



## **Daré Bioscience Announces Closing of Global License Agreement with Organon to Commercialize XACIATO™ (clindamycin phosphate vaginal gel, 2%), FDA-Approved Treatment for Females 12 and Older with Bacterial Vaginosis**

June 30, 2022

**Daré will receive a \$10 million upfront payment from Organon**

**An estimated 21 million American women experience bacterial vaginosis**

SAN DIEGO, June 30, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: [DARE](#)), a leader in women's health innovation, today announced that the exclusive license agreement entered into on March 31, 2022 with [Organon](#) (NYSE: OGN), a global women's healthcare company, has become fully effective. Under the agreement, Organon licensed global rights to XACIATO (clindamycin phosphate vaginal gel, 2%), an FDA-approved medication for the treatment of bacterial vaginosis in females 12 years of age and older. XACIATO received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis.

In connection with the closing, Daré will receive a \$10 million upfront payment from Organon. Daré is eligible to receive potential milestone payments of up to \$182.5 million and tiered double-digit royalties based on net sales. XACIATO is expected to be available commercially in the U.S. in Q4 2022.

"Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women in the U.S.," said Sabrina Martucci Johnson, President and CEO of Daré. "The Daré team identified bacterial vaginosis as an area in need of new treatment options. We are thrilled to be collaborating with Organon, one of the premier companies in women's health, as we believe Organon's commercial capabilities will ensure that XACIATO reaches the women most impacted by this condition."

### **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, fertility, and vaginal and sexual health.

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. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly 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 utilizing the active ingredient in Viagra®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone therapy following menopause. 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](http://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," "endeavor" 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 Daré's expectations about its agreement with Organon, including commercial distribution and sale of XACIATO, receipt of payments from Organon, and expected timing of commercial availability of XACIATO in the United States. 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 those expressed or implied by the forward-looking statements in this press release, including, without limitation: the risks that none of the milestones under the agreement with Organon may be achieved and none of potential milestone payments become payable; the potential for royalty payments to be subject to reductions and offsets; dependence on Organon to commercialize licensed products and on other third parties for commercial supplies of licensed products and components and Daré's lack of control over the efforts and resources expended by those third parties; general industry conditions and competition; general economic factors, including inflation, rising interest rates and currency exchange rate fluctuations; the impact of the ongoing COVID-19 pandemic; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances; new products and patents attained by competitors; Daré's ability to accurately predict its future financial condition, operating results and performance; Daré's or its licensee's ability to accurately predict future market

conditions; third-party manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of patents owned or licensed by Daré and other protections for innovative products; and the exposure of Daré, its commercial counterparties and other third parties on which it relies to litigation, including patent litigation, and/or regulatory actions. 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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