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 20, 2023

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 20, 2023, Daré Bioscience, Inc. ("Daré," "we," "us," or "our") issued a press release announcing topline results from the Phase 1 clinical study of DARE-PDM1 discussed in Item 8.01 below. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in Item 7.01 of this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under 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 (the "SEC") 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 December 20, 2023, Daré announced topline results from its Phase 1 clinical study of DARE-PDM1, an investigational, proprietary hydrogel formulation of diclofenac, a nonsteroidal anti-inflammatory drug, for vaginal administration as a treatment for primary dysmenorrhea. The DARE-PDM1 Phase 1 study, DARE-PDM1-001, was a multi-center, randomized, placebo-controlled, double-blind, three-arm parallel group study among approximately 42 healthy, premenopausal women with symptomatic primary dysmenorrhea. The study was designed to assess the systemic (plasma) and local mucosal (vaginal fluid) diclofenac pharmacokinetics (PK) and safety after a single dose and during three daily doses of vaginally administered DARE-PDM1, given in two different strengths (1% or 3% diclofenac in 2.5 mL of hydrogel) versus placebo (vaginal hydrogel, no active ingredient). The study also assessed, as an exploratory endpoint, the preliminary dysmenorrhea treatment efficacy of DARE-PDM1, when dosed in three daily doses at the onset of dysmenorrhea symptoms, compared to a no-treatment, baseline, control cycle. The study observation period encompassed approximately three menstrual cycles.

The topline data indicate that the study treatment was well-tolerated, and treatment emergent adverse events profiles were comparable between the DARE-PDM1 treatment groups and the placebo group. All adverse events were mild or moderate; most adverse events (85%) were mild. There were no early discontinuations due to an adverse event, and no serious adverse events were reported.

The vaginal fluid PK results exhibited dose proportionality for the 1% and 3% diclofenac strengths of the DARE-PDM1 study treatment. Additionally, the vaginal fluid PK results demonstrated that the product was retained in the vaginal canal through 24 hours. The plasma PK results are forthcoming.

The exploratory endpoint that evaluated the efficacy of DARE-PDM1 versus placebo in reducing dysmenorrhea-associated pain showed a promising signal, with a statistically significant decrease in pelvic/vaginal and lower back pain scores in the 1% diclofenac DARE-PDM1 treatment group compared to the placebo group, as well as a decrease in pain scores in the 3% diclofenac DARE-PDM1 treatment group. Additionally, while most participants used at least one non-pharmacologic pain relief method (e.g., heating pad) for dysmenorrhea-associated pain during the no-treatment, baseline, control cycle, the proportion of participants who used at least one non-pharmacologic pain relief method for dysmenorrhea-associated pain decreased significantly in the DARE-PDM1 treatment groups during the dosing period, but not in the placebo group. There was no difference in the exploratory assessment of frequency of use of rescue medications in the treatment phase between the three groups.

Pending the plasma PK data, the topline results of the Phase 1 study support continued clinical development of DARE-PDM1 as a treatment for primary dysmenorrhea.

The DARE-PDM1-001 study was conducted in Australia by the company's wholly-owned subsidiary, DARE Bioscience Australia Pty Ltd.

Cautionary Statement Regarding 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-PDM1's potential as a safe and effective treatment for primary dysmenorrhea and Daré's clinical development plans for DARE-PDM1. 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 report, including, without limitation, risks and uncertainties related to: the risk that topline results from a clinical trial, including the Phase 1 study of DARE-PDM1, are based on Daré's preliminary analysis of key data and, following a comprehensive review of study data, including the forthcoming plasma PK data from the Phase 1 study of DARE-PDM1, such results may change and topline results may not accurately reflect the complete results from the clinical trial; 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; 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 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 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; 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on December 20, 2023
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 20, 2023

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

Exhibit 99.1

Daré Bioscience Announces Positive Topline Pharmacokinetic and Exploratory Efficacy Results from the DARE-PDM1 Phase 1 Clinical Study

Data Support Continued Clinical Development of DARE-PDM1 and its Potential as a First-in-Category Treatment for Primary Dysmenorrhea

SAN DIEGO, December 20, 2023 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced positive topline results from the Phase 1 study evaluating the pharmacokinetics (PK), safety, and exploratory efficacy of DARE-PDM1. DARE-PDM1 is an investigational product designed to deliver diclofenac, a nonsteroidal anti-inflammatory drug (NSAID), vaginally via the company's proprietary hydrogel to treat primary dysmenorrhea, which is defined as painful menstruation in women with normal pelvic anatomy. DARE-PDM1 has the potential to be a first-in-category product, delivering diclofenac in a convenient vaginal format that may extend the duration of pain relief and reduce the risks associated with the oral delivery of NSAIDs.

The DARE-PDM1 Phase 1 study, DARE-PDM1-001, was a multi-center, randomized, placebo-controlled, double-blind, 3-arm parallel group study among approximately 42 healthy, premenopausal women with symptomatic primary dysmenorrhea. This study was designed to assess the systemic (plasma) and local mucosal (vaginal fluid) diclofenac PK and safety after a single dose and during three daily doses of vaginally administered DARE-PDM1, given in two different strengths (1% or 3% diclofenac in 2.5 mL of hydrogel) versus placebo (vaginal hydrogel, no active ingredient). The study also assessed, as an exploratory endpoint, the preliminary dysmenorrhea treatment efficacy of DARE-PDM1, when dosed in three daily doses at the onset of dysmenorrhea symptoms, compared to a no-treatment, baseline, control cycle. The study observation period encompassed approximately three menstrual cycles. The plasma PK results are forthcoming.

