Evofem Biosciences, Inc. (NASDAQ: EVFM)

Q3 2021 Results Conference Call

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Company Participants

Amy Raskopf - Vice President, IR
Saundra Pelletier - CEO
Jay File - CFO
Tim Glennon - Vice President of Business Development & Marketing

Conference Call Participants

Ram Selvaraju - H.C. Wainwright
David Amsellem - Piper Sandler
Annabel Samimy – Stifel
Melina Santoro - Morgan Stanley

Operator

Thank you for standing by and welcome to the Evofem Biosciences Third Quarter 2021 Financial Results Conference Call. At this time, all participants are in listen-only mode. After the speakers' presentation, there will be a question-and-answer session. [Operator Instructions] As a reminder, today's program is being recorded.

And now, I'd like to introduce your host for today's program, Amy Raskopf, Vice President of Investor Relations. Please go ahead.

Amy Raskopf

Thank you. Good afternoon, everyone. And welcome to the Evofem Biosciences results call for the third quarter of 2021.

If you haven't done so already, I encourage you to access the press release we issued earlier today, and the presentation that accompanies this call, 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, November 15, 2021. 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 and our most recently filed 10-Q.

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

Saundra Pelletier

Thank you Amy, and thank you everyone for joining us today.

Our focus on driving awareness and uptake for Phexxi for hormone-free birth control enabled us to reach new heights for the fourth consecutive quarter. The substantial Phexxi growth in Q3 and Q4 to-date is being elevated by the 'House Rules' DTC campaign, starring Emmy Award-winning actress Annie Murphy, which we launched on September 9th, as well as the ongoing work of our sales force with OB/GYN, nurse practitioners and midwives.

More than 19,000 prescriptions were filled in Q3, which is a 48% increase from Q2.

Q4 is off to a strong start with a spectacular October. Monthly total prescriptions, which jumped to over 7,800 in September grew 27% to a new record high in October.

I'll discuss other metrics and ongoing initiatives in greater detail after our CFO, Jay File, reviews the financial results. Jay?

Jay File

Thank you, Saundra.

Today, I'm going to focus on the third quarter of 2021 relative to Q2, since we believe sequential growth is more meaningful at this stage of our corporate development.

Solid growth in ex-factory sales of Phexxi drove a 29% increase in gross revenues in Q3. This was offset by gross-to-net adjustments, most of which were for programs that we put in place to better ensure that cost and coverage are not barriers to getting Phexxi to those women whose plans are not yet covering Phexxi at zero copay, despite the intent of the Affordable Care Act. Primarily as a result of these GTN adjustments, we saw a slight decrease in net product sales to $1.7 million for Q3.

Research and development costs were $8.7 million, up $194,000 from Q2, reflecting higher enrollment in our pivotal Phase 3 trial, EVOGUARD. Positive outcomes should enable us to expand the Phexxi label to include two new indications, the prevention of chlamydia and gonorrhea in women. As a reminder, trial costs for EVO100 are covered through the end of the year by restricted cash from the adjuvant investment last fall.

Selling and marketing costs were $30.5 million, up 12% from Q2 due primarily to higher media expenses related to the 'House Rules' DTC marketing campaign.

General and administrative costs were $5 million, down 23% from Q2 primarily due to reductions in payroll-related expenses, including stock-based compensation.

As a result, total operating expenses were $45.1 million, up 5% compared to Q2. And our loss from operations was $43.4 million.

We currently expect fourth quarter operating expenses will be lower than Q3 by several million dollars, primarily driven by a shift in our DTC strategy, away from broad awareness tactics, like television, to digital channels such as streaming, and other social media-based approaches.

As we look forward to 2022, we expect to reduce total operating expenses by approximately $50 million. The key driver will be marketing expenses, which we anticipate will be approximately 50% lower than 2021 levels.

R&D expenses are likely to remain at 2021 levels due to the ongoing EVOGUARD trial and preparations for the sNDA filing. And we expect G&A will also remain flat. We plan to provide more guidance for 2022 during our year-end 2021 calls in March.

At the close of Q3, we had $14.9 million in cash and cash equivalents as well as $9 million in restricted cash from the Adjuvant notes available for use. This totals $23.9 million for use in ongoing operations as of September 30, 2021. In October, we raised $10 million in gross proceeds from the sale and issuance of shares of our Series B preferred stock to an institutional investor. We believe our existing capital resources will be sufficient to sustain our planned operations into the first quarter of 2022.

Finally, I want to address the notice we received in late August from NASDAQ about Evofem's noncompliance with NASDAQ's listing standards because we do not currently meet the minimum bid price requirement. We have until February 21, 2022 to regain compliance. And at that time, if the stock is still trading below $1, we anticipate being able to apply for an additional six months' grace period. We have an approved asset that is growing faster than any other recently launched contraceptive brand, as well as several near-term catalysts that we believe position Evofem for success. We currently expect that will regain compliance with the listing standard within the allotted time.

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

Saundra Pelletier

Thank you, Jay.

Today, you're going to hear detailed and tactical information about Phexxi, both successes and challenges that we are working to overcome. I'm going to shed light on some tough issues to help you better understand our strategy and why we stand undaunted and highly positive about the future of Evofem and Phexxi.

