, 2019.

Research and development costs decreased to $2.6 million in the second quarter of 2020, mainly driven by a $2.3 million reduction in clinical trial expenses due to the completion of the AMPREVENCE trial in December 2019. Additionally for the quarter, there was an aggregate $1 million reduction in outside services costs and payroll-related expense, which was partially offset by a $500,000 increase in noncash stock-based compensation.

Selling and marketing costs were $10 million for the second quarter of 2020, reflecting preparations for the commercial launch of Phexxi in September. Now as a reminder, with the anticipated commercial launch, we started to break out selling and marketing expenses this year in our financials. Therefore, $1.3 million was reclassified from general and administrative expenses into sales and marketing expense for the second quarter of 2019 to conform to this presentation. As you would anticipate, the majority of the $8.7 million increase during the current quarter relates to pre-commercialization activities that Russ will expand on later in the call.

General and administrative costs increased to $9.7 million for the second quarter of 2020. The increase over the prior year quarter includes an aggregate increase of $2.1 million associated with various operational items, including the issuance of convertible debt, legal costs, payroll-related costs due to increased headcount, and other general business expenses. Additionally, there was a $2.2 million increase in noncash stock-based compensation mainly related to stock-based awards granted in February 2020.

Total other expense was $30.3 million in the second quarter of 2020, and mainly included the noncash loss on issuance and subsequent change in fair value during the period of long-term convertible notes, warrants and

purchase rights that were issued in connection with the debt transaction that closed during the second quarter of 2020.

As a result, net loss attributable to common stockholders was $52.7 million, or a loss of $0.91 per share for the second quarter ended June 30, 2020, as compared with a net loss of $35.5 million, or a loss of $0.97 per share for the prior year quarter.

We closed the quarter with $123.6 million in unrestricted cash, which gives us runway into the second quarter of 2021. This is based solely on projected expenses, and I want to highlight that anticipated Phexxi revenues would provide upside to this.

And with that, I'll turn it over to Russ.

Russell Barrans

Thank you, Jay. With just over a month until the launch of the first true contraceptive innovation in over two decades, our commercial organization is putting together an extraordinary effort into laying the foundation for broad access of Phexxi and the fast uptake among both providers and women. Today, I want to share with you a few of the highlights that underscore the strategic planning and hard work that have already yielded important results and are driving momentum into launch.

First, the market access team has been successfully making the value case for Phexxi's unique mechanism of action and the unmet need among women for a non-hormonal, woman-controlled, FDA-approved contraception. As a result of their efforts, we will soon have all the wholesale agreements in place with Phexxi in stock and ready for launch on September 8.

A huge win for Phexxi is that both First Databank and Medi-Span, the two major drug information compendiums that provide pricing and product information to the majority of insurance plans, have granted Phexxi a new classification as the first and only Vaginal pH Modulator.

I can't overstate the importance of this classification in securing and accelerating payer coverage. So typically, payers can take up to 180 days to review and to evaluate a new drug approved for formulary coverage. Our unique classification in these two drug pricing compendiums, along with our compelling clinical presentation, have helped us secure meetings with all major commercial payers and obtain early formulary inclusion at zero co-pay among several regional plans and local players, including Kaiser Permanente in Washington State and Geisinger in Pennsylvania. We remain confident that 50% to 60% of payers will have reviewed Phexxi by the time of launch, and we expect the remaining 40% to review Phexxi before the end of Q4.

Now one last thing on the market access front. We are working with the Office of Women's Health, or OWH, and the Health Resources and Services Administration, or HRSA, to update their birth control tables to include Phexxi as a new birth control option with a unique MOA.

Because there is no specific protocol or time line established for updating these tables, it's difficult to predict when we might receive a response to our request for this update. But let me be clear about something - that the establishment of the 19th category is a 'nice to have,' not a 'need to have,' for Phexxi. We are not dependent upon ACA in order for women to have affordable access to Phexxi. Our co-pay assistance program for those with commercial insurance is designed for women to pay approximately $30 out of pocket or less. And in many cases, Phexxi will be covered at zero out-of-pocket cost.

