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): November 14, 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 November 14, 2022, Daré Bioscience, Inc. ("Daré") issued a press release regarding DARE-VVA1, its investigational, proprietary formulation of tamoxifen for intravaginal administration, 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, 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 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 November 14, 2022, Daré issued a press release announcing positive topline results of its Phase 1/2 clinical study of DARE-VVA1. Daré is developing DARE-VVA1 for the treatment of moderate to severe vulvar and vaginal atrophy ("VVA"). The randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose ranging study enrolled 17 postmenopausal women with VVA and evaluated the safety, tolerability, plasma pharmacokinetics ("PK") and pharmacodynamics ("PD") of DARE VVA1. The age of the 17 study participants ranged from 49 to 68 years, with an average age of 60.9 years. Participants were randomly allocated to one of five treatment groups (approximately four participants per group) that evaluated four dose levels of DARE-VVA1 (1 mg, 5 mg, 10 mg, and 20 mg tamoxifen) and a placebo. Following a screening visit, DARE VVA1 was self-administered by study participants intravaginally once a day for the first two weeks, and then twice a week for the following six weeks for a total treatment period of 56 days. In each treatment group, participants had serial blood sampling for PK analysis and underwent safety evaluations and preliminary assessments of effectiveness. Following the completion of the treatment period, participants attended a safety follow-up visit. Fourteen participants completed the study.

The primary endpoints of the study evaluated the safety and tolerability of DARE-VVA1 by vaginal administration and determined the plasma PK of DARE-VVA1 after intravaginal application. Secondary endpoints evaluated preliminary efficacy and PD of DARE-VVA1 in terms of most bothersome vaginal symptom and changes in vaginal cytology and pH.

Intravaginal administration of DARE-VVA1 was well tolerated in the study and all treatment emergent adverse events were mild or moderate and equally distributed between participants randomized to study drug treatment versus placebo. Concentration of tamoxifen in plasma samples collected over the course of the study did not exceed 10 ng/mL, even in participants in the highest dose group (20 mg tamoxifen).

Participants who received study drug treatment had improvements in the assessments and symptoms associated with VVA. Specifically, they had decreases in vaginal pH, increases in the percentage of vaginal superficial cells, significant decreases in the percentage of vaginal parabasal cells (p=0.04), and reduction in their self-assessed most bothersome vaginal symptom reported. Regarding the most bothersome vaginal symptom reported, of the participants randomized to receive study drug treatment, 39% (5/13) reported that vaginal dryness and 62% (8/13) reported that pain with intercourse (dyspareunia) was their most bothersome vaginal symptom at baseline. At the end of the treatment period, among the participants randomized to receive study drug treatment who reported vaginal dryness as their most bothersome symptom at baseline (n=5) (moderate or severe), all those who completed the study reported that vaginal dryness was either absent (n=1) or mild (n=3). Among the participants randomized to receive study drug treatment who reported dyspareunia as their most bothersome symptom at baseline (n=8) (moderate or severe), at the end of the treatment period, four reported no longer experiencing dyspareunia, one reported mild dyspareunia, two had no change in this symptom, and one did not complete the study. Of the four participants randomized to the placebo group, two reported vaginal dryness and two reported dyspareunia as their most bothersome symptom at baseline. At the end of the treatment period, the participants randomized to the placebo group who reported vaginal dryness as their most bothersome symptom at baseline (n=2) (moderate or severe), reported that vaginal dryness was either absent (n=1) or mild (n=1), and among the participants randomized to the placebo group who reported dyspareunia as their most bothersome symptom at baseline (n=2), one reported no longer experiencing dyspareunia and one did not complete the study.

Daré believes the topline results of the Phase 1/2 clinical study support ongoing development of DARE-VVA1 as a treatment for moderate to severe VVA, and that DARE-VVA1 has the potential to be the first therapeutic specifically approved for the treatment of VVA in U.S. patients with, or at risk of recurrence of, hormone receptor-positive breast cancer.

