Evofem Biosciences, Inc. (NASDAQ:EVFM) Q4 2019 Earnings Conference Call

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Company Participants

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

Conference Call Participants

Louise Chen - Cantor
Ram Selvaraju - H.C. Wainwright
Leland Gershell - Oppenheimer
Yasmeen Rahimi - Roth Capital
Ashley Ryu – RBC
Annabel Samimy - Stifel

Operator

Ladies and gentlemen, thank you for standing by. And welcome to the Evofem Q4 and Year-end 2019 Financial Results Call. [Operator Instructions] Please be advised that today's conference is being recorded. [Operator Instructions]

I would now like to hand the conference over to your speaker, Ms. Amy Raskopf. Please go ahead, ma'am.

Amy Raskopf

Thank you. This is Amy Raskopf, Evofem Biosciences Head of Investor Relations. Today, we released our financial results for the fourth quarter and full year 2019. The press release and accompanying slides, which you can access through the webcast, are available on the Investor Relations section of the Evofem website.

Before I begin, I'd like to remind you that remarks on this call will contain forward-looking statements as stated on Slide 2. These forward-looking

statements are made only as of today, March 12, 2020. 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. 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.

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

Saundra Pelletier

Thank you, Amy. Well, hello, everybody, and thank you for joining us on the call. So this morning, I'm going to open the call with just one word, Phexxi. That's with a P and an H. P-H-E-X-X-I. That's the new brand name that the FDA has conditionally approved for our innovative, hormone-free, contraceptive gel candidate, formerly referred to as Amphora.

This strong and provocative brand name incorporates several key attributes: First, the P-H alludes to Phexxi's natural pH-regulating mechanism of action. Phexxi works by maintaining the normal vaginal pH even when semen is introduced, thereby maintaining the natural acidic environment that's inhospitable to sperm. The XX captures the 2 female chromosomes, and it probably does not hurt that it also rhymes with sexy.

Before I move on to the quarterly updates, I want to note that this conditional approval of our new brand name allows us to retire the use of the name Amphora. And although we really did love and embrace that name, the FDA determined that it was too close in spelling and pronunciation to Ampyra, a drug for adults with MS.

We were disappointed, but it turned out to be a blessing in disguise because we developed and tested a number of brand name options alongside Amphora, and women overwhelmingly agreed that Phexxi was the perfect fit and increased the appeal for this innovative new product.

Moving forward, we will refer to our Multipurpose Vaginal pH Regulator candidate as Phexxi for the prevention of pregnancy and EVO100 for the prevention of chlamydia and gonorrhea.

Now the fourth quarter of 2019 capped a year of monumental products for Evofem, and it was undoubtedly the company's most exciting and most important quarter yet. We achieved a critical milestone in November with

the resubmission of our NDA to the FDA, which granted a 6-month review and assigned a May 25 PDUFA date, so just a few short months away.

In December, we also achieved a second major milestone: positive top line results from our landmark Phase 2b trial of EVO100 for the prevention of 2 dangerous sexually transmitted infections or STIs.

Results demonstrated that EVO100 provided women a relative risk reduction of 50% in chlamydia and 78% in gonorrhea rates compared to placebo. And consistent with all previous trials, EVO100 was safe and well tolerated.

These statistically significant results are particularly compelling when you consider that according to the CDC, in 2018, the incidence of sexually transmitted infections in the U.S. rose for the fifth consecutive year in a row, with 1.8 million reported cases of chlamydia and nearly 600,000 reported cases of gonorrhea.

Additionally, there are no approved prescription products for the prevention of either of these infections. The only existing option for protection is condoms, which are not female controlled, and women often do not win the condom negotiation.

The FDA recently granted us an end-of-Phase 2 meeting, and we're looking forward to engaging with them on the Phase 3 trial design and the clinical and regulatory path forward for EVO100.

In the meantime, we are singularly focused on our rapidly approaching PDUFA date for Phexxi. We're on the cusp of making history with the first significant contraceptive advance in decades: a new, non-hormonal contraceptive with a favorable safety and efficacy profile. And I am confident that we have established a solid foundation for a highly successful launch.

Ongoing regulatory interactions with the FDA have been routine. Our manufacturing process is well defined and underway, and we're recruiting exceptional talent for our sales organization. We're also developing a comprehensive marketing strategy that we believe will be as powerful and as distinctive as our brand name.

