Daré Bioscience Reports Third Quarter 2023 Financial Results and Provides Company Update

11-09-2023 at 8:00 AM EST

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

What to Expect for the Remainder of 2023

- **XACIATO™**: receipt of $1.8 million triggered by achievement of first commercial milestone under license agreement with Organon
- **Ovaprene®**: commencement of pivotal Phase 3 contraceptive efficacy study
- **Sildenafil Cream, 3.6%:** end-of-Phase 2 meeting with FDA
- **DARE-PDM1**: Phase 1 clinical study topline data

SAN DIEGO, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the quarter ended September 30, 2023 and provided a company update.

"We are pleased with the incredible progress we have made since the beginning of the third quarter, including the U.S. launch of XACIATO™ and moving several of our product candidates forward, further positioning the company for long-term success," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The fourth quarter is also proving to be a busy one for Daré, and we remain on track to have multiple meaningful milestones by the end of 2023 as we execute on our mission to accelerate development of and bring to market innovative treatments that women want and need."

Recent Highlights

XACIATO™U.S. Launch Underway

On October 16, 2023, Daré announced the first shipment of XACIATO™ in connection with its launch in theU.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.

Progress Toward Ovaprene® Phase 3 Study Start

Following additional progress 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 Bayer, Daré remains on target to commence patient enrollment in the Ovaprene® pivotal Phase 3 clinical study in the fourth quarter of this year. Non-hormonal contraception represents a significant commercial market opportunity, and there are currently no monthly, hormone-free contraceptives approved by the U.S. Food and Drug Administration (FDA). Ovaprene® is an investigational monthly, intravaginal, hormone-free contraceptive with the 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.

Additional Positive Data for Sildenafil Cream, 3.6%

Daré has completed all study analyses of data from the exploratory Phase 2b RESPOND clinical study in preparation for the upcoming end-of-Phase 2 FDA meeting in the fourth quarter of this year. On November 2, 2023, the company reported additional positive data from the Phase 2b RESPOND study, which indicate that Daré can use its Phase 2b study approach in Phase 3. Specifically, Daré plans to propose a Phase 3 clinical study with the same co-primary endpoint structure used in the Phase 2b RESPOND study, which assesses arousal sensation and evaluates concerns related to difficulties with sexual arousal, and will propose evaluating Sildenafil Cream, 3.6% in a broader patient population of women that includes women with female sexual arousal disorder (FSAD) as well as those with arousal plus desire disorder (female sexual interest/arousal disorder, or FSIAD). 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 Portfolio Summary

- One FDA approved product, XACIATO™
- 13 development programs across 9 distinct indications
- 3 products in, or nearing, Phase 3 clinical development
- Multiple meaningful product development milestones anticipated by year end 2023

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

- **3Q-2022:** $10.0 million cash payment received under commercial license agreement with Organon

- **2H-2023**: $1.0 million cash payment received and $1.8 million first commercial milestone payment triggered under commercial license agreement with Organon

  Bacterial vaginosis is the most common vaginal condition in women of reproductive age in the United States. The condition results from an overgrowth of 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.

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

- **4Q-2022**: Investigator meeting held (with NICHD) for the pivotal Phase 3 clinical study
- **4Q-2023:** Anticipated initiation of subject enrollment in the pivotal Phase 3 clinical study, a single arm, open-label contraceptive efficacy study over 12 months (13 menstrual cycles) of use

  The pivotal Phase 3 clinical study will be conducted under a Cooperative Research and Development Agreement with the U.S. Department of Health and Human Services, as represented by NICHD, part of the NIH.

Sildenafil Cream, 3.6%
A proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical on-demand administration to treat female sexual arousal disorder and/or female sexual interest/arousal disorder.

- **2Q-2023**: Initiated Phase 1 thermography study with expected completion in 2023
- **2Q-2023:** Announced positive topline data from exploratory Phase 2b RESPOND clinical study
- **4Q-2023**: Planned end of Phase 2 meeting with the FDA to confirm Phase 3 study design

DARE-HRT1
A unique, investigational intravaginal ring designed to deliver bio-identical estradiol and progesterone continuously over a 28-day period for the treatment of moderate to severe vasomotor symptoms, as part of menopausal hormone therapy.

