Daré Bioscience Reports Full Year 2020 Financial Results and Provides a Company Update

March 30, 2021

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

SAN DIEGO, March 30, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the year ended December 31, 2020 and provided a company update.

"Despite the unique challenges posed during 2020, we achieved two important corporate firsts in 2020. We started the year in January by announcing our first commercial partnership agreement, with Bayer for Ovaprene® commercialization rights. We believe that this partnership not only validates the Ovaprene commercial opportunity and allows Daré to benefit from Bayer's expertise in development, regulatory affairs and commercialization of first-in-category contraceptive products for women, but, with up to $310 million in commercial milestone payments, plus double-digit, tiered royalties on net sales, that it will also provide capital to support broader portfolio objectives. Then, we ended the year in December with the completion of our first portfolio Phase 3 study – specifically, we announced positive topline data from the DARE-BVFREE Phase 3 study of DARE-BV1 for the treatment of bacterial vaginosis, positioning Daré for our first NDA submission," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The advances in 2020 across the portfolio set the stage for meaningful portfolio objectives in 2021."

2021 Key Portfolio Objectives

- DARE-BV1: New Drug Application (NDA) submission and strategic commercialization agreement.
- Sildenafil Cream, 3.6%: Phase 2b clinical study commencement and topline data.
- Ovaprene: Investigational Device Exemption (IDE) submission.
- DARE-HRT1: Phase 1 clinical study topline data.
- DARE-VVA1: Initiation of Phase 1 clinical study.

2020 Portfolio Accomplishments and Management Expectations for 2021

- **DARE-BV1:**
  - Daré solution: Novel, investigational thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% as a first-line, single-administration treatment for bacterial vaginosis.
  - Successful completion of the DARE-BVFREE Phase 3 clinical study in 4Q 2020.
  - Phase 3 study results: A single dose of DARE-BV1 delivered statistically significant efficacy (76.0% clinical cure rate at Day 7-14 and 70.2% at Day 21-30 (primary endpoint) in the modified intent-to-treat population). The study demonstrated DARE-BV1's potential to provide improved clinical cure rates and improved patient outcomes compared to those of current branded prescription products for treatment of bacterial vaginosis.
  - NDA submission to the U.S. Food and Drug Administration (FDA) planned for 2Q 2021.
  - Fast track and Qualified Infectious Disease Product (QIDP) designations allow for a priority review request at the time of NDA submission, which, if granted by the FDA, could lead to a 2021 PDUFA goal date.
  - Ongoing strategic discussions and other activities to support a robust market introduction in 2022, if approved. In 2021, Daré intends to finalize and announce the collaboration strategy for DARE-BV1 commercialization in the U.S.
- **Sildenafil Cream, 3.6%:**
  - Daré solution: Proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical administration to treat female sexual arousal disorder (FSAD).
  - No FDA-approved products exist today to treat FSAD.
  - Phase 2b RESPOND clinical study commenced in 1Q 2021.
  - Topline data readout targeted for year-end 2021.
  - FSAD is a physiological condition characterized by the inability to attain or maintain sufficient genital arousal during sexual activity and, of the various types of female sexual dysfunction disorders, is most analogous to erectile dysfunction in men.
  - FSAD represents a large unmet need, with an estimated 10 million women in the U.S. experiencing distress from

symptoms of low or no sexual arousal and actively seeking treatment.[1]

- **DARE-HRT1:**
  - Daré solution: Unique, investigational 28-day intravaginal ring (IVR) containing bio-identical estradiol and bio-identical progesterone for the treatment of vasomotor symptoms and genitourinary syndrome associated with menopause.
  - Enrollment in Phase 1 clinical study in Australia completed during 1Q 2021.
  - Topline data readout expected in 2Q 2021.
- **Ovaprene:**
  - Daré solution: Novel, investigational hormone-free monthly intravaginal contraceptive.
  - IDE submission to FDA planned for 4Q 2021, a requirement for initiating a pivotal contraceptive clinical study in the U.S.
  - Pivotal Phase 3 clinical study commencement planned for 1Q 2022, enabling a 6-month data readout by the end of 2022.
- **DARE-VVA1:**
  - Daré solution: Proprietary, investigational formulation of tamoxifen for vaginal administration to treat vulvar and vaginal atrophy (VVA) in women with or at risk for hormone-receptor positive breast cancer.
  - Phase 1 clinical study in Australia planned to commence during 2H 2021.
- **DARE-FRT1:**
  - Daré solution: Investigational 14-day IVR containing bio-identical progesterone for the prevention of preterm birth and broader luteal phase support as part of an in vitro fertilization regimen.
  - Continuation of pre-clinical development activities under grant awarded in 2020 by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH) supporting development activities for DARE-FRT1.
  - Phase 1 clinical trial targeted for 2022.