The team is also executing on a robust publication and presentation plan. We are slated to present this new data from AMPOWER at the College of Obstetrics and Gynecology meeting next month. But we learned yesterday, like so many other meetings, it has been canceled due to COVID-19 concerns. So we look forward to hearing more from the organizers as they consider potential virtual options for sharing this important data.

Before I turn the call over to our Chief Commercial Officer, Russ Barrans, I just want to say that Russ and I have spent our careers in women's health. We both were sales reps. We both created sales teams. We both spent a lot of time in marketing, but most importantly, Russ has been responsible for an extraordinary launch of Mirena. It is now well over $1 billion in revenue.

And as we look to recruit a premier sales organization, why this really matters is that the people that we want, they already have jobs. They want more than a paycheck. They want to go to an organization that has a true innovation, which we can deliver on, but it also matters that they are working for people that have walked their walk.

It creates a different level of credibility. And I can assure you that when you see the kinds of people that we are attracting to this organization to deliver on our launch trajectory, you will be nothing short of impressed.

So with that, I would like to turn it over to Russ, who, in my opinion, is really the only person that I would trust with the launch of Phexxi. So no pressure. No pressure, Russ. Here's to you.

Russell Barrans

Thanks, Saundra. No pressure for sure. So I got to say to you though, Saundra, I actually feel exactly the same way. I only want the most experienced sales professionals working with us on this launch, and I'm confident that we are building a world-class team.

In fact, our sales leadership team is nearly complete. We've hired a vice president of sales and two area sales directors, who bring a wealth of large pharmaceutical sales and leadership experience to the table, and we've almost completed the hiring of our 14 regional sales managers.

Now all of these leadership people have extensive experience in women's health. And I can personally speak to their expertise either because they are my former colleagues or because I track their careers, expecting this opportunity to one day bring them on to the team that is going to really change the face of contraception in this country.

So I also wanted you to know that the job postings for the 125 sales consultants went out live in February. And something within two weeks, we had received more than 3,000 applications.

Sales consultants recognize that this opportunity is really different. They are looking to join a female-forward company led by someone like yourself, Saundra, a female CEO, who has walked in their shoes, and they have an opportunity to change how women feel about birth control.

If I can, I'd like to just pivot real quick and turn to what our pre-commercial efforts are like. And I have a number of really terrific highlights I want to share. First, we intend to launch a disease awareness campaign to highlight to health care providers the unmet need that remains for new contraceptive options that, quite frankly, take hormones out of the equation.

We're excited about both the creative execution and the potential reach of this unbranded and comprehensive print and digital campaign, which we expect to launch by the end of this month. I can say one thing for sure. It will be simultaneously bold and simple at the same time.

Second, we're accelerating the time line of our direct-to-consumer or our DTC campaign. Traditionally, contraceptive DTC marketing follows about six months after your HCP campaign has been launched. That allows there to be a significant windows to help HCPs to understand what the new product's mechanism of action is, the associated efficacy data and any related safety risk that might be there.

We intend to shorten that period to four months. We are uniquely able to do this because both the mechanism of action and the clinical story of Phexxi are relatively simple, and because we believe women are eager to have access to these new non-hormonal options in contraception. So it's prudent on our part to make sure we do that as quickly as we possibly can.

Now turning to patient access, which is always a question we get asked. Our market access team is now on the ground and appropriately engaging payers in dialogue. While it's still early, let me just tell you something. The feedback we're receiving from payers thus far confirms what we've been saying all along, which is that for a majority of women, Phexxi will be a covered benefit under the ACA. And to remind you, that means no copay and no out-of-pocket deductibles.

And we're finalizing our market access strategy, including pricing and the details of our planned patient copay card for those women whose insurance does not cover them at launch, and we look forward to sharing more about those details as we get further along toward our launch in other calls.

Now finally, and this part I'm really excited about is, as a part of our launch readiness, what we've done is I asked the team to go back and take a look at what other products have done in terms of their launch trajectory.

We wanted to look at what are the most successful launches to date in women's contraception and especially look at some of those - their modality, so we could see how they fared compared to the oral contraceptive.

So what we benchmarked is 4 things: First of all, we've looked at what were the sales force sizes at launch. Second, what was the share of voice in the contraceptive advertising and detailing efforts?