As Jay mentioned, the strong top-line growth we are driving is not currently reflected in our net revenue. As we discussed on prior calls, this is primarily because of a co-pay assistance program we implemented at launch to ensure that cost and coverage are not barriers for any eligible commercial patients to get Phexxi. Our copay programs allow the Phexxi savings cards to be seamlessly applied to patients' out-of-pocket costs. In the absence of this program, not having coverage from insurers will cause a prescription to be denied at the pharmacy, which will result

in a call to the prescriber to make another choice. This will result in the loss of not only that prescription and future refills of that prescription, but it may also cause the prescriber to refrain from prescribing Phexxi in the future because pharmacy calls take time from both, the prescriber and their staff. It is for these reasons that we implemented copay assistance programs that ensure women are able to fill their Phexxi prescriptions when they face coverage denials or step edits.

If we were not using these programs to build our base of users, we believe that our net revenue would be well in line with current analyst consensus.

The reality of the situation is that due to the innovative nature of Phexxi, there is still work to be done to gain inclusion in the Office of Women's Health Birth Control Guide. Until that time, which we believe is soon, we are prevented from effectively building our prescriber base while optimizing revenue.

What does that mean exactly? It means that if the Office of Women's Health maintained a medically accurate birth control guide, we wouldn't have had to make that difficult choice to prioritize building the base of prescribers and Phexxi users, because Phexxi would be covered like the Affordable Care Act mandates, since it is the only vaginal pH modulator.

The truth is that coverage denial and step edits should not happen under the Affordable Care Act. Under the spirit of the ACA, health insurance companies should cover at least one product in each category of contraception at zero copay.

If all health insurance companies acted as they should, use of our savings programs would be dramatically lower, and we would stop supporting the prior authorization process with both our time and our money. Our net revenue and margins would dramatically improve. But clearly, some health insurance companies are acting in their own interests, not in the interest of patients. It will take a bigger power to force them to change. This is why our ACA strategy is of critical importance. And I'll come back to this in a few minutes.

The other factor to keep in mind is the healthcare provider. It takes a great deal of outreach and effort to educate OB/GYNs, nurse practitioners and midwives, and even more to get them to adjust their attitudes, behaviors, and contraceptive prescribing habits. Phexxi is both a clinical and behavioral sell. Our sales representatives are working to overcome the deeply ingrained habit, the gold standard mentality, if you will - following the norm. Meaning, the standard practice of prescribing oral contraceptives that are systemic, delivering hormones every day, when the reality is women do not have sex every day.

Our reps are doing a fantastic job. More than 10,000 healthcare prescribers have written a Phexxi prescription since launch, just over a year ago. And we continue to grow the provider base as well as to work to increase the prescription volume per provider.

The challenge is that the coverage denials, step edits and prior authorization letters, or PAs, required by some health insurance companies can easily result in prescriber fatigue. This in turn

can result in them reverting back to old habits of writing hormonal contraception - because it's easy - which puts us back at square one.

Despite how easy the process is, some prescriptions are never filled, because of the need for prior authorization letter or PA. To combat this, our reps check frequently to ask if PAs are getting done. And while 60% of the PAs that are submitted get approved by the health insurance companies, let me be obvious - 40% of women are being denied access to their contraceptive of choice.

Essentially, our reps have a two-call approach. They sell Phexxi, and they explain the simplicity of PA forms when they're needed.

We have observed real demand for Phexxi across the United States. Women everywhere are beyond hormones.

So yes, we could sacrifice prescription growth, which would improve our gross-to-net and our net revenue. We did exactly that in Q2. We changed our savings card for six weeks. During this period, many prescriptions not covered on formulary, including those that required a PA, were lost. And with that, we lost some prescribers, and a number of patients were not able to get Phexxi, the hormone-free birth control of their choice.

Halting our programs improved gross to net in Q2, but if we had not started them up again, the negative impact on prescribers and consumers alike would have translated to a business with little chance of long-term success. The near-term gain was not worth it.

So, we prioritized access to Phexxi over GTN and the bottom line, with the expectation of improvements following governmental action on the ACA. We are successfully building a strong base of healthcare providers writing the product and dramatically growing the number of women using Phexxi. More than 19,000 prescriptions were building Q3 alone, and we exceeded 10,000 TRxs for the month of October.

Our sales force efforts are dovetailing with rising consumer brand awareness, which climbed to 14% in September after just three weeks of the 'House Rules' campaign, which we launched on September 9th with our celebrity ambassador, the fabulous Annie Murphy. When I say she's fabulous, it's not just because she's famous. It is because her testimonial really speaks to the fact that she felt that her hormonal side effects made her feel like there was something wrong with her. So many women have resonated with that message because it is not just overt side effects, it's the covert side effects that also make Phexxi an excellent choice for these women.

Brand awareness continues to rise. We hit 19% in October, which is approaching the level of the most successful women's healthcare brands launched. Greater awareness is leading to more-and-more women requesting Phexxi prescriptions, and for more healthcare providers recognizing the unmet need for Phexxi. This in turn is driving new highs in prescriptions and unit sales week-after-week and month-after-month.

Comparing the six weeks before and after the 'House Rules' launch, more than 10,000 new Phexxi prescriptions were written in just six weeks, a 94% increase, and total prescriptions grew 81% to more than 13,000.

Dispensed units, which are boxes of 12 prefilled Phexxi applicators, were up 82%, with more than 15,000 Phexxi boxes dispensed in the six weeks after the 'House Rules' campaign launched. This number is higher than the number of total prescriptions because some women's Phexxi prescriptions are for more than one box of Phexxi.

