Daré Bioscience Reports 2019 Financial Results and Provides a Company Update

March 30, 2020

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

SAN DIEGO, March 30, 2020 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the year ended December 31, 2019 and provided a company update.

"During the fourth quarter of 2019 and into early 2020, we made considerable progress against our longer-term strategic and operational objectives, particularly with our later-stage candidates Ovaprene®, DARE-BV1, and Sildenafil Cream, 3.6%. This progress has helped position us for what we expect to be a transformative year for Daré. In 2020, we expect to achieve a number of important milestones that we believe will deliver value to our shareholders," said Sabrina Martucci Johnson, President and CEO of Daré.

"We started 2020 with the announcement of our exclusive licensing agreement with Bayer, a world leader in women's health, for U.S. commercial rights to Ovaprene, our investigational hormone-free, monthly contraceptive. Our agreement with Bayer is perhaps the most significant deal in our company's history as we are eligible to receive a $20 million payment to reimburse Ovaprene clinical development costs and commercial milestone payments potentially totaling up to $310 million, in addition to tiered, double-digit royalties on net sales. Moreover, we believe that Bayer is the ideal partner for Ovaprene, given its track record in women's health and unparalleled expertise commercializing first-in-category contraceptive products. We ended 2019 with the announcement of the positive Ovaprene data that led to the partnership with Bayer, as well as important alignment with the FDA on the planned DARE-BV1 Phase 3 clinical study for the treatment of bacterial vaginosis and on the planned Phase 2b clinical study of Sildenafil Cream, 3.6% for Female Sexual Arousal Disorder."

Ms. Johnson added, "We are currently on track to conduct and report topline results from the planned Phase 3 study of DARE-BV1 before the end of 2020, as well as to report topline results of the planned Sildenafil Cream, 3.6% Phase 2b study in 2021 and the planned Ovaprene pivotal study in 2022. As a result of the COVID-19 pandemic, these are unprecedented times, circumstances are rapidly evolving, both from a macroeconomic perspective and in our industry, and we will continue to assess our circumstances and development timelines. We believe our unique accelerator model, with our variety of programs and diversity of indications and development stages, enables us to react quickly to the highly dynamic and uncertain environment that we find ourselves facing today. As a result, we believe we are well-positioned to deliver the topline clinical data and regulatory actions projected over the next three years."

Portfolio Highlights:

- Ovaprene - 4Q 2019 – announced positive topline results of the postcoital test (PCT) clinical study of Ovaprene, Daré's investigational hormone-free, monthly contraceptive.
- Sildenafil Cream, 3.6% - 4Q 2019 – announced alignment with FDA on the design and novel primary endpoint patient-reported outcome (PRO) instruments for the planned Phase 2b clinical study of Sildenafil Cream, 3.6% for the treatment of Female Sexual Arousal Disorder (FSAD), the female sexual dysfunction disorder most analogous to erectile dysfunction in men.
- DARE-BV1 – 4Q 2019 – announced FDA clearance of the investigational new drug (IND) application for DARE-BV1, enabling a 2020 pivotal Phase 3 study of DARE-BV1 for the treatment of bacterial vaginosis.

Corporate Highlights

- 4Q 2019 – Completed acquisition of Microchips Biotech, Inc.
- 1Q 2020 – Executed Ovaprene license agreement with Bayer HealthCare, LLC

Operating Results

- General and administrative expenses were approximately $5.3 million for 2019, as compared to approximately $4.7 million for 2018, with the increase due primarily to additional staff and staff-related expenses and higher insurance costs, partially offset by a decrease in expenses for accounting, legal and other professional services.
- Research and development expenses were approximately $8.5 million for 2019, as compared to approximately $6.4 million for 2018, due primarily to increased costs of development activities for DARE-BV1, Ovaprene, DARE-HRT1, DARE-FRT1 and Sildenafil Cream, 3.6%, and increased personnel costs, partially offset by an increase in grant funding related to Ovaprene and decreased costs of development activities for pre-clinical stage product candidates.
- License expenses were approximately $0.5 million for 2019, as compared to $0.6 million for 2018 and represent fees due under Daré's various product license agreements.
- Comprehensive loss for 2019 was approximately $15.1 million, as compared to approximately $16.8 million for the prior year. While Daré's overall operating expenses were higher in 2019, comprehensive loss decreased primarily because there was an impairment of goodwill for 2018 totaling approximately $5.2 million and no impairment charge in 2019.

Cash and Cash Equivalents

- Cash and cash equivalents were approximately $4.8 million at December 31, 2019, as compared to $6.8 million at December 31, 2018.
- Since January 1, 2020, Daré received cash gross proceeds of approximately $8.1 million through a combination of the upfront payment under its license agreement with Bayer, the sale and issuance of approximately 3.3 million shares of its common stock in at-the-market offerings, and the sale and issuance of approximately 1.7 million shares of its common stock upon the exercise of warrants it issued in 2018. Net proceeds to Daré from these transactions are approximately $7.9 million.

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, 2019 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 3266966. 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 3266966. The call and webcast replay will be available until April 6, 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 (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, and the potential payments and non-monetary benefits to Daré under its agreement with Bayer. 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; Daré's ability to continue as a going concern; Daré's ability to raise additional capital when and as needed, to advance its product candidates; 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.
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2019	2018
Cash and cash equivalents	$ 4,780	$ 6,806
Other receivables	555	31
Prepaid expenses	1,109	403
Property and equipment, net	64	9
Other non-current assets	935	578
Total assets	$ 7,443	$ 7,827
Current liabilities	5,612	1,091
Contingent consideration	1,000	-
Lease liabilities long-term	390	9
Total stockholders' equity	441	6,727
Total liabilities and stockholders' equity	$ 7,443	$ 7,827

Daré Bioscience, Inc.
Consolidated Statement of Operations
(in thousands, except share and per share data)

	Years Ended December 31, 2019	2018
Operating expenses		
General and administrative	$ 5,266	$ 4,656
Research and development expenses	8,546	6,414
License expenses	533	625
Impairment of goodwill	-	5,187
Total operating expenses	14,345	16,882
Loss from operations	(14,345)	(16,882)
Other income	81	143
Net loss	$ (14,264)	$ (16,739)
Deemed dividend from trigger of round down provision feature	(789)	-
Net loss to common shareholders	(15,053)	(16,739)
Foreign currency translation adjustments, net of tax	(6)	(78)
Comprehensive loss	$ (15,059)	$ (16,817)
Loss per common share - basic and diluted	$ (0.97)	$ (1.57)
Weighted average number of common shares outstanding:		
Basic and diluted	15,579	10,732

Source: Daré Bioscience, Inc.