Third, how long does it take to get to penetration to peak sales? And fourth, what was the awareness of consumers based on DTC? Because these are the 4 things that will often determine what your launch trajectory looks like. And based on our comparative analysis of these metrics, we really believe that what we have planned for our spend and for our emphasis, coupled together with the appeal of a natural, female-controlled contraceptive with a very favorable side effect profile, will put Phexxi right in line with the success of those other launches.

Now I would like to turn it back over to our Chief Commercial - our Financial Officer, Jay File, to discuss the 2019 financials.

Justin File

For the year ended December 31, 2019, total operating expenses decreased 32% to $52.7 million compared to the prior year. Research and development costs decreased 49% to $22.2 million during 2019. Of that decrease, $21.2 million was due to completion of the clinical phases of AMPOWER and AMPREVENCE.

General and administrative costs decreased 11% to $30.5 million during 2019. Non-cash stock-based compensation decreased by $7.2 million, and professional services and personnel costs were $3.8 million lower due to the absence of onetime costs associated with our merger that occurred in January 2018.

These were offset by a $3.4 million increase in pre-commercialization advertising, PR fees and sales support-related costs. Additionally, payroll-related expenses and consulting services increased by $2.3 million and $1.4 million, respectively, during 2019.

Total other expense was $27.3 million for the year ended December 31, 2019, primarily due to non-cash charges recognized in the first half of the year. As a result, net loss attributable to common stockholders improved to $80 million or a net loss of $1.99 a share for the year ended December 31, 2019, compared with a net loss of $125.8 million or 5 - or a net loss of $5.74 per share for the prior year.

We closed 2019 with $23.8 million in unrestricted cash and equivalents and short-term investments. Based on our current plans, we believe that we have sufficient funding through the anticipated approval of Phexxi as a first hormone-free, on-demand, women-controlled contraceptive in May. And we

are currently evaluating near-term financing opportunities to further extend that runway.

And with that, I'll turn it back to Saundra.

Saundra Pelletier

Thank you, Jay. As you may know, March is Women's History Month, and I've been reflecting on the many significant milestones that have advanced the lives of women. We are a new player in that realm, but the opportunity that we have to address the unmet sexual and reproductive needs of women is real, and it's significant.

There are more than 17 million women who don't want to get pregnant, don't want hormones in their birth control and who are fed up with their current options. What they do want is protection, control, an option that doesn't require hormones and an option that speaks to their needs. Women want more.

Phexxi for the protection of pregnancy represents a significant opportunity. Our market research tells us that there are 17 million women out there waiting for a new, hormone-free option. And if we were to reach just 885,000 of those 17 million women, and they fill their prescriptions seven times in a year, that's $1 billion market opportunity.

Looking even further in the future, we have a significant opportunity to help prevent the transmission of chlamydia and gonorrhea, two dangerous STIs that affects approximately 2 million people every year. We're excited about the potential here, and we look forward to working with the FDA to determine our best path forward. This is going to be a transformative year for Evofem and for women, and we're thrilled to have you with us on this journey.

So with that, I would like to open up the call for questions and turn it back to the operator.

Question-and-Answer Session

Operator

Thank you. [Operator Instructions] Our first question will come from Louise Chen with Cantor. Please go ahead.

Louise Chen

Hi. Thanks for taking my questions. I had two for you. So Russ, you had mentioned Mirena on the call. Do you think Phexxi's launch trajectory can equal that of Mirena? Why or why not?

And the second question I had for you is, congratulations on the conditional approval of the name for Phexxi. Is this a good read through to the FDA approval that's expected at your upcoming PDUFA date or not? Thank you.

Russell Barrans

So great. Well, thank you for that question. And usually, when the question like that is asked, everyone around the table smiles because they say, well, Russ is going to get to talk about Mirena, and they think that, that's something that...

Saundra Pelletier

Excites you. Yes.

Russell Barrans

But to answer the question, so one of the key things, I think, is that having been there and done that through that whole process. I was able to see, first of all, what were some of the issues that you would have around bringing an educational awareness to the HCPs, making sure that women aware of current options.

So when I look at the whole Mirena family, where we really think we're most like is going to be like the Skyla, Kyleena launch, which happened years

later. But once the whole category had been established, and when they were able to go out and to do what was a pretty effective method in terms of getting people to be aware of it and such.