2,700 healthcare providers wrote a new Phexxi prescription in September, a 34% increase over August. Women are asking for Phexxi and healthcare providers are increasingly prescribing it for them.

We believe that the early results of the House Rules campaign clearly demonstrate the high unmet need. As Phexxi awareness continues to grow, we are confident so too will brand consideration, healthcare provider discussions, and ultimately conversion to Phexxi.

Turning back to ACA, we are committed to assuring that all women have access to Phexxi as their choice in contraception. There are two parallel strategies in play here, and either one should be a win for Phexxi, for women nationwide, for Evofem, and for our shareholders.

Path one is for the Office of Women's Health to update the Birth Control Guide. When it was developed, this guide listed all available birth control methods that were FDA approved at that time. Methods, not products or brands, it was developed as an educational tool, and it served the purpose.

The ACA, which was passed in March of 2010, specifies that at least one product in each category will be covered as a covered benefit at zero out-of-pocket pay to women.

Well, that was 12 years ago. The chart has not been updated since then. It is sorely outdated, and it does not include subsequent advances in contraception using new delivery methods, including Phexxi, a vaginal pH modulator, which is in our label, given to us by the FDA. We are working to get the Office of Women's Health to update the chart, to include a new vaginal pH modulator category. Phexxi is the only FDA approved product in this category. And under the current rules and regulations, it will be a covered benefit.

We believe this is the simplest and most straightforward path.

As part of our strategy, we are collaborating with the Coalition for Hormone-Free Contraceptive Coverage to raise awareness and support this issue. We launched a petition on September 17th and in just six weeks, our petition garnered over 12,000 signatures. I encourage you, listening today, to sign and share our petition to help us reach 20,000 signatures by Thanksgiving. You can access it through the QR code in our presentation or at contraceptivecoverage.com.

Two weeks ago, I spent a full week in Washington D.C. to educate key policymakers on the need to update the Birth Control Guide. I met with more than a dozen key legislators in both houses

of Congress, including Senator Susan Collins, Patty Murray, Alex Padilla and Congresspersons, Scott Peters, Eric Swalwell, Jackie Speier, Diane DeGette and Sarah Jacobs. I also gained audiences with top staff at the Federal Health Resources and Services Administration, as well as the most senior domestic policy advisors in the Vice President's office, and Wally Adeyemo, the Deputy Secretary of the Treasury.

Along with our team that has worked tirelessly on this issue, I presented our case to them as well as our petition. This demonstration of consumer demand for hormone-free birth control was very compelling to these policymakers.

The second path is for the Federal Health Resources and Services Administration, or HRSA, to issue updated guidance to insurers in the United States to prevent the chart from being a limiting factor and require that these insurers cover new and unique contraceptive methods such as Phexxi. Currently, some of these insurers are using this as a loophole to prevent women from getting coverage.

In October, four House Committee Chairs wrote a letter to the U.S. Secretary of HHS, Treasury and Labor calling for action to ensure coverage for the full range of contraceptives under the ACA. The letter mentioned that certain health insurance providers are blocking access to products that is clearly outside of the spirit and outside of the intent of ACA. The letter calls for action to stop these practices now. We see this as a very positive development and believe it is well timed, given the ongoing HRSA review of its guidance regarding contraceptive coverage.

We are optimistic that the Department's review will culminate in a favorable update to the current guidance. That said, we are developing contingency plans, while we continue to push hard in D.C.

Under the spirit of ACA, we believe Phexxi should be a covered benefit at zero copay. We are not asking them to send us to the moon. This is just an administrative update. So, we are pushing hard because it's what is right for women, it's what's intended under ACA, it's what's right for Evofem, it's what's right for our shareholders.

Turning to R&D. We continue to advance the development of EVO100 for the prevention of chlamydia and gonorrhea with the goal of expanding the Phexxi label to include these potential new indications. According to the CDC, every sexually active person is at risk of catching these common infections. There are no FDA approved prescription preventative measures. Right now, the choices are condoms or abstinence. And based on the continuing rise in reported STI rates, clearly this is not enough.

In October 2020, we initiated our pivotal Phase 3 trial with the goal of enrolling just over 1,700 women by year-end. Enrollment has been a little slower than predicted due to COVID-related issues, including labor shortages affecting our study sites, our CRO, and testing laboratories. We are constantly evaluating every available strategy and implementing new tactics to help overcome these hurdles.

Based on the challenges in the macro environment and where we are today, we now expect enrollment of our last patient in Q1. We will still report top-line results in 2022. And assuming positive results, we will file our sNDA with the FDA in Q1 of 2023.

Looking outside the U.S., discussions are ongoing with potential global and regional partners for commercialization of Phexxi in key international markets. We're very pleased that the opportunity for Phexxi and hormone-free contraception, as well as the potential opportunity in the prevention of chlamydia and gonorrhea, is resonating with many strong potential partners.

I can't go into more detail since these conversations are quite delicate, but I will tell you this: the initial opportunities will probably be in Asia Pacific or in the Latin America region.

We expect the structure will include an upfront payment commesurate with the size of the licensed market or markets, as well as milestone payments and royalties on future product sales.

