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): July 14, 2025

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 July 14, 2025, Daré Bioscience, Inc. ("Daré," "we," "us," "our" or the "Company") issued a press release regarding interim results from its ongoing Phase 3 clinical trial evaluating the contraceptive effectiveness, safety and acceptability of Ovaprene® (the "study"), the Company's investigational monthly, hormone-free intravaginal contraceptive (ClinicalTrials.gov ID: NCT06127199).

The information in this Item 7.01 and in Exhibit 99.1 to this report is being furnished and shall not be deemed to be "filed" for 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, nor shall such information be deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), whether made before or after the date hereof, regardless of any general incorporation by reference language in any such filing, except as the Company expressly sets forth by specific reference in such a filing.

Item 8.01 Other Events.

On July 11, 2025, the study's data safety monitoring board conducted a planned interim analysis focused on reviewing safety data from the study, and recommended the study continue without modification.

No new safety or tolerability concerns were identified. At the time of the interim analysis, approximately 9% of the women treated in the study had experienced a pregnancy. Approximately 17% of participants discontinued the study due to vaginal odor, the most commonly reported product-related adverse event. No serious safety concerns were identified, and overall tolerability was favorable. Participants who had completed the study reported they would be very likely or likely to use Ovaprene if it became available.

The study is a multicenter, single-arm, open-label study enrolling women aged 18–40 across five sites. As of the interim analysis, approximately 115 participants were ongoing or had completed the study. The target enrollment is approximately 250 participants completing approximately 12 months of use. The primary objective of the study is to assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene. Secondary objectives are to assess Ovaprene's 13-cycle use cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and assessments of vaginal health.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued on July 14, 2025
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: July 14, 2025

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

Positive Interim Phase 3 Results Highlight Potential of Ovaprene®, Novel Hormone-Free Contraceptive

Interim Phase 3 Results Support Ovaprene's Differentiation as a First-in-Category, Hormone-Free, Intravaginal Monthly Contraceptive

SAN DIEGO, July 14, 2025 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a biopharmaceutical company driven by a mission to challenge the status quo, making women's health a priority, today announced positive interim safety and efficacy results from its ongoing Phase 3 clinical trial evaluating the contraceptive effectiveness, safety and acceptability of Ovaprene®, the company's investigational monthly, hormone-free intravaginal contraceptive. There currently are no FDA-approved, hormone-free, monthly intravaginal contraceptives.

The trial's independent Data Safety Monitoring Board (DSMB) conducted a planned interim analysis focused on reviewing safety data from the study, and recommended the study continue without modification.

At the time of the interim analysis, approximately 9% of the women treated in the study had experienced a pregnancy, a rate consistent with the company's expectations based on the results of the pre-pivotal postcoital test clinical study of Ovaprene. These interim findings support Ovaprene's potential as a meaningful hormone-free alternative.

No new safety or tolerability concerns were identified. Approximately 17% of participants discontinued the study due to vaginal odor, the most commonly reported product-related adverse event. No serious safety concerns were identified, and overall tolerability was favorable. Participants who had completed the study reported they would be very likely or likely to use Ovaprene if it became available.

"We are encouraged by these interim results, which reinforce the potential of our hormone-free contraceptive candidate to provide women with a meaningful alternative to existing hormonal and non-hormonal methods," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "With millions of women in the U.S. seeking effective, hormone-free birth control, Ovaprene has the potential to address a significant unmet need and transform the contraceptive landscape. We look forward to the completion of the study and the final analysis of study endpoints, including the primary endpoint of pregnancy rate calculated using the Pearl Index."

According to the FDA's birth control guide (chart), the number of pregnancies expected using short-acting hormonal contraceptive methods (oral contraceptives ("the pill"), the patch (transdermal system), and the vaginal ring) is seven per 100 women, and the number of pregnancies expected using male condoms and diaphragms or sponges with spermicide is 13 and 17 per 100 women, respectively.

The ongoing pivotal Phase 3 trial is a multicenter, single-arm, open-label study enrolling women aged 18–40 across 5 sites. As of the interim analysis, approximately 115 participants were ongoing or had completed the study. The target enrollment is approximately 250 participants completing approximately 12 months of use. The primary objective of the study is to assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene. Secondary objectives are to assess Ovaprene's 13-cycle use cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and assessments of vaginal health. For more information about the study, please visit clinicaltrials.gov (NCT06127199).