So I do anticipate, as I've often said, at the time when Mirena came to the market, there was this whole need in women's health because there have been these missing elements around a long acting. And I feel like we're in the same space today where we've got so many women, and we didn't say it on this call, but 17 million women approximately are doing nothing and that won't use hormones, that we think are really ready for something like this. So I do believe that the timing is exactly right for a product like this, just as it was two decades ago when Mirena came into the market.

Saundra Pelletier

And then, Louise's second question. Do you want to...

Kelly Culwell

We - yes. So to answer the question about the read-through on the conditional approval of Phexxi, while we hope and anticipate that this will be one of many upcoming approvals, it actually is a separate decision point from the actual approval of Phexxi.

Louise Chen

Thank you.

Operator

Thank you. Our next question will come from Ram Selvaraju with H.C. Wainwright. Please go ahead.

Ram Selvaraju

Hi. Thanks so much for taking my questions. I have a few. I was wondering if maybe you could start with the sales force composition and give us some

details around that. It would be helpful for us to at least qualitatively know what you anticipate to be the overall profile in terms of their prior history, what kind of products they've previously been involved with promoting? What kind of performance track records they have and items of that nature? That would be helpful. Thank you.

Russell Barrans

Sure. Let me start there for you. And I'll just real briefly give you the structure, which is, we have two areas, east and the west. And there will be 7 managers in each one of those areas and an equal number of representatives, equally 125 that cover that.

We've worked really closely with IQVIA around the design of the sales force. So we know that we're going to be able to cover what they classify as their key highest prescribers: 93% of all the OB/GYNs and 89% of all the allied health care professionals that are considered to be the top prescribers in this category. And those that are not inside that - those few percentages, we'll cover with non-personal promotion to do that.

We're so excited about this opportunity at this time, not just because of the fact that the environment is ready for it. But as most of you who maybe have followed women's health care over the last several years, there's been a fair amount of disruption.

So a lot of the people who we have known in the past from other organizations we've worked with have either been displaced or they're in an environment today where it's not really ideal for them. The companies they're with may have announced recently that they're going to disband their women's health care.

So we've been able to achieve really, I think, a very, very experienced group of managers and leadership, and we anticipate the same thing is going to be true, simply based on the number of people who reached out to us on LinkedIn. As we know, that has now become one of the places where

employment seems to happen frequently. And the number of people who reached out already with experience in this category has been simply overwhelming, and we're really excited about putting together this world-class sales force.

Ram Selvaraju

Would it be reasonable to assume that many, if not most of the sales people that you hire, are going to be coming in with performance track records where they were like the number one or number two or in the top decile at least sort of performing salespeople at their respective organizations, at least at some point over the course of their recent careers?

Russell Barrans

Yes. That's exactly what we've been seeing. And in fact, we've kind of almost got this thing where it's hard to keep track of who's got the most awards. And so we might have to actually put up a little bit of a sports scorecard for people when they actually arrive to see who actually has. But yes, that's exactly what's been taking place so far.

And as I mentioned earlier, this excitement is really something that we've never seen before, where it's not just an opportunity to start with a start-up company like ours that's doing something innovative.

But this whole notion that they're making a big difference in something that is missing right now for women has been one of the reasons why people expressed they want to come and achieve the same kind of results here that they've done in other places.

Ram Selvaraju

Okay. And then with respect to the other indications that may potentially be pursued here. I was just wondering if you could clarify. Has the end-of-phase 2 meeting in the STI prevention indication already happened? Or has

it just been scheduled? And if it's just been scheduled, can you give us a sense of when it might actually occur?

And then also, just provide some perspectives on when you anticipate the next stage in clinical development to kick off for that indication. If you anticipate that happening before the end of this year? Thank you.

Kelly Culwell

Yes. So we have been granted a date for our end-of-phase 2 meeting, and it will happen in May. And so we are - we have prepared our briefing document for that, and we're on track for that meeting to happen. We do anticipate that we will have our first patient in for the Phase 3 study before the end of this year.

Ram Selvaraju

Okay, fantastic. And then just one other quick one. Given the recent announcement regarding PDL's decision to liquidate, I was just wondering whether you anticipate this having any potential disruptive impact either from the perspective of the stock price or from the vantage point of future capital raising. And what might potentially be done to mitigate that, if any?

Saundra Pelletier

Well, do you want to start, and I'll add?

Justin File

Yes. So I don't know if you listened in to the PDL's call yesterday. So we do know that, like you mentioned, they are looking to monetize assets by the end of the year. Ultimately, I think the main take away from that was, what Dominique really reiterated was the fact that they really don't anticipate doing anything that would be harmful to Evofem. And I think we interpret that as it really makes sense to wait for some degree of an inflection point, which is obviously the PDUFA that occurs late in May.