Meanwhile, we recently submitted our first regulatory registration outside of the U.S. in Mexico under the trademark "Femidence". This is the first of several strategic regulatory submissions planned under our 2020 global health agreement with Adjuvant Capital. The goal is to ensure that safe, effective, high-quality contraceptives and STI prevention products are made available to women and healthcare providers in low- and middle-income countries on terms that are commercially viable for Evofem. Assuming approval by the Mexican regulatory agency, we expect Femidence will be available in Mexico in early 2023.

We look forward to the day when all women, regardless of income or geography, have access to hormone-free birth control that they can use on their terms, only when they need it.

And with that, operator, please open the call for questions.

Question-and-Answer Session

Operator

Our first question comes from the line of Ram Selvaraju from H.C. Wainwright.

Ram Selvaraju

Hi. Thanks so much for taking my questions. Firstly, I was wondering if you could comment on the overall Mexican market situation as this pertains to female contraception. And how, given the unique nature of that specific target market, Phexxi might be a particularly attractive additional entrant?

Saundra Pelletier

Yes. So, thank you for the question, Ram. A couple of things I would say. Almost 50% of our enrollment in EMPOWER was women that were of Latin American descent. And some of the

feedback we received is that based on their religion, mostly predominantly Catholicism, that they love to the fact that not only does this product have no hormones, but that because it was hormone-free, it did not impact their natural cycles and the way their body worked. And they felt that that gave them a more natural way to manage their fertility. And they thought that that was incredibly positive.

So, we do believe that -- and the other thing, frankly, is that in feedback that we got in market research, they had no issues whatsoever with something that was vaginally administered. So, we feel very good that talking about the positive benefits of the product, the attributes are going to be received and the uptake is actually going to be quite rapid, frankly. So, we feel good about that.

And as we mentioned on the call, it will be a different brand name, so then we will be able to understand and focus on how we build that separate from the Phexxi brand in the U.S.

Ram Selvaraju

Great. Secondly, I was wondering if you could comment on the previously mentioned strategy for recommending Phexxi use, specifically in women who are undergoing hormonally based treatment for cancer, because obviously for those women, hormonal contraception would not be an appropriate choice. And what new developments there may have been on that front, and what you are expecting to pursue, if any, new activities aimed specifically at that target population over the course of the coming months and quarters?

Saundra Pelletier

Yes. Well, so here's what I would say to you is that -- so we have partnered and continue to partner with the group NCODA. They did a PQI, a positive quality intervention. And this positive quality intervention talks about you need to treat the total patients. Don't just treat for cancer, treat the total woman. And that when this get done treatment and they want to go back to their lives and have intimate relations with their partners, the last thing they wanted to get pregnant, to your point, Ram, because it will grow their estrogen cancers. And so, they're recommending Phexxi as the ideal product of choice. Not -- of course, because it's not hormonal, but a lot of these women have to take anti-estrogen for 5 years or 10 years, every single day, which creates a lot of vaginal dryness, a lot of pain with intercourse. So, Phexxi is actually growing amongst the oncology community.

But the other thing why I'm glad you asked this question is that when I was in D.C., I can tell you this. If people want to try to close their ears and they want to try to not listen to me because they don't want to do any hard work, when I call out the fact that their vulnerable constituents, 800,000 women get cancer every year, and how about the women last year and the year before, and how about their daughters, and how about their sisters? And do they want to be part of a movement that denies these vulnerable women coverage? Or do they want to be part of a movement that provides access for all women, but in particular, these vulnerable women? And I will tell you that the cancer patient was a way that they could get behind it.

Now, you would hope that they would care about the 23 million women that are also beyond hormones, but in some cases, when they thought that was a bridge too far, helping a "bad pharma company" just didn't seem to meet their standards, no one could deny that that population was deserving and vulnerable and that the one company who is actually innovative, actually innovative, not coming out with more hormones in a different delivery system, that is actual innovator, should not be denied access.

And the final thing I will say is that I actually agitated to the point where I said, look, who is going to be motivated as a pharma company to innovate in women's health when a company like ours has provided a copay card to allow access and which we're no longer going to be able to continue to do, because we have to stop that at some point. And we're not going to be available anymore, because we might go out of business, because the Office of Women's Health is denying innovation in the category. So, we have been very fierce about that message.

And I'm glad that you asked, because I really want our shareholders to hear that we're not being polite and going and having a cookies and tea party. We're going there saying, listen, you better wake up, because we're not being polite, because you're not doing the right thing and the Office of Women's Health is not doing the right thing. And insurers are using it as a loophole.

Sorry, Ram. I went on a little soapbox crazy there, but sorry about that. But thanks for the question.

Ram Selvaraju

That's very helpful. Lastly, just wanted to get some additional details regarding some commercial aspects. Firstly, I was wondering if, on the marketing front, you feel that given the critical mass of awareness that has been built around Phexxi with the 'House Rules' campaign and the other initiatives from a DTC perspective, whether you believe that at this juncture it's the appropriate point to transition into different kind of marketing approach and different kind of marketing strategy that isn't quite as capital intensive, and that this in fact would not really sacrifice the ongoing commercial growth, because as I mentioned, the critical mass of awareness has been built? And then secondly, just very quickly on pricing. I understand that you folks took a price increase relatively recently. Do you anticipate pricing for Phexxi to remain stable on an ongoing basis from here on and regardless of what happens with the copay card?

Saundra Pelletier

Yes. So, I'll take the first one and then I'll let Jay jump in. So, to your point, we were very, very strategic about how long we ran the Annie Murphy 'House Rules' campaign, knowing that we needed to build a solid base so that once we weaned off the most expensive piece, which is television, then we would be able to maintain that base and continue to grow. And I would tell you that, getting to 19%, it was very, very significant.

