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

November 12, 2020

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

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

"We made great progress toward our strategic and operational objectives during the third quarter. I'm proud to report that despite this year's challenging operating environment, our team continued to execute efficiently, allowing us to maintain our progress toward our anticipated milestones for 2020 and 2021," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The completion of the DARE-BVFREE pivotal study of DARE-BV1 for the treatment of bacterial vaginosis will be an important milestone for Daré. We expect to report topline results from this Phase 3 study before the end of 2020 and to submit a new drug application to the FDA in the first half of 2021 if the study is successful. It has been roughly two years since we licensed the rights to the DARE-BV1 program, and the rapid pace at which we have advanced its development is evidence of the strength of the entire Daré team."

"The DARE-BVFREE topline data read-out in Q4 2020 represents the first in a series of anticipated milestones for our later-stage clinical-stage product candidates," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "In 2021, we are planning to initiate a Phase 2b study of Sildenafil Cream, 3.6%, our candidate for female sexual arousal disorder, the sexual dysfunction condition in women most analogous to erectile dysfunction in men, and look forward to reporting topline data from this study by the end of 2021. FSAD is a highly pervasive condition for which no FDA-approved product exists. A safe, effective and convenient option for women is long overdue, and we hope to be able to provide such a solution. In 2021, we also look forward to advancing Ovaprene®, our investigational hormone-free, monthly contraceptive, into a pivotal study that we expect, if successful, to support a premarket approval submission to the FDA."

U.S. commercial rights for Ovaprene are subject to a license agreement with Bayer, which was announced earlier this year.

Recent Business Highlights

- DARE-LARC1: Received approximately $0.9 million in funding that remained under a pre-existing grant from the Bill & Melinda Gates Foundation in further support of DARE-LARC1 development activities. Development of DARE-LARC1 has been supported by a total of approximately $20.5 million in grant funding from the foundation, including this recent disbursement.

- DARE-FRT1: Received a Notice of Award of a grant of approximately $0.3 million from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH). NIH funding is awarded in phases and Daré may be eligible to receive up to a total of approximately $2.3 million in grant funding for the DARE-FRT1 program based on the grant application it submitted to support the DARE-FRT1 Phase 1 human clinical study. DARE-FRT1 is being developed for the prevention of preterm birth and broader luteal phase support as part of an in vitro fertilization regimen. The potential additional grant funding of approximately $2.0 million is contingent upon satisfying specified requirements and the availability of funds in the future.

- Strategic CRO partnership: Entered into an agreement with Avomeen, an accredited, independent contract research, development, and manufacturing organization specializing in chemical analysis and product development, under which Avomeen will provide contract product development laboratory services with a team specifically assembled to support the advancement of Daré's innovative pipeline.

Third Quarter 2020 Financial Results

- General and administrative expenses were approximately $1.4 million for the third quarter of 2020, a modest increase over the approximately $1.3 million incurred in the third quarter of 2019, with increased personnel costs, rent and facilities expenses and stock-based compensation expense partially offset by lower expenses for professional services.

- Research and development expenses were approximately $6.2 million for the third quarter of 2020, as compared to approximately $2.0 million for the third quarter of 2019. The increase was due primarily to increased expenses related to development activities for DARE-BV1, Ovaprene and DARE-LARC1, and higher personnel costs, with such expenses partially offset by grant funding related to both Ovaprene and DARE-LARC1, and a decrease in costs related to development activities for DARE-HRT1 and Sidenafil Cream, 3.6%.

- License expenses, which reflect payments due under Daré's various product license agreements, were approximately

$25,000 for the third quarter of 2020, as compared to approximately $133,300 for the third quarter of 2019.

- Comprehensive loss for the third quarter of 2020 was approximately $7.6 million, as compared to approximately $3.4 million for the same period in the prior year, substantially due to a greater loss from operations in the third quarter of 2020.

- Net cash provided by financing activities for the nine months ended September 30, 2020 was approximately $16.7 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 $5.4 million at September 30, 2020, compared to approximately $4.8 million at December 31, 2019.

Recent Developments

- Additional cash of approximately $4.5 million (net of fees) was raised from sales of common stock in "at-the-market" offerings and under the company's equity line after third quarter-end through November 11, 2020.

- As of November 11, 2020, approximately 38 million shares of Daré common stock were outstanding.

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 ongoing and planned clinical trials and the company's ability to raise additional capital when needed. Due to the high level of uncertainty regarding the duration and impact of the COVID-19 pandemic on the U.S. and global economies, workplace environments and capital markets, Daré is unable to predict with any reasonable accuracy the full extent to which the pandemic will impact 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 September 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 6519434. The live webcast can be accessed under "Presentations, Events & Webcasts" in the Investors section of the company's website at http://ir.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 6519434. The call and webcast replay will be available until November 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 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 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 topline results of the DARE-BVFREE study and submission of an NDA for DARE-BV1 to the FDA, the potential for NDA filing and regulatory approval to market DARE-BV1 based on a single successful Phase 3 study, commencement and announcement of topline results of clinical studies of Sildenafil Cream, 3.6% and Ovaprene, the potential for Sildenafil Cream, 3.6% to be the first FDA-approved product to treat female sexual arousal dysfunction, the potential for a premarket application filing and regulatory approval to market Ovaprene based on a single successful contraceptive efficacy study, and potential additional grant funding from the NICHD for development of DARE-FRT1. 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; 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.

Contact:

Investors on behalf of Daré Bioscience, Inc.:
Lee Roth
Burns McClellan
lroth@burnsmc.com
212.213.0006

Source: Daré Bioscience, Inc.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses				
General and administrative	$ 1,353,069	$ 1,318,986	$ 4,772,382	$ 3,903,545
Research and development expenses	6,203,753	1,966,230	14,131,007	6,172,192
License expenses	25,000	133,333	58,333	408,333
Total operating expenses	7,581,822	3,418,549	18,961,722	10,484,070
Loss from operations	(7,581,822)	(3,418,549)	(18,961,722)	(10,484,070)
Other income	(986)	25,471	2,454	86,703
Net loss	$ (7,582,808)	$ (3,393,078)	$ (18,959,268)	$ (10,397,367)
Deemed dividend from trigger of down round provision feature	$ (6,864)	$ -	$ (6,864)	$ (789,594)
Net loss to common shareholders	$ (7,589,672)	$ (3,393,078)	$ (18,966,132)	$ (11,186,961)
Foreign currency translation adjustments	$ 672	$ (15,378)	$ (10,182)	$ (15,674)
Comprehensive loss	$ (7,589,000)	$ (3,408,456)	$ (18,976,314)	$ (11,202,635)
Loss per common share - basic and diluted	$ (0.24)	$ (0.20)	$ (0.69)	$ (0.76)
Weighted average number of common shares outstanding:				
Basic and diluted	31,588,152	16,683,411	27,381,508	14,756,213

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	September 30, 2020 (unaudited)	**December 31, 2019**

Cash and cash equivalents	$ 5,389,414	$ 4,780,107
Working capital (deficit)	$ (980,230)	$ 831,526
Total assets	$ 7,661,742	$ 7,442,788
Total liabilities	$ 9,047,630	$ 7,001,962
Total stockholders' equity (deficit)	$ (1,385,888)	$ 440,826

Source: Daré Bioscience, Inc.