We do know that they've engaged Torreya to explore opportunities, but every indication that we have, at least pulling from the communications from their press release and discussion yesterday, it will be a very methodical process and shouldn't be anything excessive or damaging to us. At least, from what we're seeing right now.

Saundra Pelletier

And the other thing just to add, Ram, is that in the positive is that we have been very actively engaged with Torreya and with PDL. And so the parties that are interested, obviously, want to talk to the company, and they want to do their own diligence. And so we have been very collaborative, and we - in all these ongoing discussions.

So we feel good about the process. And one, we wish it wasn't happening at all, of course, but we have been very engaged and included, and we feel good about that. So we don't feel as vulnerable as you might think because we're very active. And the parties that are interested are serious players who we would like to have as shareholders. So - so far, so good.

Ram Selvaraju

And just for clarification, so that may mean that whoever winds up taking on the Evofem stake that PDL currently holds could potentially also step in and perform the function that you were previously anticipating PDL would perform? Is that reasonable?

Saundra Pelletier

Yes, that is reasonable.

Ram Selvaraju

Thank you.

Operator

Thank you. Our next question will come from Leland Gershell with Oppenheimer. Please go ahead.

Leland Gershell

Hey, guys. Good morning. Thanks for taking my questions. Sounds like the plan's really coming together. Wanted to ask just on the DTC delay shortening, you'd mentioned from 6 to 4 months, Russ. So I just want to drill on that further. Is that something that you worked out with the agency? Or is that something which you presumptively feel you'd be able to get? And then I've got a follow-up, too. Thanks.

Russell Barrans

Yes, Leland, there's actually no formalized guidelines that require a certain amount of time. What the agency really asked people to do in our situation is to assure that the health care provider community is fully brought up to speed.

And so what we've done just based on even like discussions with people like yourself as an example, we find that the story is not so complicated and the patient profile of who it'd be for is not so difficult. And the fact that from a safety perspective, we had less than 2% discontinuation in our trial based on side effects, that we feel like we could move that up.

And the reason that we picked that timing is because then if you start looking from the end of November all the way through, say, mid-January, that's not an ideal time to be trying to launch a DTC campaign. Therefore, it was prudent on our part to try to launch it early in Q4 instead of waiting towards that 6-month mark.

Leland Gershell

Okay. Thanks. That's helpful. And then I also wanted to ask, I know the PDUFA's still a little ways away, but to the extent that you've had labeling discussions, if you've had them, and if there are any limitations that we

should be aware of? And I only ask that because of other experiences we've had with other products from other companies in this category irrespective of the fact that, of course, those are hormonal products unlike Phexxi? Thanks.

Kelly Culwell

Sure. So our interactions with the FDA during the review period have been routine. We actually would anticipate sort of as a standard routine practice that they would start labeling negotiations about a month before our PDUFA date. So we've not had any formal discussions with the agency around labeling. But we would anticipate that start in late April.

Leland Gershell

Okay. And then my last question, I guess, for either Russ or Jay, kind of a commercial financial question. Is as you look at your budget for the initial launch, and you're going to have, obviously, your sales organization and the online kind of social media-based marketing initiatives, I know you're not giving guidance at this point, but if you could maybe comment on what the proportional spend you would allocate to those would be over, let's say, the first 12 months of launch?

Justin File

Yes, yes, sure, not a problem. And I kind of - I guess, I'll kind of reiterate some general comments on that area that we've kind of given in piecemeal and maybe a little bit of an update, too.

So just kind of working through the various components, we do anticipate that the annualized sales force itself will be approximately $35 million. And now that DTC range on an annualized basis is going to fall within the $30 million to $50 million range and give - some of it depends on when Russ pulls the trigger, but we believe that's a more accurate range of when DTC will be on an annual basis.

Overall G&A, we do anticipate that it's going to be relatively consistent with not a lot of fluctuations, should continue in the mid-20s. And at the commencement of the Phase 3 for STI that Kelly had mentioned, overall, we're anticipating that could run about $35 million. That obviously will be spread out across the length of the trial, which would be a greater part of the year, 1.5 years. So the majority of the costs could fall in 2021.

