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 28, 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 March 28, 2024, Daré Bioscience, Inc. (the "Company"), issued a press release announcing its financial results for the fiscal year ended December 31, 2023, 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 March 28, 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: March 28, 2024

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

Daré Bioscience Reports Full Year 2023 Financial Results and Provides Company Update

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

2023 Highlights and Anticipated 2024 Milestones

- **XACIATO™** (clindamycin phosphate) vaginal gel 2% is available by prescription in the United States to treat bacterial vaginosis under license agreement with commercial collaborator Organon
- **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 successful completion of end-of-Phase 2 meeting with FDA; forthcoming additional FDA feedback; Phase 3 design, development, and collaboration strategy updates

SAN DIEGO March 28, 2024 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the year ended December 31, 2023 and provided a company update.

"We are pleased with the incredible progress we made in 2023 with our late-stage candidates and on-market product, including the U.S. launch of XACIATO™, Sildenafil Cream Phase 2b study completion and Ovaprene Phase 3 study commencement, which put us on track for meaningful milestones in 2024 across multiple programs. In addition, we are excited about the increased attention that women's health has received more broadly," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "I had the pleasure of attending in person both the ARPA-H Sprint for Women's Health announcement event in Boston in February and the White House reception in March in honor of Women's History Month where President Biden signed an executive order dedicated to advancing women's health research, and it is encouraging to see further, comprehensive action aimed at increasing investments in women's health. They bring focus to and financial support for the entire ecosystem working to boldly innovate for women. We look forward to continuing to execute on our mission to accelerate development of and bring to market innovative treatments that women want and need, and to evaluate a wide range of financing opportunities to fund our robust portfolio. Our 2023 achievements demonstrate our commitment to advancing our late-stage candidates – all of which represent a first-in-category opportunity – while seeking to continue to deliver value for all Daré stakeholders."

In 2023, Daré announced the first shipment of XACIATO™ in connection with its launch in the United States, had 15 interactions with the U.S. Food and Drug Administration (FDA) across six product candidates / indications, commenced the Phase 3 clinical study for its hormone-free monthly intravaginal contraceptive candidate Ovaprene, completed the Phase 2b study of its investigational Sildenafil Cream product for female sexual arousal disorder and the Phase 1 study of its investigational vaginal diclofenac product DARE-PDM1 for menstrual pain, and received IND clearance for DARE-VVA1, its hormone-free candidate for sexual pain.

XACIATO™ U.S. Launch Underway

XACIATO (clindamycin phosphate) vaginal gel 2% is indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older. *Please see below for important safety and other information.*

Bacterial vaginosis is the most common vaginal condition in women of reproductive age in the United States, affecting approximately 23 million women. The condition results from an overgrowth of certain bacteria, which upsets the balance of the natural vaginal microbiome and can lead to symptoms of odor and discharge. Bacterial vaginosis may self-resolve in up to 30% of women, but most symptomatic women require treatment. If left untreated, bacterial vaginosis may lead to serious complications. Bacterial vaginosis has also been shown to disproportionately affect non-Hispanic Black and Mexican American women.

On October 16, 2023, Daré announced the first shipment of XACIATO™ in connection with its launch in the U.S., triggering a $1.8 million first commercial milestone payment from collaborator Organon. XACIATO™ provides a new therapeutic option for the millions of women suffering from bacterial vaginosis in the U.S. On January 10, 2024, Organon announced that XACIATO is available nationwide by prescription to treat bacterial vaginosis.

As an on-market product, XACIATO represents a non-dilutive source of revenue for Daré. Daré is eligible to receive double digit royalties based on net sales and up to $180 million in potential milestone payments from Organon. Quarterly revenue and launch updates will be provided throughout 2024.

Ovaprene® Phase 3 Study Start

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 17 sites across the United States, supported by a central advertising campaign for the study that launched in March 2024. Phase 3 study recruitment and data updates will be provided as relevant throughout 2024.

Positive Data for Sildenafil Cream, 3.6%

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 has 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 identified in the Phase 2b study and proposed to the FDA for Phase 3 clinical development were those where Daré's post-hoc analyses of the Phase 2b study data showed that Sildenafil Cream demonstrated statistically significant and meaningful patient improvement. Daré is continuing to interact with the FDA as the FDA reviews, specifically, the data generated on the proposed endpoints to take forward into Phase 3 development. The FDA has indicated it anticipates providing additional feedback on the Phase 3 design in 2Q-2024.

Daré's planned 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 FDA feedback, Phase 3 study design and plans, as well as any relevant updates on its collaboration strategy as available in 2024.

DARE-PDM1

A proprietary, investigational formulation of diclofenac for intravaginal administration to treat menstrual cramping pain (dysmenorrhea).

In December 2023, Daré announced positive topline results from the Phase 1 study evaluating the pharmacokinetics (PK), safety, and exploratory efficacy of DARE-PDM1. DARE-PDM1 is an investigational product designed to deliver diclofenac, a nonsteroidal anti-inflammatory drug (NSAID), vaginally via the company's proprietary hydrogel to treat primary dysmenorrhea, which is defined as painful menstruation in women with normal pelvic anatomy. DARE-PDM1 has the potential to be a first-in-category product, delivering diclofenac in a convenient vaginal format that may extend the duration of menstrual pain relief provided by and reduce the risks associated with the oral delivery of NSAIDs. Based on the positive results, Daré is evaluating next steps in the development program.