Turning now to the sales organization. We have completed the recruitment of the 70 sales representatives and regional managers who will be responsible for engaging OB/GYN offices across the country, and we expect them to be fully trained and in the field on September 8th. On average, this team has 15 years of pharmaceutical sales experience, half of which has been in women's health. I told my team that we have to strive to be COVID-proof. This is what I mean by that: planning to succeed in the context of the new business rules COVID has created. Now the surveys we've seen, and

there are many of them, indicate offices are likely to see those with whom they already have a relationship. This is a critical distinction we understood was a key factor in today's environment. So by design, we have recruited people who have continued to have HCP access and will enable them to launch Phexxi in the most successful manner possible.

Next, the commercial team has been laser focused on the development of our consumer awareness program, as we build out our Phexxi Concierge Experience, our comprehensive telemedicine platform, to facilitate women's access to Phexxi from the comfort of their own home, if that's what they would like. As part of our 'Coming Soon' activities, we've launched the initial HCP-facing website on www.phexxi.com, and you can expect the consumer page to be live at launch. We're also preparing to initiate the Phexxi digital media channels in mid-August.

Recognizing the heightened use of social media during this COVID-19 environment, we continue to refine our tactical planning using an artificial intelligence approach to ensure that we target and consistently engage with our key target segments of both women and HCPs. The Phexxi Concierge Experience is evolving to facilitate women's access to Phexxi through a digital experience from the comfort of their own home.

While a woman can still follow a traditional path in visiting her personal HCP to discuss Phexxi, our comprehensive online services provide an alternative, a modern path to contraceptive access, if you will. Within a few minutes, she can quickly learn about Phexxi, complete an asynchronous survey that will enable her to chat online or speak with one of over 10,000 HCPs in our telehealth partners' telemedicine network and, ultimately, gain a prescription for Phexxi if she and her HCP agreed that Phexxi is right for her.

The Phexxi Concierge Experience does not stop there. A woman will be able to provide her insurance information for co-pay and prior authorization support. She can connect with her local retail pharmacy or she can have her Phexxi shipped right to her door, and it will also provide for her refill

reminders and support so that she never runs out of her Phexxi. This first-class access model is just one of the many examples of how Evofem is investing to improve the reproductive health and well-being of women.

Now for something I'm really proud of, I want to share with you a sneak peek of the final Phexxi packaging and individual applicator foils, which reflect the brand's unique value proposition. Now I realize I am biased, but I absolutely love the way that this great design turned out. And in market research, women responded enthusiastically about the look and the feel of this Phexxi packaging.

In summary, we are firing on all cylinders heading into our final days before launch.

- With Phexxi's differentiated profile and strong commercial and clinical presentations, it is now a unique classification in two of the most important drug pricing compendiums.
- Solid headway with payers reinforces our confidence that we will have 50% to 60% of commercial review and coverage of Phexxi at launch, with the remainder expected by the end of the fourth quarter;
- Phexxi social media channels will be launched by mid-August.
- Finally, the introduction of the Phexxi Concierge Experience for women seeking a non-hormonal option and the recruitment of a best-in-class sales organization with a specific emphasis on women's healthcare experience, let me say, but with a lot of blood, sweat, and tears of joy, we are ready to launch Phexxi on September 8.

And with that, I'll turn the call over to Dr. Kelly Culwell, our Chief Medical Officer.

Kelly Culwell

Thank you, Russ. The medical and clinical teams have been equally busy building a robust and comprehensive publication and presentation strategy, and continuing the development of EVO100 for the prevention of urogenital chlamydia and gonorrhea in women.

We began in April with three data sets from the pivotal Phase III AMPOWER clinical trial, which were accepted for presentation at the annual meeting of the American College of Obstetricians and Gynecologists and published in the association's prestigious *Green Journal* supplement. This was followed by publication of the full AMPOWER manuscript in the peer-reviewed journal *Contraception* in July.

