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): December 16, 2024

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 December 16, 2024, Daré Bioscience, Inc. ("Daré," "we," "us," "our" or the "Company") issued a press release announcing Phase 3 clinical development plans for Sildenafil Cream, 3.6% ("Sildenafil Cream") following discussions with the U.S. Food and Drug Administration ("FDA"). Sildenafil Cream, an investigational topical cream formulation of sildenafil, is being developed as an on-demand treatment for female sexual arousal disorder ("FSAD") in premenopausal women. A copy of the press release is furnished as an exhibit to this report.

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 December 16, 2024, we announced that we will submit the protocol and statistical analysis plan for an adequate and well-controlled Phase 3 clinical study of Sildenafil Cream in premenopausal women with FSAD, reflecting the FDA's recommendations, to the FDA in the first quarter of 2025, and that we are targeting mid-2025 for commencement of the Phase 3 study. As previously reported, a second confirmatory Phase 3 study will be required to support a New Drug Application (NDA) submission for Sildenafil Cream.

Consistent with our completed exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, the planned Phase 3 study will include a 12-week double-blind treatment period evaluating Sildenafil Cream compared to placebo cream. The planned Phase 3 study will have co-primary efficacy endpoints – one assessing arousal sensations and one assessing associated distress, which will be the same co-primary endpoints for arousal sensations and associated distress used in the Phase 2b RESPOND study. In addition, secondary efficacy endpoints to assess improvement in orgasm, desire, and distress and interpersonal difficulties will be included in the Phase 3 study, as they were in the Phase 2b RESPOND study.

Cautionary Statement Regarding Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, without limitation, statements relating to Sildenafil Cream's potential as an on-demand treatment for FSAD in premenopausal women, Daré's plans for continued clinical development of Sildenafil Cream, including Phase 3 trial design and statistical analysis plan and the timing of commencing the first Phase 3 study, Daré's expectations that the Phase 3 trial design and statistical analysis plan will reflect the FDA's recommendations and have the characteristics of an adequate and well-controlled clinical study, and the anticipated pathway for FDA approval of Sildenafil Cream for the treatment of FSAD in premenopausal women. To the extent that statements contained in this report are not descriptions of historical facts, they 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. Forward-looking statements are based on current expectations and assumptions that are subject to known and unknown risks and uncertainties. Actual results, performance or achievements could differ materially from those expressed or implied by the forward-looking statements as a result of various factors, including, without limitation: potential insufficiency of Daré's capital resources to advance the development of its product candidates, including Sildenafil Cream for the treatment of FSAD, on communicated timelines, or at all; failure or delay in starting, conducting and completing clinical trials of a product candidate, including the first Phase 3 clinical study of Sildenafil Cream, including due to lack of sufficient capital resources; 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 inherent uncertainty of outcomes of clinical trials of drug products and Sildenafil Cream in particular given the complexity of FSAD and the limited clinical trial precedent from which to draw experience; the risk that, as with the Phase 2b RESPOND study, the planned Phase 3 study may fail to demonstrate statistically significant differences between Sildenafil Cream and placebo users in the co-primary and secondary efficacy endpoints even though the Phase 3 study will exclude patients with FSAD with concomitant orgasmic dysfunction and concomitant genital pain; the risk that development of Sildenafil Cream requires more clinical or nonclinical studies than Daré anticipates, including to generate additional data that may be needed to assess product safety or appropriately qualify any ingredient (other than sildenafil) for the vaginal route of administration; 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; 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 clinical and/or nonclinical study data; Daré's ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; 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 loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; 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 or reimbursement from third-party payers; 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 product 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. For a detailed description of Daré's risks and uncertainties, please refer to Daré's annual report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 28, 2024, its quarterly report on Form 10-Q filed with the SEC on November 14, 2024, and its current reports on Form 8-K subsequently filed with the SEC. You are urged to consider these factors carefully in evaluating the forward-looking statements in this report and are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement. Daré undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date of this report, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on December 16, 2024
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: December 16, 2024

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

Exhibit 99.1

Daré Bioscience Announces Phase 3 Plans for Sildenafil Cream, 3.6%, in the Treatment of Female Sexual Arousal Disorder (FSAD)

FSAD is clinically analogous to erectile dysfunction in men.
To date, there are no FDA-approved pharmacological treatments for FSAD; Daré's Sildenafil Cream has the potential to receive the first FDA approval for FSAD.

