Daré Bioscience Reports Second Quarter 2023 Financial Results and Provides a Company Update

08-10-2023 at 8:00 AM EDT

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

Second Half 2023 Anticipated Milestones (target indication(s))**:**

- **XACIATO™** First Commercial Sale
- **Ovaprene®** (hormone-free monthly contraception) – Pivotal Phase 3 Contraceptive Efficacy Study – Patient Enrollment to Begin 4Q2023
- **Sildenafil Cream, 3.6%** (female sexual arousal disorder and female sexual interest/arousal disorder) - preparations for end-of-Phase 2 meeting with FDA
- **DARE-PDM1** (primary dysmenorrhea) – Phase 1 Clinical Study Topline Data
- **Menopause programs**: IND related activities for **DARE-HRT1** (vasomotor symptoms of menopause) and **DARE-VVA1** (vulvovaginal atrophy, a common condition in postmenopausal women, including those whose menopause resulted from receiving certain breast cancer treatments); Phase 3 and Phase 2 clinical study initiation plans, respectively

SAN DIEGO, Aug. 10, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the quarter ended June 30, 2023, and provided a company update.

"We are particularly proud of the milestone we reached in June – the announcement of the topline data from our exploratory Phase 2b RESPOND study evaluating topical Sildenafil Cream, 3.6% as a treatment for female sexual arousal disorder. This study was the first at-home, Phase 2 clinical study by a pharmaceutical drug development company to address a distressing condition for women that is analogous to erectile dysfunction for men utilizing a novel topical cream formulation of sildenafil, the active ingredient in Viagra®," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The group receiving Sildenafil Cream in the RESPOND study demonstrated improvements in arousal lubrication, orgasm and sexual desire, which persisted through the end of study assessment. Based on data from the study, demonstrating improvement in multiple facets of female sexual dysfunction, and because there is no FDA-approved product for the treatment of female sexual arousal disorder or female sexual interest/arousal disorder, Sildenafil Cream has the potential to be a first-in-category product with a market opportunity comparable in size to the erectile dysfunction market."

"We also remain very enthusiastic about rest of 2023 given two highly anticipated milestones," said Ms. Johnson. "First, we are on track to begin patient enrollment in what we believe will be the single pivotal Phase 3 study for Daré's late-stage portfolio candidate, Ovaprene, an investigational, hormone-free, monthly intravaginal contraceptive designed to be an easy-to-use monthly option with effectiveness approaching hormonal methods and whose U.S. commercial rights are under a license agreement with Bayer. Second, we are looking forward to the U.S. commercial launch of XACIATO™ by our global collaboration partner, Organon. Finally, later this year we expect to announce the topline findings from our DARE-PDM1 Phase 1 trial, a multi-center, randomized, placebo-controlled, double-blind, 3-arm parallel group study of approximately 36 healthy, premenopausal women with primary dysmenorrhea, also referred to as menstrual cramps and pain. Prevalence rates of dysmenorrhea vary but range from 50% to 90%. Recent market research suggests that the global market for dysmenorrhea treatment was valued at $13 billion in 2022 and is expected to increase to $28.5 billion by 2029[1]."

1H-2023 In Review and 2H-2023 Anticipated Developments

Period	Portfolio Asset	Development/Outcome
1Q-2023	DARE-HRT1	Announced positive topline pharmacokinetic (PK) data from Phase 1/2 clinical study
	DARE-PDM1	Commenced Phase 1 clinical study
2Q-2023	Sildenafil Cream, 3.6%	Announced positive topline results of exploratory Phase 2b RESPOND clinical study
2H-2023 (expected)	XACIATO™	First commercial sale
	Ovaprene®	Initiation of enrollment in pivotal contraceptive study conducted with NICHD
	Sildenafil Cream, 3.6%	Preparation for end-of-Phase 2 meeting with FDA
	DARE-PDM1	Announcement of topline results of Phase 1 clinical study

	DARE-VVA1	IND preparation and other activities to allow initiation of Phase 2 clinical study
	DARE-HRT1	IND preparation and other activities to allow initiation of Phase 3 clinical study

Daré Portfolio Summary

- One FDA approved product, XACIATO™
- 13 development programs across 9 distinct indications
- 3 products in, or nearing, Phase 3 clinical development
- Key XACIATO, Sildenafil Cream, and Ovaprene milestones anticipated during 2H-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 click here for full prescribing information.