So, I would say this. I would say that we feel very confident that the base is built, that going to these other social media outlets are going to be a way to not just maintain, but continue to grow the business.

So, yes, we needed a broad awareness and we needed to be appropriately provocative, so that we would be memorable, and people would want more, so that when we go to these other social media channels, they are going to be interested in looking. They are going to know that it's not going to be on television necessarily, but it's going to be in other social media outlets that are obviously going to be more cost-effective for us.

Also, I want you to know that Annie Murphy has agreed to be our ambassador for a full year. So, that wasn't just the one and only. She is going to continue to do other things on other social media outlets, because I have never met a more passionate advocate for a brand. I really mean it. She is in love with Phexxi, which is wonderful.

So, yes, we feel that the base is built. We don't feel that there is going to be a downturn. We feel very good about that. And we also have been very smart about shifting and dialing back a little bit on social media influencers. We now have enough data run and enough metrics to know what is working exactly, what are the social media channels we should continue to invest in, what are the ones that didn't actually deliver as much as we hoped, and we are stopping those. So, it's actually a very specific menu of what we're going to continue, what we're going to stop, but we feel very, very good that we're going to continue to grow the base.

Now, as far as the price increase, you're right. We did take a price increase, and we did that, frankly, based on looking at a proxy of the market dynamics, what were other contraceptive products doing, across the board. And so, Jay, I don't know if you want to speak to that.

Jay File

Yes. We did do an annual price increase that was effective October 1st, part of the natural process with the pharmaceutical, we assess that on an annual basis. We do not anticipate doing any other adjustments until approximately the same time next year. So, we're at stable at 294. and light of any other business changes that might come with our copay programs.

Saundra Pelletier

And Ram, just to add to that only because, when I've interacted with you, I don't want to pretend I know how you think. But I know that you do full circle. And here is what I mean by that is that when I got back from D.C., although, I really do believe that we were memorable, our voice was heard, and people know that we are serious and we are going to keep pounding the pavement until we get success. I came back and met with the team, and said, we need to be realistic. And what needs to happen is that we need to really look at the copay card. We need to not rip off the bandage completely, but we need to significantly dial that back. So, that women aren't going to zero, like they would when they get our own category, but they have to give some additional co-pay.

Now, a lot of these women are already using the product, they love the product, and they've seen the benefits and the attributes. So, we feel confident that we can continue to maintain them as users of Phexxi.

But you will see in Q1 an improvement in our gross to net, and you will see over the year an improvement in our revenues as a result of that, which is important. We built our base, we did it strategically. We did it by design and now, our sales force is going to have to really continue to pull through.

Operator

Our next question comes from line of David Amsellem from Piper Sandler.

David Amsellem

Thanks. So, I just have a couple questions. First, I understand the sort of palpable frustration with policy makers today. But I guess, looking forward, what happens if you just can't get where you need to be in terms of coverage under the ACA mandate? Do you think about potentially looking to evaluate strategic alternatives? Does it get to a point where potentially it makes more sense for the asset to be a part of a larger portfolio? So, maybe the other way of asking it is, without its own category, can Phexxi get to critical mass with people from being a standalone company? Thanks.

Saundra Pelletier

So, here is the answer that right now, as we've said before, we have 55% coverage and with prior auth that is basically bringing it up to about 70% of the prior auths that are going through. But here's what I want you to hear is that we have made a decision as an organization, based on the demand that plans have seen. So for example, the plans that are denying us and are saying, well, if you don't have your own, -- if you're not a method, I'm sure this chart -- and the one thing I want to make sure everybody understands is that this chart by the Office of Women's Health, the Office of Women's Health said to us, listen. This is only supposed to be an educational tool. Why do you keep bothering us? This is not supposed to be a proxy for healthcare plans to make decisions. And we say, well, we understand that, we know what your attention is, but the reality is healthcare plans are using it as a loophole. And they're telling us that if we don't give them a 60 or greater percent discount, they will not let women get coverage. And moreover, they're saying to some women, they have to fail on each other contraceptive products.

Now, this is not the majority, it's the minority, but here's what's been happening lately is we've reached out to those same plans. Those same plans have said, okay, fine. We have seen all the prior auths come through. We have seen that you are creating a groundswell for this product, and we're going to negotiate with you on better terms. So, instead of asking you for a 60% discount, let's start playing ball.

So, the short answer is, yes, this organization can be viable with Phexxi for non-hormonal contraception and the forthcoming label expansion for chlamydia and gonorrhea, because we will contract.

Some people unfortunately have had to contract at 50% or 60%, and those are three-year contracts. We, thank goodness, decided not to do that. We built our base of users and now the contract will be somewhere between 20% to 30%.

Do I wish it was lower? Yes. But we will contract to get the kind of coverage that we need for our Phexxi patients until we get our own category. So that is the plan, frankly, is that we'll do -- and what I'd say is that we've already started these conversations to say, until we get our own category, we need to now contract with you.

But, the great thing is that now those percentages are going to be much lower because we built demand.

David Amsellem

Okay. That's helpful. And then secondly, to the extent that you get STI prevention added, can you talk to the extent to which that gives you more leverage with payers or maybe another way of asking it is if we're talking about a contracting game is having STI prevention in the label something that ultimately will give you better terms.

