UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 10, 2022

DARÉ BIOSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36395**	**20-4139823**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3655 Nobel Drive, Suite 260
San Diego, CA 92122
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(858) 926-7655**

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock	**DARE**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On October 10, 2022, Daré Bioscience, Inc. (“Daré”) issued a press release regarding Ovaprene®, its investigational hormone-free monthly intravaginal contraceptive, a copy of which is attached as Exhibit 99.1 to this report.

The information contained in this Item 7.01, including in Exhibit 99.1 hereto, is being “furnished” and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 7.01 and in Exhibit 99.1 shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Daré, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On October 10, 2022, Daré issued a press release announcing that the U.S. Food & Drug Administration (“FDA”) approved an Investigational Device Exemption (“IDE”) application allowing Daré to conduct a single arm, open-label pivotal contraceptive efficacy study of Ovaprene. The clinical study will evaluate Ovaprene’s effectiveness as a contraceptive device along with its safety and usability over a 12-month (13 menstrual cycles) duration. Initiation of recruitment for the study is targeted for mid-2023. If successful, the study is expected to support a premarket approval (“PMA”) application to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene. The FDA provided Daré with recommended additional study design considerations. Such additional study design considerations do not need to be addressed to initiate and conduct the study. However, implementing such study design considerations will further position the study to collect safety and effectiveness data to support the submission of a PMA application.

Forward-Looking Statements

Daré cautions you that all statements, other than statements of historical facts, contained in this report, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” “contemplate,” “project,” “target,” “objective,” or the negative version of these words and similar expressions. In this report, forward-looking statements include, but are not limited to, statements relating to Dare’s expectation that the planned pivotal clinical study of Ovaprene, if successful, would serve as the primary clinical support for future marketing approvals, the timing of initiation of subject recruitment into the study, and the ability to successfully implement the additional study design considerations recommended by the FDA to further support a potential PMA application. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Daré’s actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements, including, without limitation: the risk that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; Daré’s ability to design and conduct successful clinical trials, to enroll a sufficient number of patients, to meet established clinical endpoints, to avoid undesirable side effects and other safety concerns, and to demonstrate sufficient safety and efficacy of its product candidates; Daré’s dependence on third parties to conduct clinical trials and manufacture and supply clinical trial material and commercial product; Daré’s ability to raise additional capital when and as needed to advance its product candidates, execute its business strategy and continue as a going concern; the loss of, or inability to attract, key personnel; general industry conditions and competition; general economic factors, including inflation, rising interest rates and currency exchange rate fluctuations; the impact of the ongoing COVID-19 pandemic; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances; new products and patents attained by competitors; Daré’s ability to accurately predict its future financial condition, operating results and performance; Daré’s or its licensee’s ability to accurately predict future market conditions; third-party manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of patents owned or licensed by Daré and other protections for innovative products; and the exposure of Daré, its commercial counterparties and other third parties on which it relies to litigation, including patent litigation, and/or regulatory actions. Daré’s forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of Daré’s risks and uncertainties, you are encouraged to review its documents filed with the SEC including Daré’s recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Daré undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued on October 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DARÉ BIOSCIENCE, INC.

Dated: October 11, 2022

By: */s/ Sabrina Martucci Johnson*
Name: Sabrina Martucci Johnson
Title: President and Chief Executive Officer

Exhibit 99.1

Daré Bioscience Announces IDE Approval for a Single Arm, Open-Label Pivotal Contraceptive Efficacy Study of Ovaprene®, an Investigational Hormone-Free Monthly Intravaginal Contraceptive

Ovaprene has the Potential to be the First FDA-Approved Monthly, Self-Administered, Hormone-Free Contraceptive Product

SAN DIEGO, October 10, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced that the U.S. Food & Drug Administration (FDA) approved an Investigational Device Exemption (IDE) application allowing Daré to conduct a single arm, open-label pivotal contraceptive efficacy study of Ovaprene®, an investigational hormone-free monthly intravaginal contraceptive. The IDE approval reflects that the FDA determined the Company provided sufficient data to support the initiation and conduct of the study. The IDE submission included the results of the postcoital test (PCT) clinical study of Ovaprene, in which Ovaprene prevented essentially all sperm from entering the cervical canal across all women and all cycles evaluated. PCT clinical trials have been used as a surrogate marker for contraceptive effectiveness.