Financial Highlights for Fiscal Year ending December 31, 2020

- Cash and cash equivalents: $4.7 million at December 31, 2020, compared to $4.8 million at December 31, 2019.
- Net cash from financing activities during FY2020 was approximately $25.1 million and consisted of approximately $23.0 million (net of fees) from sales of common stock, approximately $1.8 million from warrant and option exercises and approximately $367,000 in forgivable loan proceeds under the Paycheck Protection Program. In addition to these financing activities, the company received approximately $3.2 million in grant funding, $1.0 million from a license fee, and approximately $192,000 under Australia's research and development tax incentive program bringing total net cash received during FY2020 to approximately $29.5 million.
- General and administrative expenses were approximately $6.5 million in FY2020, an increase of approximately $1.3 million over such expenses incurred in FY2019 reflecting higher expenses related to personnel, legal, professional and accounting services, insurance premiums, rent and facilities and stock-based compensation.
- Research and development expenses were approximately $20.8 million in FY2020, as compared to approximately $8.5 million in FY2019. The $12.2 million increase was due primarily to increases in expenses related to clinical and other development activities for DARE-BV1 and Ovaprene and expenses related to preclinical-stage programs including DARE-LARC1, as well as higher personnel costs, with such expenses partially offset by grant funding and cash received under Australia's research and development tax incentive program.
- License expenses, which reflect up-front and annual license fees due to licensors under Daré's various product license agreements, were approximately $83,000 in FY2020, as compared to approximately $533,000 during FY2019.
- Comprehensive loss for FY2020 was approximately $27.4 million, as compared to approximately $15.1 million for FY2019.

Recent Financial Developments

- Between January 1, 2021 and March 29, 2021, Daré received additional cash of approximately $11.5 million, consisting of approximately $11.3 million (net of fees) from sales of common stock under the company's "at-the-market" offerings program and equity line, approximately $50,000 from warrant exercises, and approximately $139,000 from grant funding.

- In January 2021, the company was notified that the principal balance of its loan obtained through the Paycheck Protection Program and all accrued interest was fully forgiven by the U.S. Small Business Administration.

- As of March 29, 2021, approximately 47.3 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.

[1] Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for Strategic Science & Technologies, LLC.

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 year ended December 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 6441759. 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 6441759. The call and webcast replay will be available until April 13, 2021.

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 novel, investigational 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 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 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 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 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 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. In this press release, forward-looking statements include, but are not limited to, statements relating to Daré's expectations for clinical development and FDA review of its product candidates, including the timing of commencement of and topline results and other data from its clinical studies, the timing of its NDA and IDE submissions, the potential timing of FDA approval and clearance, respectively, of such submissions, the commercial potential of Daré's product candidates, Daré's strategy and plans for commercialization of DARE-BV1 in the U.S., the potential for FDA approval of DARE-BV1 based largely on the results of the DARE-BVFREE Phase 3 study, DARE-BV1's potential ability to improve clinical outcomes compared to current branded prescription products for the treatment of bacterial vaginosis, the potential for FDA approval to market Ovaprene based largely on Daré's planned Phase 3 contraceptive safety and efficacy study, the potential benefits of Daré's agreement with Bayer, including the potential significance to Daré of the commercial milestone payments and royalties on net sales, and the potential for Sildenafil Cream, 3.6% to be the first FDA-approved product to treat FSAD. 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 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; 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 developments by competitors make Daré's product candidates less competitive or obsolete; failure of Daré's product candidates, if approved, to gain market acceptance or obtain adequate coverage from third-party payers; 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; 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.:
Tom Masterson
Allele Capital Partners
tmasterson@allelecapital.com
646.573.3216

Source: Daré Bioscience, Inc.

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

	Years Ended December 31,	
	2020	**2019**
Operating expenses:		
General and administrative	6,549,508	$ 5,265,438
Research and development expenses	20,769,416	8,546,108
License expenses	83,333	533,334
Total operating expenses	27,402,257	14,344,880
Loss from operations	(27,402,257)	(14,344,880)
Other income (expense)	1,514	81,050
Net loss	$ (27,400,743)	$ (14,263,830)
Deemed dividend from trigger of down round provision feature	$ (6,863)	$ (789,594)
Net loss to common shareholders	$ (27,407,606)	$ (15,053,424)
Foreign currency translation adjustments	$ 11,237	$ (5,897)
Comprehensive loss	$ (27,396,369)	$ (15,059,321)
Loss per common share - basic and diluted	$ (0.91)	$ (0.97)
Weighted average number of common shares outstanding:		
Basic and diluted	30,091,469	15,578,959

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheet Data

	December 31, 2020	**December 31, 2019**
Cash and cash equivalents	$ 4,669,467	$ 4,780,107
Working capital (deficit)	$ (676,689)	$ 831,526
Total assets	$ 7,550,712	$ 7,442,788
Total liabilities	$ 8,702,445	$ 7,001,962
Total stockholders' equity (deficit)	$ (1,151,733)	$ 440,826

Source: Daré Bioscience, Inc.