Saundra Pelletier

No question. Having STI in the label will give us better term across the board, frankly, even with the groups that we have great terms with. Yes. Because I think the big thing that a lot of these plans see is that the recurrence that is happening. And so, having something for the prevention of both chlamydia and gonorrhea, they've actually -- proactively -- indicated to us that it will give us better terms. So, we think that those expanded indications are going to give us leverage across the board. They're going to give us leverage with payers and contracts, and they're also going to give us leverage with continuing to identify partners outside of the U.S. with -- to do arrangements with licensed deals. So yes, we think it's going to be a very, very significant value-add to the brand.

David Amsellem

Okay. And then last question is let's again assume that you don't get to where you want to go with the Office of Women's Health. But you do have STI prevention in the label. So, looking longer term, what is your view on what the steady state gross-to-net ultimately will be in that scenario?

Saundra Pelletier

Jay, do you want to opine on that?

Justin File

Yes. I mean, Dave, that's a great hypothetical. In general, really what it will come down to ultimately is any sort of outside negotiations and ultimate contracting that we would need to do that Saundra was just referring to that we believe ultimately could get that down to 20% to 30% versus their requests to being around 60%. The interesting part with STI, and we've done some initial payer research is that we do see that they would give without issue - we'll call the Phexxi plus with an STI indication - a script to those women that are requesting it and that are on other forms of birth control. So, we do think we have some additional leverage in that capacity that even if it's not used for contraception, there is still that additional use for prevention of the chlamydia and gonorrhea.

So, I think ultimately to answer your question, you'll see it definitely come down, because of that contracting, the basis points ultimately will determine on the basis of those final negotiations we have with those PBMs.

Saundra Pelletier

Well, also, just to add, David, we are looking at very serious ways to lower our cost of goods. And what I mean by that is our manufacturing team is very, very savvy. So, we're looking at everything from packaging configurations, to amount of product in packages, to literally looking at tech transferring to sites that can really give us more operational efficiencies.

So, in the next 18 months, by the time, we are on the market with our expanded label, we definitely feel that our cost of goods will be much, much lower, which will also help the overall brand equity.

David Amsellem

Thank you.

Operator

Thank you. Our next question comes from the line of Annabel Samimy from Stifel. Your question, please?

Annabel Samimy

Hi. Thanks for taking my question. There's obviously a challenging time for you. So, just going back to the plans that have seen enough prior authorizations, such that they're willing to come to the table and start negotiating a rebate that is more reasonable to you - what timeframe should we be thinking about that in terms of getting these plans on board and what percent of those plans that are -- what percent of covered lives could this potentially represent to you, if you actually are successful at signing these plans?

Saundra Pelletier

Okay. So, here is what I would tell you: I would say that if we're starting the conversations now, the contracting will go into place in Q1, and we won't see an impact until Q2. I think that is realistic. It's about 30 million additional lives.

And so, if we get the contract negotiations completed Q1 -- not if -- we've already started, so I give you Q1 being conservative -- implemented Q2, 30 million additional lives. We feel like that is a very realistic assumption and timeline.

And to give you an idea, I mean, look, there are some plans that are completely female patient focused, right? They're just doing the right thing because they know it's a mandate and it's the right thing to do. And the handful of plans that are, are places like CVS and United. And so, those are the places where we are having positive conversations based on the demand that they've seen.

But yes, 30 million lives is what we expect we will be able to impact.

Annabel Samimy

Okay, great. And then, when you think about, I guess the rebates that you've been offering, so I know that you had to pull back on some of the copay assistance -- not the rebates, I'm sorry, the copay assistance that you've been offering. I know that you've had to pull back on that to a certain degree, but then I guess this quarter, because it was impacting the fulfillment, you brought them back. I guess, you're providing that assistance again.

Where's the right balance that we should think about going forward, as far as the level of copay assistance you're going to provide? Is there some kind of way you can quantify it for us a little bit, just so how would you frame the modeling?

And then, a follow-up question to that also on balance, obviously you're in a very promotion-sensitive market and you're still going to be providing some kind of social media presence. But again, where's the balance there? You've got about -- with the $10 million, you got about $24 million in cash left and practically speaking that's not going to last if the level of spend that you have right now, even with the reduction. So, I guess, I'm trying to understand all those pieces and maybe I asked two questions in one, but I wanted to make sure I got them all.

Saundra Pelletier

No, it's okay. I'm going to try to remember them all. So, the first one is... from June of this year until the end of this year, the copay assistance program is going to remain the same. In May, we turned it off, and that's when we saw a major decline in our prescriptions in May. And based on that decline, here's what we said to ourselves. We're launching Annie Murphy, September 9th. It is insane to launch Annie Murphy after the investments that we made and the big push that we are going to have, and have all of these women in droves go to get Phexxi and have them be denied. We are going to lose these patients forever. That is not a smart strategy.

So that's what -- to be candid, we wanted to see what would happen. We wanted to see -- we really wanted to see how reliant women are on the ACA and what's going on with these 18 categories. So, that's why we shut it off in May.

So, then, we turned it back on in June and it's been the same from June till the end of this year. At the end of this year, that's when we are going to make adjustments.

