

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 7, 2021

**DARÉ BIOSCIENCE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36395**  
(Commission  
File Number)

**20-4139823**  
(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
<b>Common stock</b>	<b>DARE</b>	<b>Nasdaq Capital Market</b>

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 8.01 Other Events.

On December 7, 2021, the U.S. Food and Drug Administration ("FDA") approved the New Drug Application for DARE-BV1, trade name XACIATO™ [zah-she-AH-toe] (clindamycin phosphate vaginal gel, 2%), for the treatment of bacterial vaginosis in female patients 12 years of age and older. XACIATO is a clear, colorless, viscous gel, which contains clindamycin at a concentration of 2%. A single-dose user-filled disposable applicator delivers 5 g of vaginal gel containing 100 mg of clindamycin.

XACIATO received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis. As a result of the QIDP designation, XACIATO is expected to receive a five-year extension of the three years of market exclusivity available to the product based on the submission of new clinical data that were essential to its approval. Strategic partnering discussions and other activities intended to support a robust market introduction of XACIATO in 2022 in the United States are ongoing and a conference call to discuss the partnership and market introduction strategy will be scheduled once definitive partnership agreement is finalized and executed.

### *Cautionary Statement Regarding Forward-Looking Statements*

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act. To the extent that statements contained in this report are not descriptions of historical facts, they are forward-looking statements. Forward-looking statements include statements relating to the robust market introduction of XACIATO in 2022 and the finalization and execution of a definitive partnership agreement for XACIATO. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties. Actual results could differ materially from those anticipated as a result of various factors, including, without limitation, the risks and uncertainties inherent in the commercialization of XACIATO and to do so on communicated timelines and the failure to timely establish third-party partnerships or collaborations to commercialize XACIATO. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in the forward-looking statements, as well as risks relating to Daré's business in general, please refer to Daré's annual report on Form 10-K filed with the SEC on March 30, 2021, and its quarterly reports filed with the SEC on each of November 10, 2021 and August 12, 2021, and its current and future periodic reports 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. Unless otherwise required by law, Daré expressly disclaims any obligation to update publicly any forward-looking statements, whether as result of new information, future events or otherwise.

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**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.

Dated: December 7, 2021

**DARÉ BIOSCIENCE, INC.**

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