"We are encouraged by these data which indicate that our candidate, DARE-PDM1, was well-tolerated and safe for premenopausal women in both treatment groups," said Dr. Annie Thurman, Medical Director of Daré Bioscience. "The most common interventions for primary dysmenorrhea include oral NSAIDs and hormonal contraceptives, which often can produce undesirable side effects such as an increased risk of gastrointestinal adverse events, including nausea, vomiting, bloating, or ulcerations. These topline Phase 1 data indicate that by leveraging a vaginal route of administration, we can provide a more convenient and accessible treatment option for women that addresses the pain-related symptoms of the condition while minimizing side effects commonly seen with the use of oral medications."

"DARE-PDM1 utilizes a well-known and well-characterized active pharmaceutical ingredient for primary dysmenorrhea delivered by our novel hydrogel technology, which is designed to keep the product from leaking out of the vagina and may increase the vaginal residence time," said David Friend, PhD, Chief Scientific Officer for Daré Bioscience. "The PK findings support that the product is retained in the vagina for a prolonged period, which we believe will contribute to the efficacy of the treatment."

DARE-PDM1 Phase 1 Topline Results

The Phase 1 study results indicate that the study treatment was well-tolerated, and treatment emergent adverse events profiles were comparable between the DARE-PDM1 treatment groups and the placebo group. All adverse events were mild or moderate; most adverse events (85%) were mild. There were no early discontinuations due to an adverse event, and no serious adverse events were reported.

The vaginal fluid PK results exhibited dose proportionality for the 1% and 3% diclofenac strengths of the DARE-PDM1 study treatment. Additionally, the vaginal fluid PK results demonstrated that the product was retained in the vaginal canal through 24 hours, which is similar to the vaginal retention demonstrated in the PK study of Daré's FDA-approved vaginal gel product, which uses the same proprietary hydrogel technology.

The exploratory endpoint that evaluated the efficacy of DARE-PDM1 versus placebo in reducing dysmenorrhea-associated pain showed a promising signal, with a statistically significant decrease in pelvic/vaginal and lower back pain scores in the 1% diclofenac DARE-PDM1 treatment group compared to the placebo group, as well as a decrease in pain scores in the 3% diclofenac DARE-PDM1 treatment group. Additionally, while most participants used at least one non-pharmacologic pain relief method (e.g., heating pad) for dysmenorrhea-associated pain during the no-treatment, baseline, control cycle, the proportion of participants who used at least one non-pharmacologic pain relief method for dysmenorrhea-associated pain decreased significantly in the DARE-PDM1 treatment groups during the dosing period, but not in the placebo group. There was no difference in the exploratory assessment of frequency of use of rescue medications in the treatment phase between the three groups.

Pending the plasma PK data, the topline results of this Phase 1 study support continued clinical development of DARE-PDM1 for primary dysmenorrhea.

The DARE-PDM1-001 study was conducted in Australia by the company's subsidiary, DARE Bioscience Australia Pty Ltd.

At the conclusion of the development program, if successful, Daré intends to leverage the existing safety and efficacy data for diclofenac to utilize the U.S. Food and Drug Administration's (FDA) 505(b)(2) pathway to obtain marketing approval of DARE-PDM1 in the U.S.

About Primary Dysmenorrhea

Primary dysmenorrhea is defined as painful menstruation in women with normal pelvic anatomy, typically described as cramping pain in the lower abdomen before or during the menstrual period. Recent market research suggests that the global market for dysmenorrhea treatment was estimated to be valued at USD $13 billion in 2022 and that the size of this market is expected to increase to USD $28.5 billion by 2029. Oral NSAIDs, such as oral diclofenac products, are often recommended for temporary relief from the painful symptoms of primary dysmenorrhea. Because there are currently no FDA-approved vaginal diclofenac treatment options for primary dysmenorrhea, DARE-PDM1 has the potential to be a first-in-category product, delivering diclofenac in a convenient vaginal format that may extend the duration of pain relief and reduce the risks associated with the oral delivery of NSAIDs.

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, vaginal health, reproductive health, menopause, sexual health and fertility.

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. 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 (FSAD) and/or female sexual interest/arousal disorder (FSIAD) utilizing the active ingredient in Viagra®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. 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 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 DARE-PDM1’s potential as a safe and effective treatment for primary dysmenorrhea, DARE-PDM1’s potential to demonstrate better safety and tolerability compared with oral NSAID medications and/or hormonal contraceptives commonly used to treat primary dysmenorrhea, Daré’s clinical development plans and anticipated FDA approval pathway for DARE-PDM1, and the potential market opportunity for DARE-PDM1, if approved. 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 topline results from a clinical trial, including the Phase 1 study of DARE-PDM1, are based on Daré’s preliminary analysis of key data and, following a comprehensive review of study data, including the forthcoming plasma PK data from the Phase 1 study of DARE-PDM1, such results may change and topline results may not accurately reflect the complete results from the clinical trial; 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; 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 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 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; 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. 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Contacts:

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Source: Daré Bioscience, Inc.