



## Daré Bioscience Reports First Quarter 2020 Financial Results and Provides Company Update

05-14-2020 at 8:00 AM EDT

### **Conference Call Today at 4:30 p.m. Eastern Time**

SAN DIEGO, May 14, 2020 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the first quarter ended March 31, 2020 and provided a company update.

"The first quarter was an active one for Daré, beginning with the commercial licensing agreement with Bayer for Ovaprene and continuing with important progress in advancing the development of each of our later-stage product candidates," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "There is continued uncertainty with respect to the impact of the COVID-19 pandemic on businesses and economies across the world. However, we are on track to start the DARE-BV1 pivotal clinical study in July and report topline data for the study before the end of the year. In addition, we currently believe that we will be able to report topline data for our planned Phase 2b study of Sildenafil Cream, 3.6% in female sexual arousal disorder in 2021 and topline data for our planned pivotal contraceptive study of Ovaprene in 2022. On today's conference call, we plan to review meaningful updates on our later-stage clinical programs, recent financing developments and the innovative alliance with Health Decisions that we announced on Monday and that we believe will accelerate our clinical development efforts in a time and cost-efficient manner."

### **First Quarter 2020 Business Highlights**

- Ovaprene® – License agreement with Bayer for the U.S. commercial rights to our investigational hormone-free, monthly contraceptive.
- DARE-BV1 – FDA Fast Track Designation for the treatment of bacterial vaginosis; preparations for Phase 3 study this year.
- Sildenafil Cream, 3.6% – Positive data from thermography study presented at the International Society for the Study of Women's Sexual Health (ISSWSH) Annual Meeting 2020.

### **First Quarter 2020 Financial Results**

- General and administrative expenses were approximately \$1.9 million for the first quarter of 2020, as compared to approximately \$1.3 million for the first quarter of 2019, with the increase due primarily to increased expenses for accounting, legal and professional services and higher personnel and insurance costs.
- Research and development expenses were approximately \$2.4 million for the first quarter of 2020, as compared to approximately \$1.7 million for the first quarter of 2019. The increase was due primarily to expenses related to development activities for DARE-BV1, Ovaprene, DARE-HRT1, and DARE-VVA1, and for the microchip-based contraceptive program acquired in the fourth quarter of 2019, and increased personnel costs, with such expenses partially offset by grant funding related to both Ovaprene and the microchip-based contraceptive program.
- License expenses, which reflect payments due under Daré's various product license agreements, were approximately \$12,500 for the first quarter of 2020, as compared to \$112,500 for the first quarter of 2019.
- Comprehensive loss for the first quarter of 2020 was approximately \$4.3 million, as compared to approximately \$3.0 million for the same period in the prior year substantially due to a greater loss from operations in the first quarter of 2020.
- Net cash provided by financing activities for the first quarter of 2020 was approximately \$6.9 million and consisted of net proceeds from sales of common stock in "at-the-market" offerings and proceeds from exercises of warrants and options.
- Cash and cash equivalents were approximately \$5.0 million at March 31, 2020, compared to approximately \$4.8 million at December 31, 2019.

### **Recent Developments**

- Third Notice of Award of approximately \$731,000 in grant funding received from the National Institutes of Health for the Ovaprene program, with \$428,000 of that amount received after March 31, 2020 as reimbursement of Ovaprene postcoital test clinical study expenses.
- Additional cash of approximately \$2.0 million (net of fees) raised after March 31, 2020 from sales of common stock in “at-the-market” offerings. As of May 12, 2020, approximately 26.6 million shares of Daré common stock are outstanding.
- Execution of a purchase agreement with Lincoln Park Capital Fund, LLC for the potential sale of up to \$15 million in shares of Daré common stock over a 36-month period at times and in amounts controlled by Daré, subject to the satisfaction of conditions in and the limitations under the agreement.
- Announcement of a partnership agreement with Health Decisions, Inc., a full-service contract research organization (CRO) with expertise in clinical development of women’s health products, intended to facilitate advancement of key Daré programs in a capital-efficient manner.

COVID-19 Update: Daré continues to monitor the pandemic, its associated restrictions and their potential effects on the company’s business, financial condition and results of operations, including the potential impacts on the company’s planned clinical trials and its ability to raise additional capital when needed. Due to rapidly evolving circumstances, Daré is unable to predict with any reasonable accuracy the full financial and business impact of the pandemic on its business, financial condition or results of operations at this time.

