Daré Bioscience Completes Previously Announced Equity Financing

09-05-2023 at 8:00 AM EDT

Company looks forward to anticipated 2023 milestones, including first commercial sale of XACIATO™, enrollment in Ovaprene® pivotal Phase 3 study, and topline data from DARE-PDM1 Phase 1 study

SAN DIEGO, Sept. 05, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced the completion of its registered direct offering of common stock and warrants to purchase common stock priced at-the-market under Nasdaq rules with an institutional investor and an investor affiliated with the licensor of one of the company's early stage product candidates. The aggregate gross proceeds to Daré, before deducting offering expenses payable by Daré, were $7.0 million. The closing occurred on September 1, 2023.

"This financing strengthened our balance sheet, providing cash to help us deliver on important portfolio milestones this year," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "In addition to the commercial launch of XACIATO in the U.S. by Organon, we are looking forward to the commencement of patient enrollment in our pivotal Phase 3 clinical study of Ovaprene, our investigational, hormone-free, monthly intravaginal contraceptive, and topline data from our Phase 1 clinical study of DARE-PDM1, an investigational proprietary hydrogel formulation of diclofenac we are developing as a vaginally administered treatment for primary dysmenorrhea, more commonly referred to as menstrual cramps and pain," continued Ms. Johnson. "We also look forward to an end-of-Phase-2 meeting, targeted for 2023, with the FDA for our Sildenafil Cream, 3.6% program, to support Phase 3 commencement in early 2024; our investigational formulation of sildenafil is designed to treat female sexual arousal disorder and/or female sexual interest/arousal disorder utilizing the active ingredient in Viagra®. In addition, we are pleased to announce that we previously entered into a license agreement with Douglas Pharmaceuticals, a New Zealand based pharmaceutical company, under which we acquired exclusive rights to develop and commercialize in the United States an investigational, novel proprietary lopinavir and ritonavir combination soft gel vaginal insert for the treatment of cervical intraepithelial neoplasia, also known as cervical dysplasia. There is no FDA-approved pharmaceutical treatment for cervical dysplasia, a precancerous condition in women strongly linked to HPV infection, the most common sexually transmitted infection in the U.S. Current surgical procedures to treat cervical dysplasia are invasive and can adversely impact future pregnancies. A pharmaceutical approach could provide women with an important alternative to surgery to treat this condition."

Daré's completed equity financing included minority participation by an investor affiliated with Douglas.

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 commercial launch of XACIATO in the U.S., plans and expectations with respect to Daré's product candidates, including anticipated timing for commencement and conduct of clinical trials, announcement of topline results and meetings with the FDA, and the anticipated FDA approval pathway for a product candidate, 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; 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; 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 loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, and public health emergencies on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including their potential impact on Daré's ability to timely commence, 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 impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; 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.

Contacts:

Investors on behalf of Daré Bioscience, Inc.:
Lee Roth / Julia Weilman
Burns McClellan
lroth@burnsmc.com / jweilman@burnsmc.com
646.930.4406 / 646.732.4443

OR

Media on behalf of Daré Bioscience, Inc.:
Jake Robison
Evoke Canale
jake.robison@evokegroup.com
619.849.5383

Source: Daré Bioscience, Inc.



Source: Daré Bioscience, Inc.