
**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): June 30, 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	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 2.01 Completion of Acquisition or Disposition of Assets.

As previously reported, on March 31, 2022, Daré Bioscience, Inc. (“Daré,” “we,” “us,” or “our”) and an affiliate of Organon & Co., Organon International GmbH (“Organon”), entered into an exclusive license agreement (the “License Agreement”), pursuant to which Daré agreed to grant Organon exclusive worldwide rights to develop, manufacture and commercialize XACIATO™ (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.

Following the satisfaction of the closing conditions under the License Agreement, on June 30, 2022 (the “Effective Date”), the License Agreement became fully effective. Daré will receive a \$10.0 million non-refundable and non-creditable upfront payment from Organon by early in the third quarter of 2022. Daré is eligible to receive tiered double-digit royalties based on net sales of licensed products 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.

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 License 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. Royalty payments are subject to customary reductions and offsets.

Unless terminated earlier, the License 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, Organon may terminate the License 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.

Under the License Agreement, Daré is 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 our manufacturing costs plus a single-digit percentage markup.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement, a redacted copy of which was filed with the Securities and Exchange Commission (“SEC”) on May 12, 2022 as Exhibit 10.1 to our quarterly report on Form 10-Q for the quarterly period ended March 31, 2022 and is incorporated herein by reference. The closing of the transactions contemplated by the License Agreement might be considered a disposition of assets reportable under Item 2.01. Accordingly, we are reporting the closing as if Item 2.01 were applicable. We determined, however, that the transactions contemplated by the License Agreement do not involve the disposition of a business.

Item 7.01 Regulation FD Disclosure.

On June 30, 2022, Daré issued a press release announcing that the License Agreement is fully effective, a copy of which is furnished as Exhibit 99.1 to this report.

The information under this Item 7.01 and in Exhibit 99.1 is being furnished and is not being filed for purposes of Section 18 of the Securities and Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, regardless of any general incorporation language in any such filing, except as shall be expressly set forth by specific reference in such a filing.

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 Securities and Exchange Act of 1934. 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 development, manufacture and commercialization of XACIATO, the timing of the first commercial sale of XACIATO, and any future licensed product under the License 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 risk that payments to Daré under the License 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
2.1 +#	Exclusive license agreement by and between Organon International GmbH and Daré Bioscience, Inc., dated as of March 31, 2022
99.1	Press release issued on June 30, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Portions of this exhibit have been redacted in compliance with paragraphs (b)(2)(ii) and (b)(10) of Item 601 of Regulation S-K. The omitted information, which is marked in brackets in the exhibit, is not material and is the type that we treat as private or confidential.

This exhibit was filed with the SEC on May 12, 2022 as Exhibit 10.1 to our quarterly report on Form 10-Q for the period ended March 31, 2022 and is incorporated herein by reference.

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: June 30, 2022

By: /s/ Sabrina Martucci Johnson

Name: Sabrina Martucci Johnson

Title: President and Chief Executive Officer



Daré Bioscience Announces Closing of Global License Agreement with Organon to Commercialize XACIATO™ (clindamycin phosphate vaginal gel, 2%), FDA-Approved Treatment for Females 12 and Older with Bacterial Vaginosis

Daré will receive a \$10 million upfront payment from Organon

An estimated 21 million American women experience bacterial vaginosis

SAN DIEGO, June 30, 2022 (GLOBE NEWSWIRE) – Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women’s health innovation, today announced that the exclusive license agreement entered into on March 31, 2022 with Organon (NYSE: OGN), a global women’s healthcare company, has become fully effective. Under the agreement, Organon licensed global rights to XACIATO (clindamycin phosphate vaginal gel, 2%), an FDA-approved medication for the treatment of bacterial vaginosis 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.

In connection with the closing, 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.

“Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women in the U.S.” said Sabrina Martucci Johnson, President and CEO of Daré. “The Daré team identified bacterial vaginosis as an area in need of new treatment options. We are thrilled to be collaborating with Organon, one of the premier companies in women’s health, as we believe Organon’s commercial capabilities will ensure that XACIATO reaches the women most impacted by this condition.”

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.

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 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 hormone therapy following menopause. 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

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," "endeavor" 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, receipt of payments from Organon, and 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 Daré's 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 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 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 inflation, rising interest rates and currency exchange rate fluctuations; the impact of the ongoing COVID-19 pandemic; 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 licensee'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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