

Technology

Birth Control Gel Approved as First No-Hormone Option in Decades

By [Bailey Lipschultz](#)

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- ▶ FDA approves Evofem's contraceptive gel, Phexxi, for women
 - ▶ Annual sales estimated to be more than \$400 million by 2024
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A new birth control gel is the first non-hormonal contraceptive to win FDA approval in decades, bringing another option to the \$5.4 billion market.

The gel, marketed as Phexxi by Evofem Biosciences Inc., works by making pH levels in the vagina inhospitable to sperm when applied up to an hour before sex.

The approval marks a rare new option in the contraceptive market, which has been dominated by pills for the past 60 years. The last wholly new type of birth control without hormones was the female condom, approved in 1993.

"This is for women who aren't using hormonal contraceptive, who want to prevent against pregnancy and won't use an IUD (intrauterine device)," Evofem Chief Executive Officer Saundra Pelletier said by telephone. "Our product is the only contraceptive product with no hormones, with no systemic side effects, and that women use only when they need it."

Shares of Evofem reversed an initial drop to rise 2.5% at 1:07 p.m. in New York after the thinly traded biopharmaceutical company won its first regulatory approval. The stock has fallen about 20% this year.

Oppenheimer analyst Leland Gershell, who recommends investors buy shares, forecast annual sales in the U.S. could reach \$440 million by 2024. The company is still working on the exact pricing, which is expected to be in-line with branded birth control pills. However, it anticipates health insurance companies will pay between \$250 and \$275 per pack of 12 prefilled applicators.

Rather than "replace or compete with the pill" out of the gate, Pelletier said the company is looking to first target the 17 million U.S. women who identify "as beyond hormone," meaning they either don't want to use or can't use a hormonal contraceptive.

Currently approved hormonal products can trigger side effects like pain, nausea, headaches, bleeding, mood changes and weight gain. Traditional birth control pills can also cause blood clots and increase the risk of heart problems like a stroke or heart attack.

In Phexxi trials, more than 10% of women experienced vaginal burning and itching, which was the most common side effect of the gel. However, Evofem said the events decreased with each consecutive cycle.

While similar, at first glance, to over-the-counter spermicides -- which work by blocking the entrance to the cervix and slowing sperm -- the gel differs in that it uses vaginal pH levels to create an acidic environment to prevent fertilization.

In a late-stage clinical study of about 1,400 women, Evofem said the gel prevented pregnancy 93.3% of the time when it was used correctly and 86% of the time overall. That compares to an effective rate for spermicides at 82% when used correctly and 72% overall, according to Planned Parenthood. The group recommends the use of spermicide in addition to another methods like condoms.

[Read more: Better Birth Control Could Exist, But It Wouldn't Pay for Pharma](#)

Evofem is planning to start a pivotal study of the gel for the potential prevention of chlamydia and gonorrhea in women later this year, which could also boost its appeal to users and investors. It expects to start the study later this year after a mid-stage [trial met](#) its primary and secondary targets in December.

The gel is expected to be available in September with a “staged launch” focused on areas where businesses shut from the coronavirus are reopening more rapidly. The company says it will also look to buck the trend of uninspiring launches for women’s health products, taking advantage of social media promotions and online influencers. The company is planning for a “very big” social push ahead of Valentine’s Day and will then expand into other media avenues, Pelletier said.

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