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): August 12, 2024

DARÉ BIOSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36395**	**20-4139823**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 2.02 Results of Operations and Financial Condition.

On August 12, 2024, Daré Bioscience, Inc. (the "Company"), issued a press release announcing its financial results for the quarter ended June 30, 2024, a copy of which is furnished as Exhibit 99.1 to this report.

The information under this Item 2.02 and in Exhibit 99.1 is being furnished and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on August 12, 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: August 12, 2024

By: */s/ Sabrina Martucci Johnson*

Name: Sabrina Martucci Johnson

Title: President and Chief Executive Officer

Daré Bioscience Reports Second Quarter 2024 Financial Results and Provides Company Update

Conference Call and Webcast Today at 4:30 p.m. ET

Development Program Highlights and Anticipated 2024 Milestones

- **Ovaprene®** hormone-free monthly intravaginal contraceptive candidate pivotal Phase 3 contraceptive efficacy study recruiting across the United States
- **Sildenafil Cream, 3.6%** topical formulation of sildenafil being developed to treat female sexual arousal disorder continued operational progress toward a planned Phase 3 study; additional FDA feedback forthcoming; Phase 3 design, development, and collaboration strategy updates

SAN DIEGO August 12, 2024 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, today reported financial results for the quarter ended June 30, 2024 and provided a company update.

“In addition to the continued commercialization by our collaborator Organon of XACIATO™ (clindamycin phosphate) vaginal gel 2%, the first FDA-approved product to emerge from our portfolio and a treatment for bacterial vaginosis in females aged 12 and older* that is available by prescription nationwide, we continue to advance our first-in-category Phase 3 development candidates. Enrollment in our Phase 3 study of Ovaprene, our potentially first-in-category hormone-free monthly intravaginal contraceptive candidate, is ongoing at sites across the U.S. and we continue to see a robust response to the central advertising campaign that went live in March. We are continuing our interactions with the FDA regarding the Phase 3 program for Sildenafil Cream 3.6% in female sexual arousal disorder. While we await additional FDA feedback, we have been performing operational activities to support the planned Phase 3 program. Despite its high prevalence, there are currently no FDA-approved treatments for female sexual arousal disorder,” said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. “The progress across our portfolio, along with the $22 million we secured in the non-dilutive strategic royalty financing we announced in the second quarter, puts Daré on track for meaningful milestones in 2024. In addition, we are excited about the increased attention on the health and wellbeing of women, including by grant making agencies, and continue to execute on our mission to accelerate development of and bring to market innovative treatments that women want and need by advancing our late-stage candidates – all of which represent a first-in-category opportunity – as we seek to deliver value for all Daré stakeholders.”

**Please see below for important safety and other information.*

Ovaprene® Phase 3 Study

Ovaprene is a novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer HealthCare.

Working with study collaborators at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH) and commercial collaborator Bayer, Daré commenced patient enrollment in the Ovaprene® pivotal Phase 3 clinical study in December 2023. Non-hormonal contraception represents a significant commercial market opportunity, and there are currently no monthly, hormone-free contraceptives approved by the FDA. Ovaprene® has potential to be a disruptive product in the contraceptive category and an important option for women who cannot use hormone-based birth control products or prefer not to do so.

Recruitment is currently underway at 20 sites across the United States, supported by a central advertising campaign for the study that launched in March 2024. Phase 3 study updates will be provided as relevant throughout 2024. Based on the current average enrollment rate across the 20 study sites, we anticipate that approximately half of our target number of participants to complete the study, or 125 women, will complete approximately 6 months of product use by the end of the second quarter of 2025.

Sildenafil Cream, 3.6% Progress toward Phase 3 Study

Sildenafil Cream is a proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical on-demand administration to treat female sexual arousal disorder.

Daré completed all study analyses of data from the exploratory Phase 2b RESPOND clinical study and held an end-of-Phase 2 meeting with the FDA in December 2023. In prior quantitative studies, Sildenafil Cream increased genital tissue blood flow, and the Phase 2b at-home study was specifically designed to identify the patient population that experienced the most meaningful improvement from Sildenafil Cream and the questions to ask them that best reflect that improvement. The patient population and the endpoints proposed to the FDA for Phase 3 clinical development were those where Daré's exploratory post-hoc analyses of the Phase 2b study data showed that Sildenafil Cream demonstrated statistically significant and meaningful patient improvement. Daré continues to interact with the FDA on the development program for Sildenafil Cream as a treatment for female sexual arousal disorder, and is awaiting additional feedback from the FDA on the proposed endpoints, as well as additional information on data that may be needed in an NDA submission to appropriately qualify any ingredient (other than sildenafil) for the vaginal route of administration. Daré also requested clarification on the safety database (size and duration exposure) that the FDA will require for an NDA submission. Initiating a Phase 3 study is contingent on aligning with the FDA regarding the foregoing. Based on FDA feedback we have received, two successful Phase 3 clinical studies of Sildenafil Cream will be required to support an NDA for Sildenafil Cream for the treatment of FSAD, and we anticipate that each Phase 3 study will cost approximately $15.0 million. We will take into account our capital resources before initiating a Phase 3 study.

