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## A women's health startup tried to drum up interest for a much-needed drug. Many men didn't get it

By [Rebecca Robbins](#) @rebeccadrobbins

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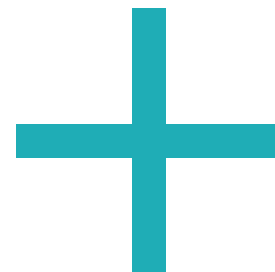
Three of the four members of Antiva's management team are women. From left, vice president of nonclinical development Sarah Walter, CEO Gail Maderis, and chief medical officer Dr. Oranee Daniels. *Christie Hemm Klok for STAT*

SOUTH SAN FRANCISCO, Calif. — The startup's pitch seems compelling, even commonsensical: About 500,000 women in the U.S. need surgery every year for precancerous cervical lesions caused by the human papillomavirus. The surgery can lead to devastating reproductive consequences.

[Antiva Biosciences](#)<sup>1</sup>, a 6-year-old drug maker, is working on a first-in-class treatment that, if successful, could make that surgery unnecessary.

But when it comes to making that case to investors and doctors — particularly the men who dominate those professions — it has often been an uphill battle. Male OB-GYNs have questioned the need for a drug, saying they think surgery is adequate; male VCs have been skeptical, too.

“It’s very safe to say that we got more traction in VC firms where there was a woman partner who was in a decision-making role,” Antiva CEO Gail Maderis said in a recent interview in the startup’s offices here in a corporate office park sandwiched between San Francisco and Silicon Valley. “It’s just much easier for them to relate to the need for this.”



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Antiva has been getting a front-row view of the challenges involved in pitching a company focused on women’s health — a field that many believe has long been given short shrift in terms of money and ideas.

But the company’s story also speaks to an emerging wave of companies led by female executives and investors who are seeking to champion treatments and services for conditions that affect women.

Women-led biotechs are [working on new drugs](#)<sup>3</sup> to prevent pregnancy, treat fertility problems, and restore sex drive. There are telemedicine platforms aimed at women, as well as startups marketing genetic and hormonal fertility tests; another new women-led company is [building a network](#)<sup>4</sup> of boutique clinics focusing on fertility and egg freezing.

Antiva is trying to address a condition known as cervical neoplasia, in which people infected with HPV develop lesions on the cervix. The company has completed an early-stage safety study in 16 women and plans to release data toward the end of this year. The topical drug is self-administered with an applicator not unlike the kind used to insert a tampon.

“What we want to do is basically make cervical neoplasia as easy as treating a yeast infection,” Maderis said.

That pitch has not always gone over well, though.

Maderis pointed to a meeting she took with one prospective VC investor. He seemed to express disinterest. The next day, though, Maderis got a sheepish phone call from the investor, who said he had gone home and told his wife, a physician, about the company. He said he had not at first understood the importance of what Antiva was trying to do — and that his wife had urged him to take a deep dive on the firm. (In the end, that investor did not take a stake in the company.)

One man who did see big potential in Antiva is David Kabakoff, a San Diego-based VC at Sofinnova Ventures. His firm is invested in the company and he’s taken a seat on its board.

Over the past few years, as part of their due diligence process, Kabakoff and his team have made several dozen calls to OB-GYNs to ask them what they think of Antiva's pitch.

The data were limited and anecdotal, but the trend was unmistakable: Male physicians tended to express skepticism about the need for a drug. Female physicians tended to say new treatment options are badly needed.

"There was clearly a gender bias associated with the feedback," Kabakoff said.

(A fellow investor and board member, Canaan Partners VC Wende Hutton, and Antiva's chief medical officer, Dr. Oranee Daniels, told STAT that they heard the same thing in making their own due diligence calls to physicians.)

Antiva isn't the only company to encounter resistance trying to get male VCs interested in funding women's health. Famously the maker of a [smart breast pump](#)<sup>7</sup> beloved by mothers last year turned to online crowdfunding because it could not win over enough VCs; an entrepreneur working on a device to treat women with low sex drive [had a hard time](#)<sup>8</sup> getting traction, too.

There have been exceptions to the reluctance. Big money has been poured into treatments for breast cancer. A flurry of new products are trying to help women with fertility and contraception. And just last week, the Food and Drug Administration [cleared the first-ever app](#)<sup>9</sup> to prevent pregnancy.

But, as Kabakoff sees it, there's still hesitation among VCs when it comes to women's health, much of it stemming from concerns about how they're going to make money.

"I think the concern in the investment community about women's health has nothing to do with whether there are unmet needs in the market, but with the fact that there are relatively few large pharma players who are in the business," Kabakoff said. "And after all, there are only two exit opportunities that we have for these companies: One is we sell them. The other is we take them public."



Mr. and Mrs. Potato Head toys are kept on display in Antiva's office, symbols of the company's mission to develop its drug to treat precancerous lesions in men and women, respectively, infected with HPV. The figurines grasp the applicator that's used to administer the topical medication. *Christie Hemm Klok for STAT*

The [HPV vaccine](#)<sup>10</sup>, now increasingly given to older children and young adults, is seen as a public health triumph, effective in preventing the infection that can lead to cancer, most often of the cervix, throat, and anus. But no such revolution has yet arrived for people who are already infected with HPV and at elevated risk for these cancers; there are no drugs, after all, for cervical neoplasia.

