

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): March 31, 2022

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
Common stock

Trading Symbol(s)
DARE

Name of each exchange on which registered
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 March 31, 2022, Daré Bioscience, Inc. ("Daré"), entered into an exclusive license agreement (the "Agreement") with an affiliate of Organon & Co., Organon International GmbH ("Organon"), pursuant to which Organon will obtain exclusive worldwide rights to develop, manufacture and commercialize XACIATO™ [zah-she-AH-toe] (clindamycin phosphate vaginal gel, 2%) and other future intravaginal or urological products for human use formulated with clindamycin that rely on intellectual property controlled by Daré. XACIATO was approved by the U.S. Food and Drug Administration in December 2021 for the treatment of bacterial vaginosis in female patients 12 years of age and older.

Under the Agreement, Daré will receive a \$10.0 million non-refundable and non-creditable payment following the effective date of the Agreement and will be entitled to receive tiered double-digit royalties based on net sales and up to \$182.5 million in milestone payments as follows: \$2.5 million following the first commercial sale of a licensed product in the United States, which is expected to occur during the fourth quarter of 2022; and up to \$180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets. The royalty period for each licensed product will continue on a country-by-country basis from the first commercial sale of the licensed product in the country until the expiration of the later of (i) the date that no valid patent claim would be infringed in the absence of the license granted under the Agreement by the sale of the licensed product in the country, (ii) 10 years after the end of the month in which the first commercial sale of the licensed product in the country occurred, and (iii) the expiration of regulatory market exclusivity for the licensed product in that country.

Under the Agreement, Daré will be responsible for regulatory interactions and for providing product supply on an interim basis until Organon assumes such responsibilities. Until such time, Organon will purchase all of its product requirements of XACIATO from Daré at a transfer price equal to Daré's manufacturing costs plus a single-digit percentage markup.

The effective date of the Agreement will occur following the satisfaction of closing conditions that include receipt of all applicable approvals, or the expiration or termination of all applicable waiting periods, required under applicable antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Unless terminated earlier, the Agreement will expire on a product-by-product and country-by-country basis upon expiration of the applicable royalty period for each licensed product. In addition to customary termination rights for both parties, following the first anniversary of the effective date of the Agreement, Organon may terminate the Agreement in its entirety or on a country-by-country basis at any time in Organon's sole discretion on 120 days' advance written notice.

The Agreement includes customary representations and warranties, covenants and indemnification obligations of each party.

In addition, the terms of the Agreement provide Organon exclusive worldwide rights of first negotiation for specified potential future Daré products.

The foregoing description of the Agreement describes the terms material to Daré, does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which Daré intends to file with its quarterly report on Form 10-Q for the quarterly period ending March 31, 2022, with certain private or confidential provisions or terms redacted.

Item 7.01 Regulation FD Disclosure.

On March 31, 2022, Daré and Organon issued a joint press release announcing that they entered into the Agreement, 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.

Cautionary Statement Regarding Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act 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 Agreement becoming effective, the development, manufacture and commercialization of XACIATO, the timing of the first commercial sale of XACIATO, and any future licensed product under the Agreement by Organon. 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 that the closing conditions in the Agreement may not be satisfied or waived and the Agreement may not become fully effective or may be terminated early; the risk that payments to Daré under the Agreement may be significantly less than anticipated or potential amounts; Daré's dependence on Organon, its affiliates and/or its sublicensees to commercialize XACIATO and on other third parties to supply XACIATO and its components for commercial sale, and Daré's lack of control over the efforts and resources that any of these third parties devotes to the manufacture and commercialization of XACIATO and any future licensed product. 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 31, 2022, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on March 31, 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.

Dated: March 31, 2022

DARÉ BIOSCIENCE, INC.

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



News Release

Organon Media Contacts:	Karissa Peer (614) 314-8094 Kate Vossen (732) 675-8448	Organon Investor Contacts:	Jennifer Halchak (201) 275-2711 Edward Barger (267) 614-4669
Daré Media Contacts:	Jake Robison (619) 849-5383	Daré Investor Contacts:	Lee Roth (212) 213-0006

Organon Enters into Global License Agreement to Commercialize Daré Bioscience's XACIATO™ (clindamycin phosphate vaginal gel, 2%), FDA-Approved Treatment for Females 12 and Older with Bacterial Vaginosis (BV)

An estimated 21 million American women experience BV

JERSEY CITY, N.J. & SAN DIEGO, C.A., March 31, 2022 – Organon (NYSE: OGN), a global women's healthcare company, and Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced they have entered into an agreement whereby Organon will license global rights to XACIATO (clindamycin phosphate vaginal gel, 2%). XACIATO is an FDA-approved medication for the treatment of bacterial vaginosis (BV) in females 12 years of age and older. XACIATO received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis.