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 press release, forward-looking statements include, but are not limited to, statements relating to DARE-VVA1's potential as a safe and effective therapy for VVA, DARE-VVA1's potential to become a new standard of care as the first FDA-approved product for the treatment of VVA specifically in an HR+ breast cancer patient population, the importance of the Phase 1/2 clinical study results to Daré and DARE-VVA1, and the anticipated regulatory approval pathway for DARE-VVA1. 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 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; 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; the effects of the COVID-19 pandemic, macroeconomic conditions and geopolitical events on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on Daré's ability to timely enroll, conduct and report results of its clinical trials and on the ability of third parties on which Daré relies to assist in the conduct of its business to fulfill their contractual obligations to Daré; 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; cyber attacks, security breaches 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued on November 14, 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: November 14, 2022

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

Exhibit 99.1

Daré Bioscience Announces Positive Topline Results from DARE-VVA1 Phase 1/2 Clinical Study

DARE-VVA1 Demonstrated Improvement in Vaginal Cytology Parameters and Bothersome Symptoms of Vulvar and Vaginal Atrophy (VVA), Supporting Ongoing Development

Investigational Therapy for Women with VVA Who Cannot, or Should Not, Take Supplemental Estrogen, Including Women with Hormone Receptor-Positive (HR+) Breast Cancer

There are Currently No FDA-Approved Products Labeled for VVA Treatment for Patients with or at Risk of Recurrence of HR+ Breast Cancer

SAN DIEGO, November 14, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced topline data from its Phase 1/2 clinical study of DARE-VVA1, a novel intravaginal proprietary formulation of tamoxifen being developed for the treatment of moderate to severe vulvar and vaginal atrophy. The randomized, double-blind, placebo-controlled study was designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of DARE-VVA1 in postmenopausal participants with moderate to severe VVA. The topline data from the study demonstrated safety and tolerability of DARE-VVA1, as well as improvement in the vaginal cytology parameters and the bothersome vaginal symptom associated with VVA. DARE-VVA1 has the potential to be the first therapeutic specifically approved for the treatment of VVA in U.S. patients with HR+ breast cancer. There are currently no FDA-approved products labeled for VVA treatment in HR+ breast cancer patients.

Globally, breast cancer is the most frequently diagnosed cancer type, accounting for over two million cases each year. Approximately 4 million U.S. women have a history of invasive breast cancer, and of all breast cancer diagnoses in U.S. women, it is estimated that more than 68% are HR+. VVA prevalence in postmenopausal breast cancer survivors is estimated at 42% to 70%.

"There is a clear unmet need for an effective non-hormonal treatment for VVA caused by anti-cancer endocrine therapy in patients diagnosed with HR+ breast cancer. Commonly, estrogen-based therapies delivered through creams, intravaginal rings, and vaginal suppositories are prescribed for the treatment of VVA symptoms. However, the use of estrogen-based products for the treatment of VVA in HR+ breast cancer patients can be challenging for both healthcare providers and their patients as the use of estrogen products, in any form, is often contraindicated for this patient population," said Sabrina Martucci Johnson, President and Chief Executive Officer of Daré Bioscience. "If we are successful, vaginally-administered DARE-VVA1 has the potential to become a new standard of care as the first and only product approved in the U.S. for the treatment of VVA specifically in an HR+ breast cancer patient population."

“We are highly encouraged by the positive topline results of the Phase 1/2 study of DARE-VVA1 as this study is a critical step in developing a potential non-hormonal treatment alternative for VVA,” said Dr. Annie Thurman, Medical Director of Daré Bioscience. “The symptoms of VVA adversely impact quality of life for women, particularly women also undergoing HR+ breast cancer treatment and management.”

DARE-VVA1 Phase 1/2 Clinical Trial Study Design

The Phase 1/2 study evaluated different doses of DARE-VVA1, a tamoxifen vaginal insert, in 17 postmenopausal women with VVA. The study was a randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging study that evaluated the safety, tolerability, plasma pharmacokinetics (PK) and pharmacodynamics (PD) of DARE-VVA1. Eligible participants were randomly allocated to one of five treatment groups (approximately 4 participants per group) that evaluated four dose levels (1 mg, 5 mg, 10 mg, and 20 mg) and a placebo. Following a screening visit, DARE-VVA1 was self-administered intravaginally once a day for the first two weeks, and then twice a week for the following six weeks for a total treatment period of 56 days. In each treatment group, participants had serial blood sampling for PK analysis and underwent safety evaluations and preliminary assessments of effectiveness. Following the completion of the treatment period, participants attended a safety follow-up visit.

The primary endpoints of the study evaluated the safety and tolerability of DARE-VVA1 by vaginal administration and determined the plasma PK of DARE-VVA1 after intravaginal application. Secondary endpoints evaluated preliminary efficacy and PD of DARE-VVA1 in terms of most bothersome vaginal symptom and changes in vaginal cytology and pH.

The study was conducted by the company’s wholly owned subsidiary in Australia.

Topline Results of the Phase 1/2 Clinical Trial

The age of the 17 postmenopausal women with VVA who participated in the study ranged from 49 to 68 years (average age: 60.9). Fourteen women completed the study.