But I guess, to kind of wrap it all into one and a concise statement for you, overall, even though we're not quite giving any sort of revenue guidance as of yet, we still anticipate that ultimately, we will be to breakeven by the end of 2022.

Leland Gershell

Perfect. Thanks very much.

Operator

Thank you. Our next question comes from Yasmeen Rahimi with Roth Capital.

Yasmeen Rahimi

Hi, Team. I have three different questions for you. So question number one is, I know you guys have been working diligently trying to find non-dilutive running opportunities. However, we're headed - your PDUFA date is right in May as we're dealing with all the challenges associated with coronavirus and the market conditions.

So can you help us visualize - obviously, in order to put a competitive commercial plan together, you need the cash for it. So given the market condition, given the -- also, I'm certain discussions with strategics are being slowed down with the pandemic that's going on. So how is that handicapping you in the next few months? Everyone's lives are being affected through that.

Question number two is, if you could give us a little bit (of) color on how your - and I know that pricing discussion began after the label negotiations - what kind of work have you done in terms of how important is copays for women and pricing?

And then the third bucket is just more color on sort of the prevention of gonorrhea and chlamydia trials. What are known of the trial design that we can be assured of being part of it? Those are sort of three different things.

Saundra Pelletier

Okay. So with that, why don't you start with non-dilutive options?

Justin File

Absolutely. Yes, good question and understandably why that would come up. As you know as well that we don't sit around and wait for things to happen. We're pretty darn proactive.

So we've been very active in really looking for opportunities to really kind of bolster our working capital position up through and including beyond PDUFA at the end of May.

As such, we're not really anticipating this to be a - the current market conditions to be a handicap to us currently at all because we have been ahead of the curve. I do expect some near-term movement on that.

And then ultimately, we still are on plan to execute everything that we have lined up for pre-commercialization phase and don't anticipate any slowdown in activities at all even once PDUFA hits.

Saundra Pelletier

Then Russ, you want to talk about copay?

Russell Barrans

Yes. So as many people know, when you bring out new products to market, the payers have up to 6 months to determine what they're going to do with it. Most have indicated that they will have us at covered position in ACA out of the gate.

We will have a copay card that has already been determined, and that copay card will allow for women to get their first one at no copay, no deductible at all, just so it acts like a sample because sampling today has become more challenging.

And then moving forward from that point, as their plans start covering it, they won't require the copay card, but those who do will still have it in place to assure that, that's the case.

And in terms of pricing, we're actually working still right now with Putnam [ph] who does a lot of this pricing work, to determine what our optimal pricing would be from that perspective. And so we'll be able to give clear guidance later on.

Saundra Pelletier

Kelly?

Kelly Culwell

Yes. So with regards - I think the question around the Phase 3 trial was around study design and any sort of ideas on what that looks like at this point. We do anticipate that the study design for the Phase 3 trial will be similar to what we saw with AMPREVENCE.

However, it is one of the topics that we're going to be discussing with the FDA at the end-of-Phase 2 meeting. And so we'll be able to provide additional clarity after we've had discussions with the FDA and their agreements on our plans moving forward.

Saundra Pelletier

Yasmeen, does that answer your questions?

Yasmeen Rahimi

Yes. Thank you, team. They are pretty answered.

Operator

Thank you. Our next question will come from Randall Stanicky with RBC Capital Markets. Please go ahead.

Ashley Ryu

Hi, good morning. This is Ashley on for Randall. So there seems to be an increase in interest in the women's health space, one of the bigger announcement more recently being Merck announcing a spin, and that "spinco" will be looking for BD opportunities in the space.

So I guess, as you guys think about building out a platform here, does this uptick in interest generally kind of change anything in terms of your strategic plan, whether that means that you're seeing more opportunities to partner internationally or anything else? And is there any update on the international front? Thanks.

Saundra Pelletier

Yes. So thanks for the question. So I guess here's what I would say is that, one, we are absolutely thrilled, as I'm sure you can imagine. We know that women are the health care consumers. We know that women often make the decisions for themselves and their children and their spouses and their parents. And so we are really excited about the uptick in interest.

But to be even more direct, the short answer is yes. We actually have had an incredibly positive influx of collaborative calls and discussions with people

who have assets that would really fit perfectly in a U.S. platform, meaning a commercialization team.

And creating a sales organization is no small task, and it takes a lot of discipline, and we intend to have the premier women health care sales organization. We already have amazing medical science liaisons. We have our payer team that's exceptional. So putting a product in our portfolio makes perfect sense.