Simultaneously, we have been advancing the scientific presentation of data from the Phase IIb AMPREVENCE trial, evaluating EVO100 for the prevention of urogenital chlamydia and gonorrhea. First up is a poster presentation at the U.S. Centers for Disease Control and Prevention's virtual 2020 STD Prevention Conference in September. We are also working to secure publication of the full manuscript of this landmark clinical trial in a peer-reviewed publication in the next few months.

In the meantime, preparations for our pivotal Phase III trial of EVO100 are advancing right on track. We have selected our clinical research organization, ICON, who was also the CRO for AMPREVENCE. Based on our initial discussion with the FDA in May, we are planning to move forward with a randomized placebo-controlled Phase III clinical trial that is similar to AMPREVENCE. This trial will enroll women who have recently been successfully treated for a prior infection with either chlamydia or gonorrhea, and women who are at risk for future infection. Our Type C meeting with the FDA is scheduled for August 19th, and we expect to enroll our first subject in the fourth quarter of 2020.

Given the increasing incidence of chlamydia and gonorrhea, which has now exceeded more than two million cases reported annually, and the absence of

any FDA-approved products to prevent their transmission, we believe the need and the opportunity for EVO100 is significant. We are eager to undertake what we expect will be the first clinical trial to enable regulatory filings in the U.S. and the EU for the prevention of these two common and dangerous STIs.

And with that, operator, we'd like to open the call for questions.

Question-and-Answer Session

Operator

[Operator Instructions]. Our first question comes from the line of David Amsellem with Piper Sandler.

David Amsellem

Thanks. I just have a few questions here. First, this is a question for Russ. Just on -- first on the decision about a 19th category, can you just walk us through kind of mechanically how we should think about the next few months and timing of that? I know you emphasize that it's a nice to have, not a need to have, but I still think it would be helpful to understand the process there and, to the extent you'd get that category, implications for reimbursement. So that's number one.

And then secondly, I had a question about telemedicine. And I know you've talked about this previously, but can you just remind us what your thinking is regarding not just sales force sizing, but your ability to reach target physicians virtually, and how you think that will impact the initial rollout of Phexxi, one way or another? And I have a couple of follow-ups, but I'll just stop there for now.

Russell Barrans

Great. Thanks, David. Appreciate those questions, and I'll try to be succinct and brief on those for you. While other companies really have messaged how important the 19th category is for them, what we've really kind of stated,

because of where we're at, we've seen from the payer environment already that nearly everyone is putting us on even before they've reviewed it for ACA coverage, either -- even if it's in a nonpreferred position. So in those particular cases, when you start looking at that and you say, "Well, if a woman, for example, in a nonpreferred position, had a $75 co-pay," if we pay basically $45 of that, we can get her down to a place where she is not out-of-pocket any more than what we have looked at in market research as an acceptable amount of money, and that still leaves us a very healthy opportunity in terms of our margins on it with that respect.

So that's why we say, for us, it isn't absolutely a have to have, but it is a nice to have, and we are working towards that. We are still in communications with HRSA and the Office of Women's Health, and we do have confidence, based upon what we saw when we presented that same data to the compendiums, the way they viewed it was that it was, in fact, a unique MOA and put it into that Vaginal pH Modulator class. So we actually believe that, that's going to be to our benefit.

But we're not forced in a situation where we get to launch if we don't have that established at that point that will really impact us in a tremendous way. Clearly, we would like to see that happen because we are about making sure that all women have access and that there are no barriers to them receiving that, and that 19th category could help us just facilitate that into a greater way.

In terms of our sales force and how we believe that we've been able to, as I've said to my team, try to be somewhat COVID-proof. One of the things that we had decided when we moved, as most people would remember initially, before COVID we were planning on 125, is we've taken a pretty good look at that based on some of the data that's been coming out from organizations like IQVIA that have represented where businesses are starting to open and how it's happening. One of the things that many of the managers that were in the hiring process did was go to those people who had expressed interest in joining us that had experience, and they were able

to really understand that they would have access that maybe other people wouldn't have. We've also put together, and we'll have it launched later in the summer, which is quickly coming to an end, a portal that health care providers can go to that give them all the details they need to know about Phexxi. Because we have the good fortune of having a really clean safety profile, there is a way for them to be able to do that on an, as I call it, asynchronous level that will give them the information they need to feel confident to prescribe the product.