So, we're going to make copay adjustments and they will be -- it's going to be a step approach. Meaning, for example, right now, if we're buying women down to zero, so quite literally our whole team is here this week, looking at the different plans in the different regions. So for example, in some places, we will take it to 50%, other places will take it -- these women will have to pay 50%. Other times, they'll have to pay 75%. So, we are looking to try to figure out how to slice that up. But at a minimum, it's going to be a 50% approach. So, that will increase our gross to net. That will not go into place until Q1, but you should see shifts in Q1. What we saw is just happened right away, I mean, right away. So, that's why.

So, June to the end of the year, you should continue your same modeling, but the modeling should shift for Q1 of 2022. Let me just pause there. Jay, are you agreeing with all that?

Jay File

Absolutely.

Saundra Pelletier

Okay. Then? Oh, market. Yes. So, it is a promotion sensitive market. So, here's the things that I want you to hear. So, some of the things that we're doing might sound a little grassroots. Interestingly, it's working very well.

So, now with a lot of colleges opening up, we're doing a very serious college campus push where our reps are educating the healthcare providers on campus. We literally have a push through a whole variety of sororities. They are doing healthcare days where we are talking about Phexxi on all the college campuses. We are doing a huge push through the pageant association, through all the professionals cheerleading teams, they have a groundswell. Women, when they love something, I know this is an obvious statement, but they tell other women. And we have identified these groups of women as very big social media pushers, so to speak. So, we are continuing our regular social media channels outside of television, but we are also looking at different outreach, through campuses and through these associations that we think are actually going to be very, very, very important.

All of these young women we have found are saying to us in all of the feedback, when they went to college, their mother made them go on birth control, because she was so worried they were going to get pregnant. And all of a sudden, they started crying for no reason. Then all of a sudden they started to have anxiety. While their family thought, well, they were just nervous because they were in school, so they got put on an anti-anxiety product, or they got put on an

anti-depressant, and then finally they realized two semesters later that perhaps it was their hormonal birth control that was making them not feel like themselves.

So, a lot of these young women are very empowered and they're very vitriolic, and they themselves, we did not point this, they called themselves the Phexxi babes. And they're creating this groundswell where they really feel that they are doing yoga and they're eating healthy, and they care about their fertility and they care about getting pregnant when they want to. And so, we're doing a lot more of those kinds of efforts now that COVID has dissipated on college campuses, but we're still very committed to the social media channels outside of TV.

So, you're still going see Phexxi. We're definitely not going away. It's just the television ads are the things that are going to dissipate.

Annabel Samimy

Okay. And then, finally, and practically speaking, where are we in terms of being able to manage all of this with the cash position that you're in. And last year you told the first quarter. So kind of running out of time here, on either another non-diluted source of financing, or deal making, so what options really do you have? And I actually have another follow-up question.

Jay File

So, yes. So, as stated on the call, obviously, we've got runway into the first quarter and you are exactly right. We've got the potential for non-dilutive sources, continuing to work towards several of these potential licensing agreements that we think are good opportunities to get Phexxi outside the U.S. And then, we continually assess additional alternatives that can be good sources of external capital into the company to push us further into 2022, with the most effective cost of capital.

We've got some great, fantastic momentum since the DTC campaign with House Rules. We see that continuing to build and anticipate it to get to grow through the end of the year. We think we're in a strong position to really leverage that as we near the end of the year.

Annabel Samimy

Okay. And then, one last final question on the work in Washington and the Office of Women's Health, was it outright rejection or just sort of like speaking platitudes and they kind of sent you off packing -- like what actually is the dynamic there?

Saundra Pelletier

Here's what I would tell you. I would tell you that the team that I went with from Evofem would give you a slightly different narrative than I gave you. They would tell you that they thought the meetings were very positive, that they are very optimistic, and they were pleasantly surprised at how much movement we saw.

Now, I believe that that storybook of the turtle and the hare is a fairy tale for a reason -- the hare always wins. And so, I am very impatient and frustrated by nature, and I just can't believe it, because it's called the Office of Women's Health. I mean, hello! You know, so you know, I'm agitated, but I would say this to you is that no one sent us packing -- quite seriously, no one didn't get it. So everybody got it. Everybody understood that we innovated in the category. Everybody understood that this was unlike anything else and a vaginal pH modulator, it made sense. It made sense to everybody, honestly, men, women, advocacy groups, everyone that we met with. And I do mean this, all of them. I'll give you an example. Several of them wrote letters and emails that they showed me, to Secretary Becerra, and they copied the Office of Women's Health. We gave them a template, they edited it. And those letters said, it is time for you to update the chart. We recognize that it's intended as an educational tool. And even if that's the intent, it's still not accurate because if it's an educational tools, it should have a new innovation, a vaginal pH modulator.

So, real action was taken, and we got people. And I'm not kidding, when they said, okay, well, we'll contact the Office of Women's Health, I said, well, can you do it now? I have a template and if you could send it right now, I can help you to start it. Okay, well, we will call them. Could you call them now? Why don't we do it now? How about you call them now? Can I call you at the end of the day to see how the call went? We were persistent to a point of a little bit annoying, which we needed to be.

So, I would say to you that there was not one bad meeting. I mean that sincerely. Everyone responded in a very positive, appropriate way. My frustration was that Secretary Becerra is really the key lever to make the Office of Women's Health today. That's what we know. We also know his wife is an OB/GYN interestingly.

So, we now are on to our next series of follow-ups. And a lot of them said -- I'll give you another example. Somebody said to me, you know what, maybe we should get you to testify. I even had senators - Susan Collins contacted the Office of Women's Health and said, you need to give this woman an audience. You need to let her appeal to you directly, because you need to update the charts.