"We are driven to bring forward innovative options that support women's health and wellness, and we are motivated to accelerate the development and introduction of differentiated product candidates, like Ovaprene, which is both hormone-free and designed to be conveniently kept in place vaginally continuously over the weeks between menstruation," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience. "When it comes to contraception, many of the top-selling brands in the category are delivering both convenience and efficacy, suggesting that women and healthcare providers have a preference for contraceptive methods that are effective, that don't need to be administered every day, and that don't require action at the time of intercourse."

In order for the planned study to serve as the primary clinical support for a future marketing approval or clearance, the FDA provided additional study design considerations with the IDE approval letter.

"The FDA communication," Ms. Johnson continued, "confirms our alignment on a number of key aspects of the clinical study, including the adequacy of a 12-month (13 menstrual cycles) duration. The additional study design considerations provided by the FDA are considered by the FDA to be recommendations that do not need to be addressed in order for us to initiate and conduct this study. However, implementing the guidance that we received from the FDA will further position this pivotal study to collect safety and effectiveness data that will support the submission of a Premarket Approval (PMA) application. Therefore, we look forward to working with our collaborators at the NIH and at Bayer to review and implement the recommendations and we are targeting mid-year 2023 study recruitment initiation."

The multi-center, single arm, non-comparative, pivotal Phase 3 contraceptive study of Ovaprene will evaluate its effectiveness as a contraceptive device along with its safety and usability. If successful, Daré expects the pivotal study to support marketing approvals of Ovaprene in the U.S. and other countries.

In July 2021, Daré entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health (NIH), to collaborate on the pivotal Phase 3 study of Ovaprene. The agreement gives Daré access to the full contraceptive clinical trial expertise of the NICHD clinical trial network while also sharing the costs of the Phase 3 pivotal study with the NICHD. The NICHD will hold an Ovaprene clinical trial investigator meeting in December of this year.

In January 2020, Daré and Bayer announced an exclusive licensing agreement for U.S. commercial rights to Ovaprene. Under the agreement, Daré received an upfront payment and access to Bayer's extensive clinical and market capabilities while retaining control over Ovaprene's development and regulatory approval process. Bayer received the right to obtain exclusive rights to commercialize the product in the U.S. following completion of the pivotal clinical trial being undertaken by Daré. If Bayer, in its sole discretion, makes payment to Daré of $20 million, which Daré intends to apply to reimbursement of clinical study costs, then the exclusive license to commercialize Ovaprene in the U.S. will become effective. Daré will also be entitled to receive commercial milestone payments potentially totaling $310 million, in addition to double digit tiered royalties on net sales.

If Ovaprene is approved by the FDA, it could be the first monthly non-hormonal contraceptive product for women and a first-in-category option for women seeking a hormone-free, self-administered and monthly birth control method.

About Daré Bioscience

Daré Bioscience is a biopharmaceutical company committed to advancing innovative products for women's health. The company's mission is to identify, develop and bring to market a diverse portfolio of differentiated therapies that prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, fertility, and vaginal and sexual health.

Daré's first FDA-approved product, XACIATO™ (clindamycin phosphate) vaginal gel, 2% is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older, which is under a global license agreement with Organon. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly contraceptive whose U.S. commercial rights are under a license agreement with Bayer; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder utilizing the active ingredient in Viagra®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone therapy following menopause. To learn more about XACIATO™, Daré's full portfolio of women's health product candidates, and Daré's mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product and product candidates, clinical trials and other matters using the Investors section of its website (http://ir.darebioscience.com), SEC filings, press releases, public conference calls and webcasts. Daré will use these channels to distribute material information about the company, and may also use social media to communicate important information about the company, its finances, product and product candidates, clinical trials and other matters. The information Daré posts on its investor relations website or through social media channels may be deemed to be material information. Daré encourages investors, the media, and others interested in the company to review the information Daré posts in the Investors section of its website and to follow these Twitter accounts: @SabrinaDareCEO and @DareBioscience. Any updates to the list of social media channels the company may use to communicate information will be posted in the Investors section of Daré's website.

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