And then on the telemedicine side, we are continuing to partner with people who will go all the way down to helping women navigate through that, doing their insurance form, while they're filling out the asynchronous surveys and making sure so that really within a -- we've timed this out -- 5- to 15-minute period of time they could be on the phone or on their computer and get their prescription done and ready and have it sent to them within the next 24 to 48 hours.

David Amsellem

Okay. That's helpful. If I may just sneak in a quick follow-up here. As the product ramps, can you just talk about the extent to which you'd consider expanding the sales force over time? And is this sort of a paradigm over time where you can see yourself even targeting certain general practitioners? Help us understand your longer-term thinking regarding the commercial infrastructure.

Russell Barrans

One of the things that I've asked Jay specifically and Saundra is to give me the flexibility to have the rapid redeployment of resources and put them where they need to be put based on how the environment switches and turns around us. So one of the things, for example, I've kind of said is if we see the general environment around health care offices opening up to broader access, we would probably look to see about increasing that number come the first quarter of next year after we have some traction and see

where we're at. But I think the critical thing, David, that I have really focused on is to say we will allocate our resources into those channels that make the most sense. And that, as Saundra had said earlier in her presentation, I think, differentiates us from a lot of other companies.

First of all, we don't have this cumbersome infrastructure already established that we have to try to work around, but secondly, that we are willing and able to allocate where we need to go. So if we see channels opening up in the digital realm that are really flourishing, we will put our assets there. But we do think there is a nice synergy here between that and even in the PR part, which I didn't really talk about, where we see those social influencers beginning to drive the conversation. We'll put the assets where they need to go.

David Amsellem

Okay, that’s helpful. Thank you!

Operator

And our next question comes from the line of Leland Gershell with Oppenheimer.

Leland Gershell

Good morning. Thanks for taking my questions. I have a few questions. First, regulatory, just with regard to this Type C meeting coming up. Any particular issues that you'd like to highlight before heading into the STI trial? And then a couple of financial questions. First, in terms of the guidance you've given. As we think about the run rate for 2021 with 4Q costing between $42 million to $44 million in cash, should we use that kind of as a benchmark more or less for the run rate heading into '21? And then my third question is, should we see a return of a much heavier outbreaks of COVID-19 later this year and the return to shutdowns, how should we think about Evofem's approach to either redeployment or furloughing of the field force,

or heavier spending, perhaps, on online virtual activities? How should we think about that?

Kelly Culwell

Sure. So this is Kelly. Hi Leland. I'll take the first question regarding regulatory. So because of our fast-track status and QIDP designation for the chlamydia and gonorrhea indications, respectively, we have the opportunity for more interactions with the Agency than would otherwise be possible. And so this Type C meeting actually is our opportunity to present our full protocol to the division and ask for their feedback, specifically around the strategies that we may need to employ in a COVID environment, specifically around the way that we're defining our endpoints, etc., so that we can have full agreement before our anticipated first patient in at the end of the year.

Justin File

That good, Leland?

Leland Gershell

Yes, thank you.

Justin File

Perfect. I'll go in next. Yes. So as far as that runway goes, not necessarily does the Q3, Q4 spend mirror in any way what we will then start off the year, so I would not use that as kind of your proxy moving forward. We still are anticipating and assessing when we will start giving more guidance beyond the end of the year. We do assess that probably Q1 would be the first time that we might give some additional guidance, and then that will probably include some revenue at that time as well. But I would not use Q4 as what the basis is going forward into Q1. That would be a little high.

Saundra Pelletier

And then, Leland, to your last -- no, go ahead. I'm sorry. Go ahead.

Leland Gershell

I don't know, just saying it's an unfair world we're in, obviously, and wanted to see if what thought you've given to kind of what contingency plans you may have in terms of the direction depends on it may take.