Market research estimates approximately 10 million women in the U.S. are distressed from experiencing symptoms associated with FSAD and are actively seeking solutions to improve their condition.

SAN DIEGO, December 16, 2024 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, and its collaborator Strategic Science & Technologies, LLC (SST), a Cambridge, MA based novel topical drug delivery company, today announced plans for a Phase 3 study of Sildenafil Cream, 3.6%, an investigational topical cream formulation of sildenafil being developed as an on-demand treatment for female sexual arousal disorder (FSAD), reflecting U.S. Food and Drug Administration (FDA) feedback for safety and efficacy evaluations to support the indication of treatment of FSAD in premenopausal women.

"We have appreciated the FDA's collaboration on the Phase 3 design for this novel therapeutic indication for women," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "While increased attention has been focused on female sexual dysfunctions over the past several years, no pharmacologic options have yet been FDA approved for FSAD, a condition which significantly compromises a woman's ability to have a pleasurable sexual experience. We are excited about the potential for Daré's Sildenafil Cream formulation to address this critical unmet need in women's sexual health, and that there is a clear path forward on how to evaluate the safety and efficacy of this novel formulation of the same active in Viagra® so that women may have access to a safe, effective and 'on demand' solution to difficulties with sexual arousal allowing for a more intense and enjoyable sexual experience."

As an immediate next step, Daré will submit the protocol and statistical analysis plan for an adequate and well-controlled Phase 3 clinical study, reflecting the FDA's recommendations, to the FDA in the first quarter of 2025, and is targeting mid-2025 for commencement of the Phase 3 study.

A second confirmatory Phase 3 study will be required to support the New Drug Application (NDA) submission.

With Sildenafil Cream's potential to be the first FDA-approved product for FSAD, Daré is poised to create a new market category within the female sexual dysfunction space.

About FSAD and Sildenafil Cream, 3.6%

FSAD, as described in the DSM-IV, is a condition characterized primarily by a persistent or recurrent inability to attain or maintain sufficient genital arousal (an adequate lubrication-swelling response) during sexual activity, frequently resulting in distress or interpersonal difficulty. FSAD is clinically analogous to erectile dysfunction (ED) in men. As with ED in men, FSAD is associated with insufficient blood flow to the genitalia. To date, there are no FDA-approved pharmacological treatments for FSAD.

Sildenafil, a phosphodiesterase-5 (PDE-5) inhibitor, is the active ingredient in a tablet for oral administration currently marketed under the brand name Viagra® for the treatment of ED in men. Sildenafil Cream, 3.6% (Sildenafil Cream) is an investigational, proprietary cream formulation of sildenafil designed for topical administration to the vulvar-vaginal tissue on demand to increase genital blood flow and provide improvements in the female genital arousal response, while avoiding systemic side effects observed with oral formulations of sildenafil.

Market research suggests that 16% of women in the U.S. ages 21 to 60, or approximately 10 million women, are distressed from experiencing symptoms associated with FSAD, including lack of or low sexual arousal, and are actively seeking solutions to improve their condition. In comparison, the prevalence of complete ED in men is estimated to be about 5% of men at age 40, increasing to about 15% at age 70.

Completed Sildenafil Cream, 3.6% Exploratory Phase 2b RESPOND Study

The exploratory Phase 2b RESPOND study was specifically designed to identify the patient population that experienced the most meaningful improvement from Sildenafil Cream and the questions to ask them, or the patient-reported outcome (PRO) measures, that best reflect that improvement, to inform Phase 3 design for this potential first-in-category treatment for FSAD. As previously announced, safety and efficacy data from the Phase 2b RESPOND study have been published in *The Journal of Sexual Medicine* and *Obstetrics & Gynecology*, respectively:

- Thurman, et al. “Safety of topical sildenafil cream, 3.6% in a randomized, placebo-controlled trial for the treatment of female sexual arousal disorder.” *The Journal of Sexual Medicine*, 2024, 1-7. https://doi.org/10.1093/jsxmed/qdae089

- Johnson, et al. “Preliminary Efficacy of Topical Sildenafil Cream for the Treatment of Female Sexual Arousal Disorder: A Randomized Controlled Trial.” *Obstetrics & Gynecology*, 144(2):p 144-152, August 2024. DOI: 10.1097/AOG.0000000000005648

Planned Phase 3 Study

Consistent with the previously completed Phase 2b RESPOND study, the planned Phase 3 study will include a 12-week double-blind treatment period evaluating Sildenafil Cream compared to placebo cream.