The primary outcomes of this first-in-woman study were safety and plasma PK. Intravaginal administration of DARE-VVA1 was well tolerated and all treatment emergent adverse events were mild or moderate and equally distributed between participants randomized to study drug treatment versus placebo. Concentration of tamoxifen in plasma samples collected over the course of the study did not exceed 10 ng/mL, even in participants in the highest dose group (20 mg), which is 1/10th of the average steady-state concentration of tamoxifen seen with daily dosing of orally administered tamoxifen citrate tablets (20 mg and 10 mg tamoxifen) for three months (average steady-state plasma concentrations of over 100 ng/mL). Secondary outcomes of the study were preliminary efficacy and PD of DARE-VVA1 in terms of most bothersome vaginal symptom and changes in vaginal cytology and pH. Participants who received study drug treatment (at 1 mg, 5 mg, 10 mg or 20 mg doses) had improvements in the assessments and symptoms associated with VVA – specifically, they had decreases in vaginal pH, increases in the percentage of vaginal superficial cells, significant ($p=0.04$) decreases in the percentage of vaginal parabasal cells (despite the small sample size), and reduction in their self-assessed most bothersome vaginal symptom reported (either vaginal dryness or pain with intercourse).

Regarding the most bothersome vaginal symptom reported, of the participants randomized to receive study drug treatment, 39% (5/13) reported that vaginal dryness and 62% (8/13) reported that pain with intercourse (dyspareunia) was their most bothersome vaginal symptom at baseline. At the end of the treatment period, among the participants randomized to receive study drug treatment who reported vaginal dryness as their most bothersome symptom at baseline (n=5) (moderate or severe), all those who completed the study reported that vaginal dryness was either absent (n=1) or mild (n=3). Among the participants randomized to receive study drug treatment who reported dyspareunia as their most bothersome symptom at baseline (n=8) (moderate or severe), at the end of the treatment period, four reported no longer experiencing dyspareunia, one reported mild dyspareunia, two had no change in this symptom, and one did not complete the study. Of the four participants randomized to the placebo group, two reported vaginal dryness and two reported dyspareunia as their most bothersome symptom at baseline. At the end of the treatment period, the participants randomized to the placebo group who reported vaginal dryness as their most bothersome symptom at baseline (n=2) (moderate or severe), reported that vaginal dryness was either absent (n=1) or mild (n=1), and among the participants randomized to the placebo group who reported dyspareunia as their most bothersome symptom at baseline (n=2), one reported no longer experiencing dyspareunia and one did not complete the study.

Daré plans to submit data from the Phase 1/2 clinical study of DARE-VVA1 for publication in a peer-reviewed publication.

Following clinical development, Daré intends to leverage the existing safety and efficacy data on the active ingredient in DARE-VVA1, tamoxifen, to utilize the U.S. Food and Drug Administration's (FDA) 505(b)(2) pathway to obtain marketing approval of DARE-VVA1 in the U.S.

About Vulvar and Vaginal Atrophy (VVA)

VVA is an inflammation and thinning of the vaginal epithelium due to the reduction in levels of circulating estrogen. Typical symptoms include vaginal dryness, itching, burning, and painful intercourse, adversely impacting quality of life. VVA is a common condition in postmenopausal women and women with, or with a history of, HR+ breast cancer. Many breast cancer survivors experience menopausal symptoms irrespective of age as a direct consequence of their cancer treatment. Breast cancer patients treated with aromatase inhibitors refer to VVA as one of the most unpleasant side effects of treatment. The prevalence of VVA in postmenopausal breast cancer patients is estimated to be between 42 and 70 percent.

Products containing estrogen are commonly used to treat VVA. However, the use of estrogen-containing products for the treatment of VVA is often contraindicated for HR+ breast cancer patients and survivors because of the concern that estrogen use will promote recurrence of disease.

About DARE-VVA1

DARE-VVA1 is an investigational, proprietary formulation of tamoxifen for intravaginal administration with the potential to be a first-in-category treatment of VVA for women with or at-risk of HR+ breast cancer. Tamoxifen is a well-known and well-characterized selective estrogen receptor modulator (SERM) that has been prescribed by oncologists for decades for the treatment of breast cancer. In breast tissue, tamoxifen acts as an estrogen antagonist. In contrast, in other tissues such as vaginal tissues, tamoxifen has been reported to exert an estrogen-like response on vaginal cytology. Studies of tamoxifen conducted over the last 40 years have documented its estrogen-like effects on vaginal epithelium. Localized tamoxifen therapy such as DARE-VVA1 thus has the potential to counter the physiologic changes that lead to VVA without introducing estrogen back into the system.

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 intravaginal 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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