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 18, 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 July 19, 2024, Daré Bioscience, Inc. ("Daré," "we," "us," "our" or the "Company") issued a press release announcing that it regained compliance with The Nasdaq Capital Market's continued listing requirements. A copy of the press release is furnished as an exhibit to this report.

The information in this Item 7.01, including Exhibit 99.1 to this report, is being furnished and 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 Exhibit 99.1 shall not be incorporated by reference into any filing under the Exchange Act or the Securities Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

As previously disclosed, the Company was previously granted a temporary exception by the Hearings Panel (the "Panel") of The Nasdaq Stock Market LLC ("Nasdaq") to regain compliance with the $1.00 per share minimum bid price requirement for continued listing on The Nasdaq Capital Market set forth in Nasdaq Listing Rule 5550(a)(2). As required by the temporary exception granted by the Panel, the closing bid price of the Company's common stock was $1.00 per share or greater for a minimum of ten consecutive trading sessions prior to July 16, 2024.

On July 18, 2024, the Company was notified by letter from the Nasdaq Office of General Counsel that the Company regained compliance with Nasdaq Listing Rule 5550(a)(2) and the matter is now closed.

The Company is continuing activities to support progressing toward its Phase 3 pivotal studies of Sildenafil Cream, 3.6%, for the treatment of female sexual arousal disorder, for which there are currently no U.S. Food and Drug Administration ("FDA")-approved treatments. The Company continues to await expected additional feedback from the FDA on its proposed primary and secondary patient reported outcome endpoints for the Phase 3 pivotal studies of Sildenafil Cream, as well as additional information on data that may be needed in a new drug application ("NDA") submission to appropriately qualify any ingredient (other than sildenafil) for the vaginal route of administration, and for clarification on the safety database (size and duration exposure) that the FDA will require for an NDA submission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on July 19, 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: July 19, 2024

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

Exhibit 99.1

Daré Bioscience Regains Compliance with Nasdaq Minimum Bid Price Rule

SAN DIEGO, July 19, 2024 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, announced that it was notified by the Nasdaq Office of General Counsel that the Company regained compliance with the minimum bid price requirement in Nasdaq Listing Rule 5550(a)(2) as a result of the closing bid price of the Company's common stock being $1.00 per share or greater for 10 consecutive trading sessions and that the matter is closed.

"We are thrilled to announce that we have regained compliance with the Nasdaq minimum bid price rule," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "This strengthens our position in the market and enhances our ability to drive our vision forward. We look forward to the opportunity to accelerate our development efforts on key programs in our portfolio and to ultimately provide great therapeutic options for women."

"We continue to enroll participants in our pivotal Phase 3 study of Ovaprene®, our potentially first-in-category hormone-free monthly intravaginal contraceptive candidate, at sites across the U.S.," Johnson continued. "We are also continuing activities to support progressing toward a Phase 3 trial of Sildenafil Cream, 3.6% in female sexual arousal disorder, for which there are currently no FDA-approved treatments. We continue to execute on our mission to accelerate development of and bring to market innovative treatments that women want and need by advancing our late-stage candidates – all of which represent a first-in-category opportunity – as we seek to deliver value for all Daré stakeholders."

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.

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. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023. 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 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 plans and expectations with respect to Daré's product candidates, including clinical development plans, targeted indications, the potential for FDA approval of Ovaprene based on a single pivotal clinical study, and the expectation that a product candidate could be a first-in-category product. 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: 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.

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Source: Daré Bioscience, Inc.