- **4Q-2022:** Positive topline efficacy data reported from Phase 1/2 clinical study
- **1Q-2023:** Positive topline pharmacokinetic (PK) data reported from Phase 1/2 clinical study, and plans to progress to a single Phase 3 study announced

DARE-VVA1
A proprietary, investigational formulation of tamoxifen for intravaginal administration to treat vulvovaginal atrophy in women without the use of hormones.

- **4Q-2022:** Positive topline safety, tolerability, PK and pharmacodynamics data reported from Phase 1/2 clinical study
- **4Q-2023**: Activities underway to support IND submission to FDA to allow for Phase 2 study initiation

Financial Highlights for the Quarter ended September 30, 2023

- Cash and cash equivalents: $13.8 million at September 30, 2023. The company is currently evaluating a wide range of financing opportunities, including creative and innovative vehicles to fund its portfolio.
- General and administrative (G&A) expenses: $2.7 million in 3Q-2023, unchanged compared to $2.7 million in 3Q-2022, highlighting the company's continued focus on running a lean and efficient organization. G&A expenses for 3Q-2023 include increases in commercial readiness expenses and stock-based compensation expense compared to 3Q-2022, partially offset by decreases in personnel costs, general corporate overhead and professional services expenses.
- Research and development expenses: $6.7 million in 3Q-2023 as compared to $4.5 million in 3Q-2022, with the increase primarily attributable to increases in expenses related to the Sildenafil Cream Phase 2b RESPOND clinical study, clinical trial, manufacturing and regulatory affairs activities for Ovaprene, and preclinical and other development activities, partially offset by decreases in costs related to development activities for the company's Phase 1 and Phase 1-ready programs, personnel costs and expenses related to XACIATO.

Conference Call

Daré will host a conference call and live webcast today, November 9, 2023, at 4:30 p.m. Eastern Time to review financial results for the quarter ended September 30, 2023 and to provide a company update.

To access the conference call via phone, dial (888) 596-4144 (U.S.) or (646) 968-2525 (international). The conference ID number for the call is 2750536. 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 November 23, 2023.

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.

Daré's first FDA-approved product, XACIATO™ (clindamycin phosphate) vaginal gel 2% is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older, which is under a global license agreement with Organon. 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 to treat female sexual arousal disorder (FSAD) and/or female sexual interest/arousal disorder (FSIAD) utilizing the active ingredient in Viagra®; 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 expectations regarding achievement of milestones, receipt of a milestone payment, plans and expectations with respect to Daré's product candidates, including anticipated clinical trial design and timing for commencement and conduct of clinical trials and announcement of topline results, 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, and the potential market size and opportunity for a product candidate, if approved. 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 September 30,	
	2023	**2022**
Revenue		
License fee revenue	$ 1,000,000	$ -
Total revenue	1,000,000	-
Operating expenses		
General and administrative	$ 2,696,779	$ 2,651,543
Research and development	6,674,636	4,462,250
License fee expense	25,000	25,000
Total operating expenses	9,396,415	7,138,793
Loss from operations	(8,396,415)	(7,138,793)
Other income	97,319	118,950
Net loss	$ (8,299,096)	$ (7,019,843)
Foreign currency translation adjustments	(15,030)	(230,748)
Comprehensive loss	$ (8,314,126)	$ (7,250,591)
Loss per common share - basic and diluted		
Weighted average number of shares outstanding:		
Basic and diluted	91,051,642	84,822,516

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

	September 30, 2023	**December 31, 2022**
	(unaudited)	

Cash and cash equivalents	$	13,894,424	$	34,669,605
Working capital	$	(3,907,275)	$	11,414,826
Total assets	$	25,054,030	$	43,826,383
Total stockholders' equity	$	(2,288,740)	$	11,112,110

Source: Daré Bioscience, Inc.