- **3Q-2022:** $10.0 million cash payment received under commercial license agreement with Organon
- **2H-2023**: $1.0 million cash received, and $1.8 million milestone anticipated upon 1st commercial sale

Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 23 million women in the U.S.[2] 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. In addition to being the most common type of vaginal infection in women of reproductive age and having bothersome symptoms, bacterial vaginosis has been associated with certain increased health risks, including pre-term labor and infertility. [2, 3]

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 of use (13 menstrual cycles)

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 the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health.

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

Activities related to psychometric analyses to further refine the measures and resulting endpoints from the Phase 2b RESPOND study for use in a Phase 3 pivotal clinical study and preparations for data review in an end-of-Phase 2 meeting with the FDA are underway.

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 PK data reported from Phase 1/2 clinical study, and plans to progress to a single Phase 3 study announced
- **2H-2023**: Activities underway to support an Investigational New Drug application (IND) submission and Phase 3 clinical study initiation

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
- **2H-2023**: Activities underway to support IND submission and Phase 2 clinical study initiation

Financial Highlights for the Quarter ended June 30, 2023

- Cash and cash equivalents: $13.3 million at June 30, 2023.

- General and administrative expenses: $2.9 million in 2Q-2023 as compared to $2.8 million in 2Q-2022, with the current quarter's increase primarily attributable to increases in personnel costs, professional services expense, and stock-based compensation expense, partially offset by decreases in general corporate overhead expenses.

- Research and development expenses: $6.0 million in 2Q-2023 as compared to $6.8 million in 2Q-2022, with the current quarter's decrease primarily attributable to decreases in expenses related to our Sildenafil Cream Phase 2b RESPOND clinical study, and clinical trial and manufacturing and regulatory activities for Ovaprene, partially offset by increases in costs related to development activities for our Phase 1 and Phase 1-ready programs.

[1] https://www.reanin.com/report-store/healthcare/pharmaceuticals-and-therapeutics/dysmenorrhea-treatment/global-dysmenorrhea-treatment-market, accessed 5 August 2023

[2] https://www.cdc.gov/std/bv/stats.htm and https://www.census.gov/data/datasets/2017/demo/popproj/2017-popproj.html, accessed 5 August 2023

[3] https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-20352279, accessed 5 August 2023

Conference Call

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

To access the conference call via phone, dial (800) 715-9871 (U.S.) or (646) 307-1963 (international). The conference ID number for the call is 8451277. To listen to the event and view the presentation slides via live webcast, join from the Investors section of the Company's website at http://ir.darebioscience.com under "Presentations, Events & Webcasts." Callers will be able to access the presentation slides at the same location on the Company's website. Please log in approximately 5-10 minutes prior to the call to register and to download and install any necessary software. The webcast and presentation slides 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 24, 2023.

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 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 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 the commercial launch of XACIATO in the U.S., including the timing of the first commercial sale of XACIATO, plans and expectations with respect to Daré's product candidates, including anticipated 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, risk 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 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 the COVID-19 pandemic, macroeconomic conditions and geopolitical events on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on Daré's ability to timely enroll, conduct and report results of its clinical trials and on the ability of third parties on which Daré relies to assist in the conduct of its business to fulfill their contractual obligations to Daré; 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; cyber attacks, security breaches 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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Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(Unaudited)

	Three months ended June 30,	
	2023	**2022**
Revenue		
License fee revenue	$ -	$ 10,000,000
Total revenue	-	10,000,000
Operating expenses		
General and administrative	2,920,672	2,792,894

Research and development	6,043,684	6,797,784
License fee expense	25,000	25,000
Total operating expenses	8,989,356	9,615,678
Income (loss) from operations	(8,989,356)	384,322
Other income	227,124	29,676
Net income (loss)	$ (8,762,232)	$ 413,998
Foreign currency translation adjustments	$ (31,151)	$ (135,869)
Comprehensive income (loss)	$ (8,793,383)	$ 278,129
Income (loss) per common share:		
Basic	$ (0.10)	$ 0.00
Diluted	$ (0.10)	$ 0.00
Weighted average number of shares outstanding:		
Basic	86,403,117	84,682,765
Diluted	86,403,117	85,369,424

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

	June 30, 2023	**December 31, 2022**
	(unaudited)	
Cash and cash equivalents	$ 13,329,101	$ 34,669,605
Working capital	$ (2,457,536)	$ 11,414,826
Total assets	$ 23,209,954	$ 43,826,383
Total stockholders' equity (deficit)	$ (2,719,402)	$ 11,112,110

Source: Daré Bioscience, Inc.