### Conference Call

Daré will host a conference call and live webcast today at 4:30 p.m. Eastern Time to review the company’s financial results for the quarter ended March 31, 2020 and to provide a company update.

To access the conference call via phone, dial (844) 831-3031 (U.S.) or (443) 637-1284 (international). The conference ID number for the call 3387116. The live webcast can be accessed under “Events & Presentations” in the Investor Relations section of the company’s website at [www.darebioscience.com](http://www.darebioscience.com). Please log in approximately 5-10 minutes prior to the call to register and to download and install any necessary software. To access the replay, please call (855) 859-2056 (U.S.) or (404) 537-3406 (international). The conference ID number for the replay is 3387116. The call and webcast replay will be available until May 21, 2020.

### About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of 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 expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré’s product portfolio includes potential first-in-category candidates in clinical development: Ovaprene<sup>®</sup>, a hormone-free, monthly contraceptive intravaginal ring 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<sup>®</sup>; DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause. To learn more about Daré’s full portfolio of women’s health product candidates, and 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 candidates, clinical trials and other matters using its investor relations 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 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 on its investor relations website (<https://darebioscience.gcs-web.com/>) 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 on the investor relations page of Daré’s website mentioned above.

### 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,” “tend to,” or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to Daré’s expectations for clinical development of its product candidates, including the timing of commencement and announcement of topline results of planned clinical studies of DARE-BV1, Sildenafil Cream, 3.6% and Ovaprene, the potential for regulatory approval to market DARE-BV1 and Ovaprene based on a single successful Phase 3 study or contraceptive effectiveness and safety clinical study, respectively, Daré’s ability to access up to \$15 million in additional capital*

under its purchase agreement with Lincoln Park Capital Fund at times and in amounts its desires and Daré's expectations that its partnership agreement with Health Decisions will accelerate clinical development of its programs and result in cost-savings.

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: the effects of the COVID-19 pandemic on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on the ability of third parties on which Daré relies to assist in the conduct of its business, including its clinical trials, to fulfill their contractual obligations to Daré; Daré's ability to raise additional capital when and as needed to advance its product candidates and continue as a going concern; Daré's ability to satisfy the conditions in its purchase agreement to sell shares of its common stock to Lincoln Park Capital Fund and the effect of the limitations in the purchase agreement on such sales and on Daré's ability to engage in any variable rate transactions to raise additional capital; Daré's ability to develop, obtain regulatory approval for, and commercialize its product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré's product candidates in a timely manner; Daré's ability to conduct and design 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; 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 studies of that candidate; Daré's ability to retain its licensed rights to develop and commercialize a 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 candidates; the risks that the license agreement with Bayer may not become effective and, if it becomes effective, that future payments to Daré under the agreement may be significantly less than the anticipated or potential amounts; developments by Daré's competitors that make its product candidates less competitive or obsolete; Daré's dependence on third parties to conduct clinical trials and manufacture clinical trial material; 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; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; 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,	
	2020	2019
Operating expenses:		
General and administrative	\$ 1,861,765	\$ 1,277,180
Research and development expenses	2,379,804	1,693,391
License expenses	12,500	112,500
Total operating expenses	<u>4,254,069</u>	<u>3,083,071</u>
Loss from operations	(4,254,069)	(3,083,071)
Other income	1,821	31,231
Net loss	<u>\$ (4,252,248)</u>	<u>\$ (3,051,840)</u>

Foreign currency translation adjustments	\$ (22,944)	\$ 7,621
Comprehensive loss	\$ (4,275,192)	\$ (3,044,219)
Loss per common share - basic and diluted	\$ (0.18)	\$ (0.27)
Weighted average number of common shares outstanding:		
Basic and diluted	23,799,396	11,422,161

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

	<b>March 31, 2020</b>	<b>December 31, 2019</b>
	<b>(unaudited)</b>	
Cash and cash equivalents	\$ 5,047,325	\$ 4,780,107
Working capital	\$ 4,606,229	\$ 831,526
Total assets	\$ 10,213,965	\$ 7,442,788
Total liabilities	\$ 6,999,782	\$ 7,001,962
Total stockholders' equity	\$ 3,214,183	\$ 440,826



Source: Daré Bioscience, Inc.