DARE-VVA1

A proprietary, investigational formulation of tamoxifen for intravaginal administration to treat sexual pain (dyspareunia) in women without the use of hormones.

In December 2023, Daré announced that the FDA cleared its investigational new drug (IND) application for DARE-VVA1, a novel intravaginal proprietary formulation of tamoxifen being developed as a non-hormonal treatment option for moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA) associated with menopause. Products containing estrogen are commonly used to treat VVA, but some women cannot or choose not to use these products, including those with a history of hormone-receptor positive (HR+) breast cancer.

With the IND clearance from the FDA, Daré can begin planning for an anticipated Phase 2 randomized, double-blinded, placebo-controlled, dose-finding clinical study of DARE-VVA1. Such planning and preparatory activities are underway.

Financial Highlights for the Year Ended December 31, 2023 and 2024 Projections

- Cash and cash equivalents: $10.5 million at December 31, 2023. During 2023, Daré received approximately $4.7 million in nondilutive grant funding and also completed a $7.0 million registered direct offering in September and a $12.0 million royalty-backed financing structure in December, under which Daré received $5 million and may, in its sole discretion, elect to receive up to an additional $7 million in three tranches over time.

- During 2023, Daré recognized total revenue of approximately $2.8 million, which included a $1.0 million payment in July 2023 and an additional $1.8 million milestone payment in October 2023 from Daré's commercial collaborator Organon relating to XACIATO. Daré reported a net loss for 2023 of approximately $30.1 million.

- General and administrative (G&A) expenses were approximately $12.1 million for 2023, which was up approximately 8% compared to the prior year. Daré has made fiscal responsibility a top priority, maintaining a lean and focused team and managing overhead costs closely. To that end, Daré expects a reduction in 2024 G&A expenses to approximately $10.0 million (which, however, does not reflect $10 million in capital required to fund G&A expenses since approximately $3.0 million of projected 2024 G&A expenses is estimated accrual based non-cash expenses).

- Research and development (R&D) expenses were approximately $21.5 million in 2023, compared to approximately $30.0 million in the prior year, and primarily reflected the costs of the Phase 1 and Phase 2b studies of Sildenafil Cream, the Phase 1 study of DARE-PDM1, and manufacturing activities as well as preparing for and beginning enrollment in the Phase 3 study of Ovaprene. Currently in 2024, Daré's only active clinical study is the Phase 3 pivotal study of Ovaprene, for which Daré remitted in prior years all but $0.5 million of funds due to the NIH to support the study under the Cooperative Research and Development Agreement (CRADA), and therefore, planned Ovaprene expenses in 2024 will be primarily associated with certain manufacturing activities. Apart from Ovaprene related expenses, currently projected 2024 R&D expenses are primarily carry-over/ close out expenses from the studies completed in 2023. Therefore, until such time as any additional late-stage clinical study is commenced, Daré expects 2024 R&D expenses to be considerably less than the 2023 R&D expenses.

Conference Call

Daré will host a conference call and live webcast today, March 28, 2024, at 4:30 p.m. Eastern Time to review financial results for the year ended December 31, 2023 and to provide a company update.

To access the conference call via phone, dial (646) 307-1963 (U.S.) or (800) 715-9871 (international). The conference ID number for the call is 7156675. 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 April 11, 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 and milestones, targeted indications, and anticipated regulatory approval pathways, the potential for FDA approval of a product candidate based on a single pivotal clinical study, the expectation that a product candidate could be a first-in-category product, the potential market size and opportunity for a product candidate, if approved, and financial projections for 2024. 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:

Camilla White / Simona Kormanikova
Dentons Global Advisors
DareBioscience@dentonsglobaladvisors.com / 1.212.466.6450

Source: Daré Bioscience, Inc.

Dare Bioscience, Inc. and Subsidiaries
Consolidated Statement of Operations and Comprehensive Loss

	Years Ended December 31,	
	2023	2022
Revenue		
License fee revenue	$ 1,000,000	$ 10,000,000
Milestone revenue	1,800,000	-
Royalty revenue	7,885	-
Total revenue	2,807,885	10,000,000
Operating expenses		
General and administrative	12,109,691	11,243,271
Research and development	21,538,074	30,042,217
License fee expense	100,000	100,000
Total operating expenses	33,747,765	41,385,488
Loss from operations	(30,939,880)	(31,385,488)
Other income	778,489	437,750
Net loss	$ (30,161,391)	$ (30,947,738)
Net loss to common shareholders	(30,161,391)	(30,947,738)
Foreign currency translation adjustments	(9,585)	(196,338)
Comprehensive loss	$ (30,170,976)	$ (31,144,076)
Loss per common share - basic and diluted	$ (0.35)	$ (0.37)
Weighted average number of common shares outstanding:		
Basic and diluted	87,303,701	84,571,805

Dare Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets Data

	December 31,	
	2023	2022
Cash and cash equivalents	$ 10,476,056	$ 34,669,605
Working capital (deficit)	$ (2,936,897)	$ 11,414,826
Total assets	$ 21,282,215	$ 43,826,383
Total liabilities	$ 26,329,855	$ 32,714,273
Total stockholders' equity (deficit)	$ (5,047,640)	$ 11,112,110