Daré's planned initial Phase 3 study of Sildenafil Cream, 3.6% would be the first ever Phase 3 pivotal study of a therapeutic candidate for the treatment of arousal disorder in women. Daré intends to provide updates on the Phase 3 program, as well as relevant updates on the initial Phase 3 study timing and Daré's collaboration strategy as they become available.

Financial Highlights for the Quarter ended June 30, 2024

- Cash and cash equivalents: $16.4 million at June 30, 2024. In April 2024, Daré received $22 million in gross proceeds in a non-dilutive royalty monetization transaction with XOMA (US) LLC and a $1 million payment as the latest installment under an up to $49 million grant agreement with a foundation in support of nonclinical development of the investigational contraceptive, DARE-LARC1. To date, Daré has received approximately $29.3 million under the DARE-LARC1 grant agreement.
- General and administrative expenses: $2.4 million in 2Q-2024 as compared to $2.9 million in 2Q-2023, with the current quarter's decrease primarily attributable to reduced headcount and reduced professional services expense.
- Research and development (R&D) expenses: $4.9 million in 2Q-2024 as compared to $6.0 million in 2Q-2023, a 19% decrease compared to Q2-2023, with the current quarter's decrease primarily attributable to decreases in costs related to development activities for Sildenafil Cream as a result of the Phase 2b RESPOND clinical study completion in June 2023 and decreases in costs related to development activities for our other programs, offset by increases in costs related to our ongoing pivotal Phase 3 clinical trial of Ovaprene.

Conference Call

Daré will host a conference call and live webcast today, August 12, 2024, at 4:30 p.m. Eastern Time to review financial results for the quarter ended June 30, 2024 and to provide a company update.

To access the conference call via phone, dial (646) 307-1952 (U.S.) or (888) 672-2415 (toll free). The conference ID number for the call is 6756565. The live webcast can be accessed under “Presentations, Events & Webcasts” in the Investors section of the company’s website at http://ir.darebioscience.com. Please log in approximately 5-10 minutes prior to the call to register and to download and install any necessary software. The webcast will be archived under “Presentations, Events & Webcasts” in the Investors section of the company’s website at http://ir.darebioscience.com and available for replay until August 26, 2024.

About XACIATO™ (clindamycin phosphate) vaginal gel 2%

XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years and older. A single-dose user-filled disposable applicator delivers 5g of vaginal gel containing 100mg of clindamycin.

Selected Safety Information

XACIATO is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin.

Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile may need to be discontinued.

Polyurethane condoms are not recommended during treatment with XACIATO or for 7 days following treatment. During this time period, polyurethane condoms may not be reliable for preventing pregnancy or for protecting against transmission of HIV and other sexually transmitted diseases. Latex or polyisoprene condoms should be used.

XACIATO may result in the overgrowth of Candida spp. in the vagina resulting in vulvovaginal candidiasis, which may require antifungal treatment.

The most common adverse reactions reported in >2% of patients and at a higher rate in the XACIATO group than in the placebo group were vulvovaginal candidiasis and vulvovaginal discomfort.

XACIATO has not been studied in pregnant women. However, based on the low systemic absorption of XACIATO following the intravaginal route of administration in nonpregnant women, maternal use is not likely to result in significant fetal exposure to the drug.

There are no data on the effect of clindamycin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for clindamycin and any potential adverse effects on the breastfed child from clindamycin or from the underlying maternal condition.

Please see the Prescribing Information, Patient Information, and Instructions for Use.

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 plans and expectations with respect to Daré's product candidates, including clinical development plans, trial design, timelines, costs and milestones, targeted indications, and anticipated regulatory approval pathways, the potential for FDA approval of Ovaprene based on a single pivotal clinical study, the expectation that a product candidate could be a first-in-category product, and the potential market size and opportunity for a product candidate, if approved. 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:

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Source: Daré Bioscience, Inc.

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(Unaudited)

	Three months ended June 30,	
	2024	**2023**
Revenue		
Royalty revenue	$ 22,438	$ -
Total revenue	22,438	
Operating expenses		
General and administrative	2,448,130	2,920,672
Research and development	4,908,774	6,043,684
License fee expense	25,000	25,000
Total operating expenses	7,381,904	8,989,356
Loss from operations	(7,359,466)	(8,989,356)
Other income (expense)		
Sale of royalty and milestone rights, net	20,379,376	-
Other income (expense), net	(109,254)	227,124
Net income (loss)	$ 12,910,656	$ (8,762,232)
Foreign currency translation adjustments	$ 14,563	$ (31,151)
Comprehensive income (loss)	$ 12,925,219	$ (8,793,383)
Income (loss) per common share:		
Basic	$ 1.53	$ (1.22)
Diluted	$ 1.52	$ (1.22)
Weighted average number of shares outstanding:		
Basic	8,411,242	7,200,260
Diluted	8,476,231	7,200,260

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets Data

	June 30, 2024	**December 31, 2023**
	(unaudited)	
Cash and cash equivalents	$ 16,414,992	$ 10,476,056
Working capital (deficit)	$ 6,239,522	$ (2,936,897)
Total assets	$ 23,606,239	$ 21,282,215
Total stockholders' equity (deficit)	$ 2,671,506	$ (5,047,640)