

**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): April 29, 2024

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 April 29, 2024, Daré Bioscience, Inc. (“Daré” or the “Company”) entered into a Traditional Royalty Purchase Agreement and a Synthetic Royalty Purchase Agreement (together, the “Agreements”) with XOMA (US) LLC (“XOMA”).

In accordance with the Agreements, on April 29, 2024, XOMA paid \$22.0 million to Daré and, in addition, if XOMA receives total payments under the Agreements (as described below) equal to an amount that exceeds \$88.0 million, XOMA will pay \$11.0 million to Daré for each successive \$22.0 million XOMA receives under the Agreements (such \$11.0 million payments to Daré, the “Contingent Purchase Price Payments”).

Under the Agreements, Daré sold, assigned, transferred and conveyed its right, title and interest in and to the following to XOMA:

(a) 100% of the royalties and potential milestone payments Daré would otherwise have the right to receive from and after April 1, 2024 under Daré’s exclusive license agreement with Organon International GmbH, dated March 31, 2022, as amended (the “Organon License Agreement”), based on net sales of XACIATO™ (clindamycin phosphate) vaginal gel 2%, net of (i) all royalty and milestone payments due and payable and actually paid by or on behalf of Daré under Daré’s exclusive license agreement with third-party licensors TriLogic Pharma, LLC and MilanaPharm LLC, dated January 9, 2017, as amended, and (ii) all payments due and payable and actually paid by or on behalf of Daré under Daré’s royalty interest financing agreement with United in Endeavour, LLC (“UiE”), dated December 21, 2023 (the “UiE Agreement”) (such net amount, the “Purchased Receivables”);

(b) 25% of the potential future \$20.0 million payment that Daré would otherwise have the right to receive under its license agreement with Bayer HealthCare LLC (“Bayer”), dated January 10, 2020 (the “Bayer License Agreement”), if Bayer, in its sole discretion, elects to make the license granted thereunder effective following completion of the pivotal clinical trial of Ovaprene®, Daré’s investigational hormone-free, monthly intravaginal contraceptive; and

(c) a synthetic royalty of 4.0% of Daré’s, its affiliates’ and its sublicensees’ future net sales of Ovaprene, and 2.0% of Daré’s, its affiliates’ and its sublicensees’ future net sales of Sildenafil Cream, Daré’s investigational product to treat female sexual arousal disorder; *provided, however*, that, if XOMA receives total payments under the Agreements, net of any Contingent Purchase Price Payments made to Daré, equal to an amount that exceeds \$110.0 million, the foregoing percentages will be reduced to 2.5% and 1.25%, respectively (such amounts described in the foregoing clauses (b) and (c), collectively, the “Revenue Participation Right”).

As described above, at such time that XOMA receives total payments under the Agreements equal to an amount that exceeds \$88.0 million, XOMA will pay \$11.0 million to Daré for each successive \$22.0 million XOMA receives under the Agreements.

Pursuant to the Traditional Royalty Purchase Agreement, XOMA, at its sole cost and discretion, may repay in full and retire all of Daré’s payment obligations to UiE under the UiE Agreement. If XOMA does so, no further amounts in respect of the UiE Agreement will be deducted from the net royalties and net milestone payments that XOMA is entitled to receive under the Traditional Royalty Purchase Agreement. As of April 29, 2024, Daré cannot elect to receive any additional funding from UiE under the UiE Agreement without XOMA’s prior written consent.

In connection with the Synthetic Royalty Purchase Agreement, Daré granted to XOMA a security interest in certain product assets related to Ovaprene and Sildenafil Cream.

The Agreements contain certain representations and warranties regarding Daré's rights and obligations with respect to the Organon License Agreement, the Bayer License Agreement and Daré's in-license agreements relating to XACIATO™, Ovaprene and Sildenafil Cream, as well as customary representations and warranties for a transaction of this nature. The Agreements also contain customary covenants for a transaction of this nature, including covenants that limit or restrict Daré's ability to incur indebtedness or liens related to the Purchased Receivables, the Revenue Participation Right, and certain product assets related to Ovaprene and Sildenafil Cream (except pursuant to a suitable intercreditor agreement). The Agreements do not restrict Daré's ability to out-license any of its products or product candidates.

The foregoing description of the Agreements does not purport to be complete and is qualified in its entirety by reference to the Agreements, each of which the Company intends to file as an exhibit to its quarterly report on Form 10-Q for the quarter ending June 30, 2024, with certain private or confidential provisions or terms redacted.

Item 2.01 Completion of Acquisition or Disposition of Assets.