Saundra Pelletier

Yes. No, look, I think it's a really critical question, and thank you, by the way. And I hope everybody on the call has heard the unbelievable exuberance and excitement from Russ. We can barely contain him. We are making him wear weighted shoes because he is so excited.

But look, to your point, we really have been very disciplined around trying to make the entire organization, but particularly the commercial footprint, COVID-proof, and we really mean that. And so for example, we've anticipated the worst. I mean, we really have. And so what I mean by that is that we've -- when we talk about the focus we've had identifying the sales team, as an example, Manhattan, there is a high number of contraception prescribers there. But obviously, when you look at what's happening with the pandemic, right, it's an incredible hotspot. However, we purposely identified and recruited people that not only had these longstanding careers in women's health, but had relationships with these offices where trust was already established and the kind of trust where these offices and providers are still seeing women in a variety of different ways. So I guess what I wanted to say is to create the confidence that we are very mindful, that this could continue or even get worse, and the people and the places we've selected not only are going to be able to help our launch trajectory because of prescriptions based on prescribers, but they're still going to have access.

And we ensured that they would -- they literally, most of these people -- checked and identified all of these offices they're going to be calling on, even while they were in the interview process. So we could ensure that these aren't timid little kittens that are going to say, "Oh, my goodness. I can't go out and continue to make an effort." We purposely made sure that we had

the right people with the relationships. So I don't think it's too confident to tell you that I think we've already identified what could be the worst, and that's why we've selected this handful of people. Do you agree with that, Russ?

Russell Barrans

Yes. No, I really do. And Leland, just to put a final little note on that is we put a lot of pressure testing on this because there is no desire on our part whatsoever to furlough people. So we really made sure that we not only put people in positions where they have access, but one of the things that we've done is we have eliminated what we call the traditional territories. And we've moved these into regional business units in the sense of saying, they, as a region, will figure out how to work through that and make sure that they're successful using whatever is necessary. Some offices literally are saying we'll meet you in the parking lot, and they're fine with doing that kind of thing.

Leland Gershell

Thank you.

Operator

[Operator Instructions]. Our next question comes from the line of Ram Selvaraju with H.C. Wainwright.

Raghuram Selvaraju

Hi, thanks very much for taking my questions. Just two quick ones on the commercialization for Phexxi, if I may. I wanted to ask about sort of more traditional promotional channels and what role, if any, you expect those to play with regard to the overall marketing campaign, and how those basically fit into sort of the more new-fangled techniques that people are using nowadays, whether it's digital or social media. But just give us a sense of to what extent the traditional avenues, whether that's radio or whatnot, are actually relevant here.

And then I also wanted to ask if you could provide us a little bit more granularity around the competitive environment for sales force hiring, how you're seeing that playing out, and if you feel that you're effectively being able to get sort of the pick of the litter as far as salespeople are concerned. And then I had a couple of other questions regarding clinical development, but maybe we could start with those two first.

Russell Barrans

Thanks, Ram. Yes. So I'll be quick on this to simply say we are utilizing many of the traditional channels that we -- you would typically have preparing for HCPs in respect to journal advertising and those kind of things. One of the things we have ramped up a little bit is what is often referred to as nonpersonal promotion, and those are methods where you would send e-mails or faxes or even mailings to them. One of the things that we have discovered is that health care providers are still saying pretty clearly, "we want to find out especially about new drug approvals," and they're much more willing to use some of those traditional methods that maybe in the past have started becoming -- going by the wayside. So as an example, the open rate that some of the companies that use nonpersonal promotion for e-mailing has started to increase because they're not seeing people in person. So we are continuing to use that.

And one of the things that we didn't talk about, but as we just recently videoed a user experience from someone who was in the AMPOWER trial as well as one of the clinical trial investigators. And so those types of things will begin to be used promotionally, both for health care providers and for women as we move forward. We think that those mediums really work well for us because we were already pretty well geared toward a digital mentality. And so that really played in really well for us in that respect.

Did that answer it for you, Ram?

