



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

05-14-2024 at 8:00 AM EDT

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 successful completion of end-of-Phase 2 meeting with FDA; forthcoming additional FDA feedback; Phase 3 design, development, and collaboration strategy updates

SAN DIEGO, May 14, 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 March 31, 2024 and provided a company update.

"The progress across our portfolio in the first quarter, along with the \$22 million we secured in the non-dilutive strategic royalty financing we announced a couple of weeks ago, puts Daré on track for meaningful milestones in 2024," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "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 are pleased with the progress of our first-in-category Phase 3 development candidates. We continue to enroll our Phase 3 study of Ovaprene, our potentially first-in-category hormone-free monthly intravaginal contraceptive candidate, at sites across the U.S. and are thrilled with the response to the central advertising campaign that went live in March. We are also progressing toward a Phase 3 trial of Sildenafil Cream 3.6% in female sexual arousal disorder, for which there are currently no FDA-approved treatments. We are excited about the increased attention in the media, government, and grant making agencies on the health and wellbeing of women, 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 18 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.

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

Financial Highlights for the Quarter ended March 31, 2024

- Cash and cash equivalents: \$3.6 million at March 31, 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 \$29.4 million under the DARE-LARC1 grant agreement.

- General and administrative expenses: \$2.7 million in 1Q-2024 as compared to \$3.3 million in 1Q-2023, with the current quarter's decrease primarily attributable to decreases in general corporate overhead.
- Research and development (R&D) expenses: \$3.3 million in 1Q-2024 as compared to \$5.0 million in 1Q-2023, a 34% decrease compared to Q1-2023. Close-out expenses related to the Phase 2b RESPOND clinical study of Sildenafil Cream and other clinical studies conducted in 2023 contributed significantly to Daré's 1Q-2024 R&D expenses, which will not be the case in future quarters. Until Daré commences a Sildenafil Cream Phase 3 clinical study, Daré expects R&D expenses for future quarters to be lower than its 1Q-2024 R&D expenses.

Conference Call

Daré will host a conference call and live webcast today, May 14, 2024, at 4:30 p.m. Eastern Time to review financial results for the quarter ended March 31, 2024 and to provide a company update.

To access the conference call via phone, dial (646) 307-1963 (U.S.) or (800) 715-9871 (toll free). The conference ID number for the call is 5582540. 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 May 28, 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, the potential market size and opportunity for a product candidate, if approved, and financial projections. 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.

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Source: Daré Bioscience, Inc.

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

	Three Months Ended March 31,	
	2024	2023
Revenue		
Royalty revenue	\$ 9,302	\$ -
Total revenue	9,302	-
Operating expenses		
General and administrative	2,670,581	3,337,426

Research and development	3,328,520	5,020,223
Royalty expense	7,674	-
License fee expense	25,000	25,000
Total operating expenses	6,031,775	8,382,649
Loss from operations	(6,022,473)	(8,382,649)
Other income (expense)	(732,883)	340,148
Net loss	\$ (6,755,356)	\$ (8,042,501)
Foreign currency translation adjustments	(39,227)	(22,005)
Comprehensive loss	\$ (6,794,583)	\$ (8,064,506)
Loss per common share - basic and diluted	\$ (0.07)	\$ (0.09)
Weighted average number of shares outstanding:		
Basic and diluted	100,514,272	85,517,540

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

	March 31, 2023 (unaudited)	December 31, 2023
Cash and cash equivalents	\$ 3,630,603	\$ 10,476,056
Working capital deficit	\$ (7,742,348)	\$ (2,936,897)
Total assets	\$ 13,012,722	\$ 21,282,215
Total stockholders' deficit	\$ (10,999,410)	\$ (5,047,640)



Source: Daré Bioscience, Inc.