And so we are having very fruitful discussions with partners who want somebody in the U.S. And in turn, we're also looking to partners that maybe there's an opportunity where they would then look at Phexxi for their organization outside of the U.S.

So I will tell you that with the results of our Phase 2b study on chlamydia and gonorrhea, we purposely slowed down our discussions for ex U.S. licensing because all those discussions were just around the contraceptive indication.

Once people saw the clinically significant results, it actually escalated conversations with players that were larger, would allow much different and much bigger upfront payments, which would be very, very positive.

So at the end of the day, I would say that we are still having ongoing discussions, but the discussions have pivoted a little bit because we're talking about both the contraceptive and the STI indications now with partners outside of the U.S. There is no "soon to be forthcoming" announcement as of yet, but the conversations are very, very much ongoing. I don't know if you guys have anything to add? No? Okay.

Ashley Ryu

Thank you very much.

Operator

Thank you. Our next question will come from Annabel Samimy with Stifel. Please go ahead.

Annabel Samimy

Thanks for taking my call. Most of the questions have been answered, but I couldn't help notice Phexxi seems to have an interesting consumer angle to it, and it's also a simple story, the limited side effects.

In terms of your approach to the market, are you taking more of a consumer approach to make it seem less of like a prescription drug and more of like a consumer product that can be accessible to all patients? And is that part of you are angle to approach the market?

And then secondly, just - I know you touched on the payer question. And for the most part, the ACA has been pretty good about mandating coverage of contraception. But I was curious to know how much of your strategy depends on the classification - the novel classification of this drug.

If there are any changes to it, and if there are any risks to changes to ACA in terms of coverage mandate, given some of the things that are sitting at the Supreme Court. Thanks.

Russell Barrans

Great. So thanks for those questions. When we take a look at, first of all, the aspect of 'why is it a prescription,' there's two really important aspects that we think are important for it to be a prescription: One is just a counseling aspect of this. As we all know, there is no systemic activity. So if you don't use the product or you don't use it correctly, it has zero effect.

So it's important for us to make sure that all women understand how to use it and assure that they use it with each and every act of sex. So having that discussion with the health care professional is going to be really important.

It is, as you've mentioned, a very consumer-sensitive category. And we know that the women in this category who asked for a certain brand will get it. So we're making it as easy as possible for women to get it.

We'll have a very significant telemedicine effort so that women don't have to go through a lot of hoops in order to get their Phexxi sent to them or acquire it from the pharmacy. So we're responding to that pretty significantly.

And we know from the efforts we did around AMPOWER when we went out to do basically what - like DTC, where we went online digitally and posted for women who would be interested in a non-hormonal method that women are responded to this exceptionally positive. So we do anticipate that this will drive large volumes of women to go to their health care provider to ask for the product.

And when we started looking at - the next question around the ACA, one of the things that really makes us different is even without it being in a different classification, everyone has recognized that our mechanism of action is really stand-alone.

So for most of those payers, they've kind of said, even if we're not sure where this fits, we do know that it fits in as a stand-alone, and as a stand-alone, we're not required to necessarily be into one of those 18 categories that other products that maybe already have a modality that's the same as theirs, we're forced to try to see if they couldn't fit into one of those categories. So for us, we're not going to be disadvantaged in any way based on that.

What I can tell you is this, is we did our market research before, and we talked to payers who represented about 70% of the commercial lives in the United States, and we learned that they thought they would cover it. Now that our market access team is actually out there calling on those payers, what we're finding is that they're telling them face-to-face the exact same things that we heard in market research.

So we're pretty positive that not only is our strategy in line, but that we're not going to be impacted by this question of do we have to have a 19th category or not because we've been told pretty clearly that we're going to be a stand-alone and covered under ACA.

Annabel Samimy

Great. Thank you.

Operator

Thank you. I'm showing no further questions in the queue at this time. I would now like to turn the call back over to Ms. Saundra Pelletier for any further remarks.

Saundra Pelletier

I just want to thank you all again. I know that there are a lot of things that take your time, and there's a lot of distracting things happening in the world. So we really appreciate, and we're very, very grateful that you took the time to be on this call today. We appreciate your ongoing interest and your support of women's health, and we look forward to speaking with you soon and continuing to update you. So have a great rest of your day.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for your participation. You may now disconnect.