



DARÉ BIOSCIENCE.

Daré Bioscience Reports Second Quarter 2020 Financial Results and Provides Company Update

08-12-2020 at 8:00 AM EDT

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

SAN DIEGO, Aug. 12, 2020 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the second quarter ended June 30, 2020 and provided a company update.

"During the second quarter, we continued to execute on key strategic and operational objectives, despite the challenges presented by the COVID-19 pandemic," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Importantly, we initiated the DARE-BVFREE pivotal study for DARE-BV1 in June. Given the anticipated short duration of the study, we expect to report topline data from the study by year-end 2020. Positive results from this single pivotal study will enable us to submit a new drug application for DARE-BV1 with the FDA in early 2021, two years from licensing the technology."

Daré licensed the rights to DARE-BV1 and the underlying hydrogel technology at the end of 2018. The company applied for and obtained a qualified infectious disease product (QIDP) designation from the U.S. Food and Drug Administration (FDA) for DARE-BV1 in 2019, making DARE-BV1 eligible for a 5-year marketing exclusivity extension for the treatment of bacterial vaginosis in women upon approval. Daré also received Fast Track designation for DARE-BV1 for the treatment of bacterial vaginosis, which is granted by the FDA for drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address an unmet medical need. The designation offers the opportunity for more frequent interactions with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support FDA approval. The Fast Track program is intended to facilitate development and expedite review of a Fast Track drug so that an approved product can reach the market expeditiously.

"The DARE-BVFREE study represents the first of a series of important upcoming milestones for our clinical-stage product candidates that are integral to our value creation strategy," said William Rastetter, PhD, Chairman of Daré's Board of Directors. "In addition to anticipating the topline data readout for our Phase 3 study of DARE-BV1 in 2020, in 2021, we expect to report topline data from our planned Phase 2b study of Sildenafil Cream (3.6%) in female sexual arousal disorder, as well as topline data from our ongoing Phase 1 study of DARE-HRT1 for the vasomotor symptoms of menopause; and in 2022, we expect to report topline data for our planned pivotal contraceptive study of Ovaprene."

Recent Business Highlights

- Ovaprene® – Publication of a peer-reviewed article supporting the use of the postcoital test study as a predictor of contraceptive effectiveness in *Biology of Reproduction*.
- DARE-BV1 – Initiation of DARE-BVFREE pivotal Phase 3 clinical trial of DARE-BV1 in patients with bacterial vaginosis.
- DARE-HRT1 – Initiation of Phase 1 clinical trial of DARE-HRT1, a novel intravaginal ring designed to deliver non-oral, bio-identical hormone therapy for the treatment of menopausal symptoms.
- DARE-LARC1 – Receipt of \$1.6 million in additional grant funding from the Bill & Melinda Gates Foundation for the continued development of a user-controlled, long-acting reversible contraceptive. The remaining approximately \$900,000 in funding under the current grant supplement from the foundation may be awarded before the end of 2020 in further support of DARE-LARC1 development activities.

Second Quarter 2020 Financial Results

- General and administrative expenses were approximately \$1.6 million for the second quarter of 2020, as compared to approximately \$1.3 million for the second quarter of 2019, with the increase primarily due to increased personnel costs and an increase in rent and facilities expenses.
- Research and development expenses were approximately \$5.6 million for the second quarter of 2020, as compared to approximately \$2.5 million for the second quarter of 2019. The increase was due primarily to expenses related to development activities for DARE-BV1, Ovaprene and DARE-LARC1, and increased personnel costs, with such expenses partially offset by grant funding related to both Ovaprene and DARE-LARC1, and reduced costs related to development activities for Sildenafil Cream, 3.6% and DARE-HRT1.
- License expenses, which reflect payments due under Daré's various product license agreements, were approximately \$21,000 for the second quarter of 2020, as compared to \$162,500 for the second quarter of 2019.
- Comprehensive loss for the second quarter of 2020 was approximately \$7.1 million, as compared to approximately \$4.7

million for the same period in the prior year substantially due to a greater loss from operations in the second quarter of 2020.

