

Company Develops Easy-to-use Birth Control

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Women's health issues have gained greater attention over the last few decades, but we still have some catching up to do, particularly expanding contraceptive options for women, especially those that can't or don't want to tolerate the hormones released in the birth control pill.

"A lot of the pharmaceutical companies just aren't rewarded necessarily by their shareholders for investing in women's health, even though they have the commercial capacity to do it," says Sabrina Martucci Johnson, co-founder and CEO of Daré Bioscience, Inc., a company that focuses on unmet needs in women's health.

Johnson started the San Diego-based company after leaving a women's health non-profit, where she discovered many promising women's health care products had no path to commercialization.

"I realized that I could probably have a lot bigger of a social impact by starting a for-profit company that's focused on advancing these innovations for women."

A 2018 Fast-Track Small Business Innovation Research (SBIR) grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development funded a clinical trial on a new self-inserted hormone-free birth control ring called Ovaprene; the results of the clinical trial showed the product blocked more than 90 percent of the sperm, which is a good indication it could be as effective as the birth control pill, says Johnson.

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77

In January 2020, Daré entered into an exclusive license agreement with Bayer for Ovaprene. Daré received \$1 million in upfront funding and is eligible for

(continued on back)



Dare Bioscience

11119 North Torrey Pines Road, Suite 200 La Jolla, CA 92037

State-District

CA-50

Technology

Medical Device

Primary Institute

Child Health (NICHD)

Project Details from NIH RePORTER

Dare Bioscience

Contact

Christine Mauck cmauck@gmail.com

https://darebioscience.com/



up to \$310 million in milestone payments as well as tiered royalties.

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More recently, in October 2022, the company announced an Investigational Device Exemption approval by the FDA that will allow it to conduct a single-arm, open-label pivotal contraceptive efficacy study of Ovaprene. The company will also collect safety and effectiveness data in this Phase 3 study that will support the submission of a Premarket Approval (PMA) application. They are targeting mid-year 2023 to initiate recruitment for the study.

Daré's focus on women's health continues in their work on a treatment for bacterial vaginosis, a condition that affects more than 20 million women in the U.S and is linked to infertility and preterm birth, as well as a first-incategory topical cream for treating female sexual arousal disorder, the female equivalent of erectile dysfunction.

Johnson says, outside of dollars, SBIR support has been important in validating their research. "Given that women's health isn't a common therapeutic area...third party validation can be really helpful when investors and other stakeholders don't have a lot of experience in that space."