So, the final thing I would say is that, the excuse that we were given is, they are going to update the chart, they are going to make it accurate, but they have so many other things to worry about, like Roe vs Wade and COVID, and this is just an educational chart and they are going to get to it.

Now, I do believe they <u>are</u> going to get to it, and I do believe we're going to get a vaginal pH modulator category. It's that I want it <u>now</u>. And so, that was my frustration is a lack of sense of urgency. But no one said, 'we disagree'. No one said, 'you shouldn't have your own category'. No one said, 'this doesn't make sense.' None of that happened.

Annabel Samimy

Okay, great. Thank you.

Operator

Thank you. Our next comes from the line of Jeff Hung from Morgan Stanley. Your question, please?

Unidentified Analyst

Hi. This is Melina Santoro on for Jeff. Thanks for taking our questions. So, you touched on this, but can you just give a little bit more color on the net sales for this quarter and going forward? Do you kind of expect this disconnect with scripts and sales to continue until you adjust the copay assistance program that started next year, or is this when you secure the additional category of ACA or get the guidance updated with HRSA? And I have one follow-up.

Jay File

Sure. I'll go ahead and take that. Yes, so to reiterate, there was a 29% increase in gross sales. And really what it comes down ultimately is the mix that happens during that time period, as far as the women that are gaining access to Phexxi and what levers of our copay programs are triggered from that. We continue to see great increases in the ex-factory sales ongoing, we've given a little bit more guidance here in the call. We do anticipate that we will see that continuing trend upwards.

But, I wouldn't be so bold as to give you specific guidance onto -- as to the nature of you'll see Q3 repeated in Q4, because it ultimately comes down to the mix of those women that are getting prescriptions filled and their underlying coverage. What I can say is that, we do know through the end of the year, we are going to be committed to ensuring that access for those women that want the product and get experience using it are going to have that ability. And that is our number one key through the end of the year.

Then, as Saundra mentioned, we're going to go ahead and evaluate what options we have at our disposal to adjust the co-pay program. Starting at the beginning of the year, we do anticipate that we'll have impact rather quickly, even starting in January as to GTN improvement and then ongoing. And then, that separate approach that she mentioned will continue to be analyzed as we move forward in the beginning of the year. Ultimately, ACA gets kicked on. We can then even make further adjustments for even more positive lift to GTN as the year goes on.

Unidentified Analyst

Okay, great. And then, maybe just one more. Can you share with us any update on what you're seeing with the refill rate? And how you expect that to trend into next year? Thanks.

Saundra Pelletier

Tim, do you want to talk about the refill rates, because you analyzed it recently?

Tim Glennon

Just really quickly. So, we've looked at refills and we continue to monitor refills closely. And one of the things that's been really exciting is we actually hit some of the highest refill rate percentages on a weekly basis when we were coming into the launch of our celebrity campaign.

And then, after the celebrity campaign, we continue to see a large number of -- a growing number in the volume of refills weekly. But that percentage obviously went down, which was a good thing. And we're all excited about it because honestly, the number of new Rx is coming in is just really throwing that percentage off. So, the good news is we're seeing a lot more women refill. And the percentages probably aren't the best way to tell the story right now, because it's a different number as we're approaching new highs monthly.

Operator

Thank you. This does conclude the question and answer session of today's program. I'd like to hand the program back to Saundra Pelletier for any further remarks.

Saundra Pelletier

We know that many of you have been shareholders in Evofem for many years, and we know that it has been a little rough. We never expected to be launching Phexxi in the type of environment that exists today.

I want to assure you that everyone at Evofem is fighting to make this company a success. We know what needs to be done, and we execute on it every single day.

We've discussed our key initiatives throughout this call, but I want to summarize them here for you.

One, cost reduction. We are committed to reducing costs by $50 million in 2022, predominantly in marketing.

Two, increased access to Phexxi by spurring an update to the Office of Women's Health birth control chart, or guidance from the Federal Health Resources & Services Administration to ensure that we'll prevent the chart from being used to limit contraceptive choices for women.

I also want to make the comment, when I was in D.C., one of the things that you want to say to people and you want to say to politicians is that you don't want their name associated with the company that was punished for innovating. This company is going to succeed. I jousted with them to say, do you want to be in the administration when a company is no longer in existence? That is a suggestion to debate people. I believe that this company is going to be the most successful leader in women's health. And believe me, if you were on the inside, looking out to see all the positive things that are happening, there is no chance you would not agree with me.

Number three, drive the STI prevention program forward by completing the EVOGUARD trial, filing for an sNDA for Phexxi, for the prevention of chlamydia and gonorrhea.

Number four, enter into licensing agreements to get Phexxi into international markets and bring non-dilutive capital to Evofem.

And number five, continue to increase Phexxi demand in the U.S.

We work tirelessly on these initiatives, to make this company a success and increase contraceptive access for women. We remain determined, we remain proactive, and we remain highly focused. Our efforts are not gentle, nor are they timid. They are professional, but we escalate to intensity and even fierce when it is required, because succeeding in women's health is not a walk in the park, but we will succeed. And we will succeed for the shareholders that got us here, and for the women who deserve better.

We want to thank you for your ongoing support. And I hope you have a great rest of your day. Thank you very much.

Operator

Thank you, ladies and gentlemen, for your participation in today's conference. This does conclude the program. You may now disconnect. Good day.