Bayer received the right to obtain exclusive U.S. rights to commercialize the product, following completion of the pivotal clinical trial if Bayer, in its sole discretion, makes a $20 million payment to Daré. Daré may receive up to $310 million in commercial milestone payments, plus double-digit tiered royalties on net sales. The potential $20 million payment and royalty payments are subject to a third party's minority interest under a royalty purchase agreement entered into in April 2024.

About Daré Bioscience

Daré Bioscience is a biopharmaceutical company driven by a mission to challenge the status quo, making women's health a priority. Daré believes that innovation does not have to start from scratch. The company's goal is to bring to market as soon as practicable innovative evidence-based solutions that address decades of unmet needs in women's health and enhance outcomes and convenience, primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health and menopause. The potential products Daré identifies, in many cases, already have clinical proof of concept or existing safety data for the active ingredient that the company leverages. This provides optionality and flexibility, in many cases, in how Daré seeks to bring solutions to market in ways designed to optimize access for women in a fiscally responsible manner.

The first FDA-approved product to emerge from Daré's portfolio of women's health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, 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. Visit www.xaciato.com for information about XACIATO. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil citrate, the active ingredient in an oral erectile dysfunction drug for men, to treat female sexual arousal disorder (FSAD); and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. To learn more about Daré's full portfolio of women's health product candidates and mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré Bioscience leadership has been named on the Medicine Maker's Power List and Endpoints News' Women in Biopharma and Daré's CEO has been honored as one of Fierce Pharma's Most Influential People in Biopharma for Daré's contributions to innovation and advocacy in the women's health space.

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 X (formerly 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.

Forward-Looking Statements

Daré cautions you that all statements, other than statements of historical facts, contained in this press release, 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,” “on track,” or the negative version of these words and similar expressions. In this press release, forward-looking statements include, but are not limited to, statements relating to Ovaprene’s potential as a safe and effective first-in-category, hormone-free, intravaginal monthly contraceptive, Ovaprene’s potential to be the first U.S. Food and Drug Administration (FDA)-approved hormone-free, monthly intravaginal contraceptive, the importance of the interim results from the ongoing pivotal Phase 3 trial of Ovaprene to Daré and Ovaprene, and the potential that Bayer exercises it right to commercialize Ovaprene. As used in this press release, “first-in-category” is a forward-looking statement relating to the potential of a product candidate to represent a new category of product if it were to receive marketing approval for the indication for which it is being developed because Daré believes it would address a need in women’s health that is not being met by existing FDA-approved products. 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 future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, without limitation, risks and uncertainties related to: 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 develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; failure or delay in starting, conducting and completing clinical trials of a product 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; the risk that the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré’s interpretation of or conclusions regarding data from clinical studies of its product candidates; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates, or that the duration of a study or number of study subjects must be significantly greater than anticipated; Daré’s ability to raise additional capital when and as needed to execute its business strategy and continue as a going concern; the risk of delisting of Daré’s common stock from Nasdaq; the effects of macroeconomic conditions, geopolitical events, and major changes and disruptions in U.S. government policies and operations on Daré’s ability to raise additional capital or on Daré’s operations, financial results and condition, and ability to achieve current plans and objectives; Daré’s reliance on third parties to commercialize XACIATO™ (clindamycin phosphate) vaginal gel 2% and future products, if any; the risk that the current regulatory pathway known as the FDA’s 505(b)(2) pathway for drug product approval in the U.S. is not available for a product candidate as Daré anticipates; Daré’s ability to achieve the product development and other milestones required for it to receive payments under its subaward and grant agreements; the potential for termination of the subaward and grant agreements before Daré receives additional payments; the limits on Daré’s ability to sell stock under its equity line arrangement at times it may desire to raise additional capital; the loss of, or inability to attract, key personnel; the risk that developments by competitors make Daré’s product or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; failure of Daré’s product or product candidates, if approved, to gain market acceptance or obtain adequate coverage, pricing and reimbursement from third-party payors; Daré’s ability to retain its licensed rights to develop and commercialize a product or product candidate; Daré’s ability to satisfy the monetary obligations and other requirements in connection with its exclusive, in-license agreements covering the critical patents and related intellectual property related to its product and product candidates; Daré’s ability to adequately protect or enforce its, or its licensor’s, intellectual property rights; the lack of patent protection for the active ingredients in certain of Daré’s product candidates which could expose its products to competition from other formulations using the same active ingredients; product liability claims; governmental investigations or actions relating to Daré’s products or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; cybersecurity incidents or similar events that compromise Daré’s technology systems or those of third parties on which it relies and/or significantly disrupt Daré’s business; and disputes or other developments concerning Daré’s intellectual property rights. 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.

Contacts:

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Source: Daré Bioscience, Inc.