

**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 4, 2023

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
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 1.01 Entry into a Material Definitive Agreement.

On July 4, 2023, Daré Bioscience, Inc. (“Daré”), and an affiliate of Organon & Co., Organon International GmbH (“Organon”), entered into an amendment (the “Amendment”) to the exclusive license agreement dated as of March 31, 2022 between the parties. Under the Amendment, Organon will pay \$1.0 million to Daré to reimburse Daré for PDUFA fees and other manufacturing expenses and to support continued advancement of the development and commercialization of XACIATO, and the amount payable by Organon to Daré following the first commercial sale of a licensed product in the United States was revised to \$1.8 million.

The foregoing brief description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment, a copy of which Daré intends to file with its quarterly report on Form 10-Q for the quarterly period ending September 30, 2023, with certain private or confidential provisions or terms redacted.

Item 7.01 Regulation FD Disclosure.

On July 5, 2023, Daré issued a press release announcing the Amendment, a copy of which 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.

To provide for continuity of supply to support the commercial launch of XACIATOTM in the United States, additional manufacturing related activities are being performed, and Organon and Daré are working towards a 2023 U.S. launch as soon as feasible.

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 Daré’s expectations about timing of commercial availability of XACIATO in the United States. 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 risks that none of the milestones under the agreement with Organon may be achieved; dependence on Organon to commercialize licensed products and on other third parties for commercial supplies of licensed products and components and Daré’s lack of control over the efforts and resources expended by those third parties; Daré’s ability to raise additional capital when and as needed to support its operations, execute its business strategy and continue as a going concern; general industry conditions and competition; and the effects of macroeconomic conditions such as inflation, rising interest rates and geopolitical events on Daré’s operations, financial results and condition, and ability to achieve current plans and objectives. 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 July 5, 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: July 5, 2023

By: /s/ Sabrina Martucci Johnson

Name: Sabrina Martucci Johnson

Title: President and Chief Executive Officer



Daré Bioscience Provides Update on Activities to Support Commercial Launch of XACIATO™ (clindamycin phosphate) vaginal gel, 2%, FDA-Approved Treatment for Females 12 and Older with Bacterial Vaginosis

Daré to receive \$1 million in July 2023 and \$181.8 million in potential milestone payments from Organon under XACIATO global license agreement

SAN DIEGO, July 5, 2023 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reaffirmed its commitment to the commercial launch of XACIATO [zah-she-AH-toe] (clindamycin phosphate) vaginal gel, 2% with collaborator Organon (NYSE: OGN), and announced that Organon will pay Daré \$1.0 million in July 2023.

"We believe Organon's commercial capabilities and track record of success in the branded women's health category will help ensure a successful introduction of XACIATO in the United States and, ultimately, that XACIATO reaches the global population of women suffering from bacterial vaginosis, which is estimated to impact between 23% to 29% of all women worldwide," said Sabrina Martucci Johnson, President and CEO of Daré. "Daré has completed manufacturing validation activities required to support commercial launch. To provide for continuity of supply to support a robust commercial launch, additional manufacturing related activities are being performed and Organon and Daré are working towards a 2023 U.S. launch as soon as feasible. We are confident that XACIATO will be well positioned for commercial success given the knowledge and experience of Organon's sales team, which is the same sales team that helped drive the market acceptance and record sales of NEXPLANON®, coupled with Organon's payer outreach and provider and patient-centered initiatives, and we look forward to the launch later this year."

Under the amended license agreement between Daré and Organon for XACIATO, Organon will pay Daré \$1.0 million in July 2023 and will pay Daré \$1.8 million upon the first commercial sale of XACIATO. In 2022, Daré received a \$10.0 million upfront payment from Organon when the license agreement became effective. In addition to the upfront payment and the \$2.8 million described above, Daré is also eligible to receive additional potential future milestone payments of up to \$180.0 million and tiered double-digit royalties based on net sales.

As Daré previously [shared](#), the New Drug Application (NDA) for XACIATO was supported by positive results from the DARE-BVFREE Phase 3 randomized, multi-center, double-blinded, placebo-controlled clinical trial evaluating XACIATO (formerly known as DARE-BV1) for the treatment of bacterial vaginosis (NCT04370548).

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. 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 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 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.

Forward-Looking Statements

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