"Our agreement with Daré aligns well with our long-term growth strategy focused on delivering new options for women where therapeutic gaps exist," said Kevin Ali, Organon's Chief Executive Officer. "Organon will bring its commercial expertise to this collaboration so that we can deliver this option to women, specifically in a condition like bacterial vaginosis where more treatment choices are needed."

BV is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women in the U.S. The condition results from an overgrowth of bacteria, which upsets the balance of the natural vaginal microbiome and can lead to symptoms of odor and discharge.

Sabrina Martucci Johnson, Daré's President and Chief Executive Officer, commented, "Organon shares our commitment to advance critically needed innovations in women's health. We are excited to be collaborating with one of the premier companies in women's health as we believe that Organon's commercial capabilities will ensure that XACIATO reaches the women most impacted by this condition."

Daré will receive a \$10 million upfront payment from Organon. Daré is eligible to receive potential milestone payments of up to \$182.5 million and tiered double-digit royalties based on net sales. XACIATO is expected to be available commercially in the U.S. in Q4 2022. Completion of the transaction is subject to review under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close in Q2 2022.

About Organon

Organon is a global healthcare company formed through a spin-off from Merck & Co., Inc., Rahway, NJ, USA, (NYSE: MRK) known as MSD outside of the United States and Canada, to focus on improving the health of women throughout their lives. Organon has a portfolio of more than 60 medicines and products across a range of therapeutic areas. Led by the women's health portfolio coupled with an expanding biosimilars business and stable franchise of established medicines, Organon's products produce strong cash flows that will support investments in innovation and future growth opportunities in women's health. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

Organon has a global footprint with significant scale and geographic reach, world-class commercial capabilities, and approximately 9,300 employees with headquarters located in Jersey City, New Jersey.

For more information, visit <http://www.organon.com> and connect with us on [LinkedIn](#) and [Instagram](#).

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.

For more information, visit <http://www.darebioscience.com>, and follow these Twitter accounts: @SabrinaDareCEO and @DareBioscience.

Forward-Looking Statement of Organon

Except for historical information herein, this news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements about XACIATO as a potential treatment for BV, Organon's and Daré's ability to improve the lives of women, Organon's ability to deliver new therapeutic options for women, and the potential benefits of the licensing agreement with Daré. Forward-looking statements may be identified by words such as "expects," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "will" or words of similar meaning. Such statements are based upon the current beliefs and expectations of the Organon's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors; the impact of the ongoing COVID-19 pandemic and

emergence of variant strains; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances; new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; the Organon's ability to accurately predict its future financial results and performance; Organon's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Organon undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the Organon's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K, filed on March 21, 2022, available at the SEC's Internet site (www.sec.gov).

Forward-Looking Statements of Daré Bioscience

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 "will," "estimate," "believe," "expect," "eligible," "anticipate," "plan," "seek," "potential," 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 Daré's expectations about its agreement with Organon, including commercial distribution and sale of XACIATO and receipt of payments from Organon, and the expected 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 actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements in this press release, including, without limitation: the risks that closing conditions required for the agreement with Organon to become fully effective may not be satisfied or waived and that the agreement may not become fully effective or may be terminated early and the upfront payment may not become payable; the risk that none of the milestones under the agreement with Organon may be achieved and none of potential milestone payments become payable; the potential for royalty payments to be subject to reductions and offsets; dependence on Organon to commercialize the 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; general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the ongoing COVID-19 pandemic and emergence of variant strains; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances; new products and patents attained by competitors; Daré's ability to accurately predict its future financial condition, operating results and performance; Daré's or its licensor's ability to accurately predict future market conditions; third-party manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of patents owned or licensed by Daré and other protections for innovative products; and the exposure of Daré, its commercial counterparties and other third parties on which it relies to litigation, including patent litigation, and/or regulatory actions. 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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