Raghuram Selvaraju

Yes. No, that's very granular, thank you. I also wanted to just quickly ask about the clinical development side of things, particularly with regard to the STI indication. Just two quick clarificatory points there. I was wondering when specifically in the fourth quarter you believe it's most likely that enrollment would get way underway in that study? And then also if you could give me a sense of whether you feel that enrollment is likely to be shielded from any future potential impact from the pandemic. If you could just give us a sense of to what extent that trial program is likely to remain unaffected by pandemic-related restrictions.

Kelly Culwell

Yes. Thank you very much. So we haven't given specific guidance on when in the fourth quarter we anticipate enrollment, but we do think it will be earlier rather than later in the fourth quarter. And so hopefully, that's helpful. And as soon as we have more information, probably as we get ready to screen our first patient, we'll be able to provide more granularity there, but we do anticipate earlier in the fourth quarter.

With regards to COVID potentially impacting our program, we do have several different contingency plans in place in terms of our ability to continue the program during the COVID environment. We know that a lot of health care providers, and particularly the clinics where we anticipate enrolling a lot of our patients, have successfully incorporated telemedicine into their practices, particularly around sexual and reproductive health. The great news is that our primary endpoint is driven on the chlamydia and gonorrhea rates, which actually can be achieved through self-swabs -- self-vaginal swabs from home. So -- and we have confirmed that our central laboratory can, in fact, accommodate women collecting self-swabs and mailing those swabs in. And so that's an example of something that, we're going to confirm with the FDA in the Type C meeting, would be acceptable as a measurement for our primary endpoint should it be necessary.

The other thing that's great about our program is we have no real safety concerns. We've had multiple pivotal -- large pivotal trials that have conducted regular gynecologic examinations of women using our product. And so because of that, if we needed to do remote visits, either for even enrollment or the visits during the course of the trial, the monthly visits during the trial, that wouldn't be a problem because we don't necessarily have to have those monthly physical examinations to confirm the safety of our product.

So we're in pretty good position, and we're also working with ICON. They have a lot of tools at their disposal as well, especially around HIPAA-compliant telemedicine opportunities to conduct remote visits.

Operator

And this concludes our question-and-answer period. And I would like to turn the conference back over to Saundra Pelletier for any closing remarks.

Saundra Pelletier

Great. Thank you. So I'd like to thank everybody for joining us today and for standing with Evofem as we move boldly ahead with the launch of Phexxi. As you know, we are going to be bringing the only hormone-free, woman-controlled contraceptive product to millions of women whose needs have gone unmet for far too long. We have been very thoughtful and deliberate about hiring our sales organization, so that we could have sales specialists in areas where they have access to key providers, even during the COVID social distancing period. And in fact, as I said before to Leland's question, that many of the people we hired were asked to go and check with their health care providers to ensure to us that they would continue to have access should they be given the opportunity to work with Evofem.

We are confident that we have the right team. We're confident that we have the right strategy and the right tactics in place to successfully execute on the launch of Phexxi.

We have repeatedly said that what we think to be true is that in order to have a game-changing company, you need to have four things.

You need to have a true innovation, and for us, Phexxi is exactly that. With no hormones and on-demand usage by women, it makes it completely game changing.

You need to have an unmet need, and we have said repeatedly that there are 17 million women right now that are beyond hormones.

You need to have the capital in order to move your program forward. We have secured that.

And finally, you need to have the team and the strategy to execute. And I hope that what you have seen is that we have that team, and we are really excited to be here today. We've always receive a lot of wonderful comments that we are incredibly positive on these calls. I can tell you, it's not because we have not met obstacles and challenges, but it is because we know that the future of this organization and the future of Phexxi is going to be far more than bright.

And you also heard that even in this pandemic situation, contraception is the fastest-growing therapeutic area through telemedicine and telehealth. So we remain very, very confident, and we're excited about the future potential of Evofem Biosciences. We're thrilled to have you with us on the journey. We look forward to sharing more information with you on our next call. So have a great rest of your day. Thank you.

Operator

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