Analogous to previously approved treatments for ED in men, the Phase 3 study will have co-primary efficacy endpoints. Clinical programs for approved ED products have evaluated three co-primary endpoints specific to sexual arousal. For FSAD, the FDA has recommended a clinical program consistent with the Phase 2b RESPOND study, where only two co-primary endpoints were included – one assessing arousal sensations and one assessing associated distress, where distress is included as a co-primary endpoint to support the treatment effect of Sildenafil Cream. The Sildenafil Cream Phase 3 study will include the same co-primary endpoints for arousal sensations and associated distress used in the Phase 2b RESPOND study.

In addition, secondary endpoints to assess improvement in orgasm, desire, and distress and interpersonal difficulties will be included, as they were in the Phase 2b RESPOND study. Claims of treatment benefit of the symptoms (but not the indications of Hypoactive Sexual Desire Disorder or Female Orgasmic Dysfunction) can be pursued via clear endpoint definition and formal statistical testing with adjustment for multiplicity, including a plan to control the type 1 error rate, which Daré plans to include in its protocol and statistical analysis plan for the Phase 3 study.

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, sexual health, pelvic pain, fertility, infectious diseases, and menopause.

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, the active ingredient in Viagra®, 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 2022. In 2023, Daré's CEO was 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 Bioscience placed #1 in the Small Company category of the San Diego Business Journal's 2023 Best Places to Work Awards.

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,” 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 the therapeutic potential and safety profile of Sildenafil Cream, Daré’s plans for continued clinical development of Sildenafil Cream, including Phase 3 trial design and statistical analysis plan and the timing of commencing the first Phase 3 study, Daré’s expectations that the Phase 3 trial design and statistical analysis plan will reflect the FDA’s recommendations and have the characteristics of an adequate and well-controlled clinical study, the anticipated pathway for FDA approval of Sildenafil Cream for the treatment of FSAD in premenopausal women, the potential for Sildenafil Cream to be the first FDA-approved treatment for FSAD, and the potential market opportunity for Sildenafil Cream. As used in this press release, the description of a product candidate as “first-in-category” is a forward-looking statement relating to the potential of the candidate to represent a new category of product if it were to receive marketing approval for the indication for which Daré is developing it. 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: potential insufficiency of Daré’s capital resources to advance the development of its product candidates, including Sildenafil Cream for the treatment of FSAD, on communicated timelines, or at all; failure or delay in starting, conducting and completing clinical trials of a product candidate, including the first Phase 3 clinical study of Sildenafil Cream, including due to lack of sufficient capital resources; 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 inherent uncertainty of outcomes of clinical trials of drug products and Sildenafil Cream in particular given the complexity of FSAD and the limited clinical trial precedent from which to draw experience; the risk that, as with the Phase 2b RESPOND study, the planned Phase 3 study may fail to demonstrate statistically significant differences between Sildenafil Cream and placebo users in the co-primary and secondary efficacy endpoints even though the Phase 3 study will exclude patients with FSAD with concomitant orgasmic dysfunction and concomitant genital pain; the risk that development of Sildenafil Cream requires more clinical or nonclinical studies than Daré anticipates, including to generate additional data that may be needed to assess product safety or appropriately qualify any ingredient (other than sildenafil) for the vaginal route of administration; 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; 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 clinical and/or nonclinical study data; Daré’s ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; 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 loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré’s operations, financial results and condition, and ability to achieve current plans and objectives; 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 or reimbursement from third-party payers; 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 product 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:

Daré Bioscience Investor Relations
innovations@darebioscience.com
Source: Daré Bioscience, Inc.