To the extent required by Item 2.01 of Form 8-K, the information contained in Item 1.01 of this report is incorporated herein by reference.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

To the extent required by Item 2.03 of Form 8-K, the information contained in Item 1.01 of this report is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On April 30, 2024, Daré issued a press release announcing its entry into the Agreements, a copy of which is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1	Press release issued on April 30, 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: April 30, 2024

By: /s/ Sabrina Martucci Johnson

Name: Sabrina Martucci Johnson

Title: President and Chief Executive Officer

Daré Bioscience Secures \$22 Million in Non-Dilutive Strategic Royalty Financing to Advance Phase 3 First-in-Category Women's Health Product Candidates through Key Catalysts

\$22 million of non-dilutive capital at close provides significant capital to achieve objectives

Upon achieving a pre-specified return threshold, XOMA will make upside-sharing milestone payments to Daré representing 50% of the future payments otherwise payable to XOMA

Transaction allows Daré to focus on advancing Phase 3 first-in-category investigational products Ovaprene[®], a potential first FDA-approved hormone-free intravaginal monthly contraceptive, and Sildenafil Cream, 3.6%, a potential first FDA-approved treatment for female sexual arousal disorder through key catalysts

Previously announced royalty financing remains outstanding, bringing royalty-based capital committed to \$34 million

SAN DIEGO, April 30, 2024 – Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced it has closed a royalty monetization transaction with XOMA (US) LLC. Daré received \$22 million in gross proceeds at close and, following a pre-specified total return to XOMA, XOMA will make upside-sharing milestone payments to Daré equal to 50% of all remaining cash flows sold to XOMA under the transaction.

"This monetization of future net royalty and net milestone payments based on net sales of XACIATO™ (clindamycin phosphate) vaginal gel 2% under our license agreement with Organon, along with a low single digit minority interest in net payments related to future revenue from our Phase 3 candidates, Ovaprene and Sildenafil Cream, accelerates potential cash flows from the future commercial success of XACIATO and such product candidates, providing us with non-dilutive capital at an opportune time to drive shareholder value through the continued advancement of Ovaprene and Sildenafil Cream, both of which are first-in-category and represent large market opportunities," said Sabrina Martucci Johnson, President and Chief Executive Officer of Daré Bioscience.

"Importantly, this transaction ensures that Daré and our shareholders have the opportunity to participate meaningfully in XACIATO economics as commercialization progresses. The structure of these agreements also underscores the significant potential of Ovaprene and Sildenafil Cream, with Daré retaining the significant majority of future economics and the ability to achieve attractive margins through retained net sales and all commercial milestones. This transaction exemplifies our commitment to being creative, collaborative and opportunistic in seeking capital at an attractive cost to advance our potential first-in-category Phase 3 candidates to deliver value for all Daré stakeholders."

The transaction involves the sale of (a) the remaining royalties and potential milestones based on net sales of XACIATO payable to Daré under its global license agreement with Organon after deducting (i) all amounts due on such royalties and milestone payments to third-party licensors, and (ii) all payments owed by Daré under its existing royalty interest financing agreement with United in Endeavour, LLC, (b) 25% of the potential \$20 million payment due to Daré under its license agreement with Bayer relating to Ovaprene, in the event Bayer, in its sole discretion, elects to make the payment¹, and (c) a 4% synthetic royalty on net sales of Ovaprene and a 2% synthetic royalty on net sales of Sildenafil Cream, subject to an automatic decrease to 2.5% and 1.25%, respectively, as described below. Once XOMA achieves a pre-specified total return on its investment, XOMA will pay to Daré 50% of each successive \$22 million that XOMA receives under the transaction agreements, and, once XOMA achieves another pre-specified total return on its investment, the synthetic royalty rates on net sales of Ovaprene and Sildenafil Cream will automatically decrease to 2.5% and 1.25%, respectively, which, after taking into account the \$11 million payments to Daré after XOMA achieves the initial pre-specified total return, results in a lower effective royalty rate.

TD Cowen, a division of TD Securities, acted as exclusive financial advisor to Daré Bioscience on the transaction. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. served as Daré's legal advisor while XOMA was advised by Gibson, Dunn & Crutcher LLP.

Additional information regarding the transaction is available in Daré's Current Report on Form 8-K filed with the Securities and Exchange Commission today.

1 - Daré retains 75% of the potential \$20 million payment and has no downstream obligations with respect to such payment.

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 Daré’s use of proceeds from its transaction with XOMA, potential ongoing milestone payments from XOMA, the potential for lower effective synthetic royalty rates on net sales of Ovaprene and Sildenafil Cream, Daré’s expectation that proceeds from the transaction will provide sufficient capital to advance Ovaprene and Sildenafil Cream through key catalysts, the continued advancement of Ovaprene and Sildenafil Cream, the potential market opportunity for Ovaprene and Sildenafil Cream, if approved, and Daré’s ability to deliver value for all Daré stakeholders. In addition, 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.

Contacts:

Media and Investors on behalf of Daré Bioscience, Inc:

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