For women infected with HPV, lesions on the cervix usually develop without symptoms and are only detected with a [Pap test](#)<sup>11</sup>. The lesions often clear up on their own, so if they're detected at an early stage, they're just monitored closely.

But sometimes, the lesions reach a more advanced stage, elevating the risk that it could turn into cancer. When that happens, a physician performs a surgical procedure to remove the abnormal cells, essentially cutting off the tip of the cervix.

Antiva estimates that each year about 500,000 women in the U.S. reach this stage — the point at which the company hopes its drug could be substituted for surgery. The market is even larger in China, where more than 10 million women each year develop advanced cervical lesions, according to Antiva's estimates.

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Surgery is generally very effective in removing the abnormal cells — but it comes with a significant drawback. Women of childbearing age who undergo the surgery may later have difficulty conceiving, recurrent miscarriages, and preterm delivery. That can pose tough choices for women and the doctors who treat them.

“That’s always a difficult challenge for us, especially in these young women, because we want to treat them and get rid of the pre-cancer, but we also don’t want to impact their future pregnancies or their fertility potential,” said Dr. Celestine Tung, a gynecologic oncologist at Baylor College of Medicine who has no affiliation with Antiva.

Dr. Jenell Coleman, an OB-GYN at Johns Hopkins School of Medicine who also has no ties to Antiva, said that when she discusses the surgery with her patients, they will sometimes “burst into tears, like, ‘Oh my gosh, can I get pregnant? And what does this mean?’ There’s a lot more emotion behind it.” It’s a big deal, Coleman said, to “cut off a patient’s tissue — a tissue that’s all wrapped up in being a woman.”

Antiva is betting that such women will embrace a topical medication instead. And looking beyond the U.S., the company sees big public health potential in bringing its drug to developing countries, because women with limited access to health care may not get the recommended monitoring and surgery — and as a result, their lesions can progress to deadly cervical cancer.

Still, there are reasons independent of any biases associated with women’s health that might give doctors and investors pause.

For one, the company has competition. While Antiva has yet to report Phase 1 data, the rival drug maker that’s furthest along, Pennsylvania-based Inovio, is testing its drug for cervical dysplasia in a Phase 3 clinical trial. (Inovio’s drug is targeted at only the most common HPV strains, while Antiva’s has potential to work for any strain of the virus.)

There’s also no guarantee Antiva’s drug will work. Getting a topical medication to stick to the cervix is much more complicated than slathering cream on your forearm. The field is littered with failures, ranging from therapeutic vaccines that weren’t effective enough and other experimental drugs that brought too many side effects.

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The company could face hurdles getting past regulators as it tries to get approval to market its drug to treat cervical lesions. The division of the FDA that will handle that indication, the Center for Drug Evaluation and Research's Division of Bone, Reproductive and Urologic Products, has a reputation for being "a very cautious part of the agency," said Hutton, the Canaan VC. There, "the headset is do no wrong," she said.

Antiva was spun out from the lab of Dr. Karl Hostetler, a serial biotech entrepreneur and emeritus professor at the University of California, San Diego. The company's original name was Hera Therapeutics, a nod to the Greek goddess known as a protector of women.

But in 2015, executives decided to change the company's name to emphasize its broader antiviral potential. For one, the company's mission had evolved beyond just women's health. (The company is also testing whether the same compound is safe to treat HPV-caused anal lesions, another precancerous condition that primarily affects men who have sex with men, as well as people of any gender who have compromised immune systems.)

Then there was the problem of their namesake's moral character. "As Greek goddesses go, Hera is not a great role model," Maderis said. "She had a reputation for being jealous, vengeful, and vindictive."

Maderis is a longtime biotech executive who also spent more than half a decade leading a trade group for Bay Area drug makers. She had been eyeing a retirement packed with travel when, in 2015, she was approached about the opportunity to run the young startup. "It was just too good to pass up," Maderis said.

The company is strikingly diverse in an industry where men dominate the C-suite. Three of the four members of the company's management team are women; so too are seven of its 13 employees. And Hutton has become one of the company's biggest champions.

This summer Antiva [raised another \\$15 million](#)<sup>14</sup>, bringing its total disclosed funding to \$52.5 million.

The company keeps two symbolic figurines in its offices: a Mrs. Potato Head toy, representing the program to treat cervical lesions in women, and a Mr. Potato Head, for the program to treat anal lesions primarily in men. In one hand, each figurine clasps an applicator used to administer the drug; in their other hand, they clasp a condom, a reference to the testing the company had to conduct to make sure its medication didn't weaken condoms.

The figurines rotate between different offices, depending on which executive is "in the hot seat to deliver the next thing to keep driving these programs forward quickly," Maderis said.

Said Daniels, the company's chief medical officer: "When we need money, the Potato Head is with Gail. When we need clinical data, the Potato Head is with me."

## About the Author



[Rebecca Robbins](#)<sup>15</sup>

San Francisco Correspondent

Rebecca covers the life sciences industry in the Bay Area.

[rebecca.robins@statnews.com](mailto:rebecca.robins@statnews.com)<sup>16</sup>

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