- Net cash provided by financing activities for the six months ended June 30, 2020 was approximately \$11.3 million and consisted of net proceeds from sales of common stock in “at-the-market” offerings and under the company’s equity line, proceeds from exercises of warrants and options and loan proceeds.
- Cash and cash equivalents were approximately \$5.3 million at June 30, 2020, compared to approximately \$4.8 million at December 31, 2019.

Recent Developments

- Additional cash of approximately \$3.4 million (net of fees) raised after June 30, 2020 from sales of common stock in “at-the-market” offerings and under the company’s equity line. As of August 11, 2020, approximately 31.6 million shares of Daré common stock are outstanding.

Upcoming Milestones

- DARE-BV1 – topline data expected by year-end 2020; New drug application (NDA) submission anticipated early 2021
- DARE-HRT1 – topline data expected first half 2021
- Sildenafil Cream, 3.6% - topline data expected by year-end 2021
- Ovaprene – topline data expected by year-end 2022

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 June 30, 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 4097126. The live webcast can be accessed under “Events & Presentations” in the Investor Relations section of the company’s website at 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 4097126. The call and webcast replay will be available until August 19, 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 clinical-stage product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, 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®; 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.

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 clinical studies of DARE-BV1, DARE-HRT1, Sildenafil Cream, 3.6% and Ovaprene, the potential for NDA filing and regulatory approval to market DARE-BV1 based on a single successful Phase 3 study, timing of submission of a NDA for DARE-BV1 with the FDA, benefits of QIDP and Fast Track designations for the DARE-BV1 program, and potential additional grant funding for development of DARE-LARC1. 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 and continue as a going concern; 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 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, including its clinical trials, to fulfill their contractual obligations to Daré; 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 and/or nonclinical 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 June		Six Months Ended June	
	30,	30,	30,	30,
	2020	2019	2020	2019
Operating expenses:				
General and administrative	\$ 1,557,548	\$ 1,307,379	\$ 3,419,313	\$ 2,584,559
Research and development expenses	5,547,450	2,512,572	7,927,254	4,205,963
License expenses	20,833	162,500	33,333	275,000
Total operating expenses	<u>7,125,831</u>	<u>3,982,451</u>	<u>11,379,900</u>	<u>7,065,522</u>
Loss from operations	(7,125,831)	(3,982,451)	(11,379,900)	(7,065,522)
Other income	1,618	30,001	3,439	61,232

Net loss	<u>\$ (7,124,213)</u>	<u>\$ (3,952,450)</u>	<u>\$ (11,376,461)</u>	<u>\$ (7,004,290)</u>
Deemed dividend from trigger of down round provision	\$ -	\$ (789,594)	\$ -	\$ (789,594)
Net loss to common shareholders	<u>\$ (7,124,213)</u>	<u>\$ (4,742,044)</u>	<u>\$ (11,376,461)</u>	<u>\$ (7,793,884)</u>
Foreign currency translation adjustments	\$ 12,090	\$ (7,917)	\$ (10,854)	\$ (296)
Comprehensive loss	<u>\$ (7,112,123)</u>	<u>\$ (4,749,961)</u>	<u>\$ (11,387,315)</u>	<u>\$ (7,794,180)</u>
Loss per common share - basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.29)</u>	<u>\$ (0.45)</u>	<u>\$ (0.57)</u>
Weighted average number of common shares outstanding:				
Basic and diluted	<u>26,710,750</u>	<u>16,105,252</u>	<u>25,255,073</u>	<u>13,776,643</u>

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	<u>June 30,</u> <u>2020</u>	<u>December</u> <u>31,</u> <u>2019</u>
	(unaudited)	
Cash and cash equivalents	\$ 5,346,872	\$ 4,780,107
Working capital	\$ 1,693,020	\$ 831,526
Total assets	\$ 8,570,370	\$ 7,442,788
Total liabilities	\$ 8,259,115	\$ 7,001,962
Total stockholders' equity	\$ 311,255	\$ 440,826



Source: Daré Bioscience, Inc.