



Daré Bioscience Reports Third Quarter 2019 Financial Results and Provides Company Update

11-14-2019 at 8:00 AM EST

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

SAN DIEGO, Nov. 14, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the quarter ended September 30, 2019 and provided a company update.

"The third quarter was marked by tremendous progress for Daré and positioned us to reach a number of milestones in the fourth quarter of 2019 and into 2020," said Sabrina Martucci Johnson, President and CEO of Daré. "Earlier this week, we announced positive topline results of the postcoital test pre-pivotal clinical trial of Ovaprene[®], our monthly, hormone-free vaginal contraceptive candidate. The data from that study will be used to support an Investigational Device Exemption and, pending FDA review and clearance of the IDE, we plan to initiate a pivotal contraceptive effectiveness and safety study of Ovaprene in the second half of 2020."

"In the third quarter, we also advanced our DARE-BV1 and Sildenafil Cream, 3.6% programs," continued Ms. Johnson. "We completed the non-interventional study to support the content validity of patient reported outcome measures for our Phase 2b and Phase 3 clinical studies of Sildenafil Cream, 3.6%, our novel cream formulation of sildenafil with potential to be the first FDA-approved treatment option for female sexual arousal disorder. The timing of initiation of the Phase 2b clinical trial will be influenced by additional FDA guidance, which we expect to receive prior to the end of 2019. In addition, we are working on regulatory and start-up activities for a pivotal Phase 3 clinical study of DARE-BV1 for the treatment of bacterial vaginosis, so that we are positioned to report Phase 3 trial data in 2020."

"This week, we were also pleased to have announced a definitive agreement to acquire Microchips Biotech, including its innovative contraceptive program supported by up to \$20.5 million in grant funding from the Bill & Melinda Gates Foundation," said Ms. Johnson.

Quarter Ended September 30, 2019 Financial Results

- Cash and cash equivalents:
 - As of September 30, 2019, cash and cash equivalents were approximately \$2.4 million.
 - In March 2019, Daré received a Notice of Award for an additional \$982,851 of the anticipated \$1.9 million grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development. The grant serves to offset certain Ovaprene development expenses, and during the third quarter, Daré recorded grant funding of approximately \$231,000 as a reduction to research and development expense.
- General and administrative expenses were approximately \$1.3 million for the third quarter of 2019, as compared to approximately \$1.2 million for the same period in 2018.
- Research and development expenses were approximately \$2.0 million for the third quarter of 2019, as compared to approximately \$1.4 million for the same period in 2018. The increase is primarily attributable to costs related to development of DARE-BV1 and Ovaprene, including activities to prepare for the Phase 3 clinical study of DARE-BV1 and to conduct the PCT clinical study of Ovaprene, and personnel costs.
- License expenses for the third quarter of 2019 were approximately \$133,000, as compared to zero for the same period in 2018. These expenses reflect accruals of fees payable under license agreements that Daré entered into in 2018 relating to the DARE-BV1 program and the intravaginal ring drug delivery technology programs, including DARE-HRT1 and DARE-FRT1.
- Daré reported a comprehensive loss of approximately \$3.4 million for the third quarter of 2019, as compared to approximately \$2.6 million for the same period in 2018. The increase is primarily due to the increases in the company's operating expenses summarized above.

On November 11, 2019, Daré announced an agreement to acquire Microchips Biotech, Inc., a company developing a first-in-class wireless, user-controlled drug delivery platform. Microchips' cash and cash equivalents, after deducting change of control payments and other transaction-related expenses, is anticipated to be approximately \$5.7 million at the time of closing. Microchips is eligible to receive up to \$2.5 million in additional funding from the Gates Foundation in 2020 to cover the costs of ongoing development activities of its contraceptive program, which combined with amounts received to date, would bring total grant funding to approximately \$20.5 million. Daré will issue three million shares of its common stock in consideration of the cash and cash

equivalents of Microchips, less liabilities, at the time of closing to the Microchips stockholders, which include Polaris Venture Partners, MS Pace, Intersouth Partners, and Teva Pharmaceuticals. Daré may pay up to \$46.5 million in contingent consideration for product development, regulatory and funding milestones and up to \$55.0 million in contingent consideration for commercial development milestone payments, the amount of which will depend on the extent to which various milestones are achieved, as well as tiered royalty payments. Daré expects that less than \$1.3 million of the contingent consideration may become payable through 2021.

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, 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 is 3154847. 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. The conference ID number for the replay is 3154847. The call and webcast replay will be available until November 21, 2019.

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 vaginal contraceptive; 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 the company'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 Daré's plans to initiate a contraceptive effectiveness and safety study of Ovaprene in the second half of 2020 and the potential for that study to be a pivotal study, consummation of the merger transaction with Microchips, the anticipated amount of Microchips' cash balance at the time of closing of the transaction, the potential for up to \$2.5 million of additional grant funding in 2020 for Microchips' contraceptive program, Daré's expectations as to when and how much contingent consideration may become payable to Microchips' stockholders, Phase 2b and Phase 3 clinical development plans for Sildenafil Cream, 3.6% and DARE-BV1, respectively, including the timing of commencement and completion of clinical studies, the potential for the planned Phase 3 study of DARE-BV1 to be a pivotal study, and the potential for Sildenafil Cream, 3.6% to be the first FDA-approved treatment option for female sexual arousal disorder. 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 close the merger transaction with Microchips; receipt of additional grant funding for Microchips' contraceptive program; 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 promising results in pre-clinical studies may not be replicated when a product candidate is tested in human subjects; 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; 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

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

	Three Months Ended		Nine Months Ended	
	September 30, 2019		September 30, 2019	
	2019	2018	2019	2018
Operating expenses:				
General and administrative	1,318,986	\$ 1,175,049	3,903,545	\$ 3,635,413
Research and development expenses	1,966,230	1,446,548	6,172,192	4,750,823
License expenses	133,333	-	408,333	350,000
Impairment of goodwill	-	-	-	5,187,519
Total operating expenses	3,418,549	2,621,597	10,484,070	13,923,755
Loss from operations	(3,418,549)	(2,621,597)	(10,484,070)	(13,923,755)
Other income (expense)	25,471	47,122	86,703	101,492
Net loss	\$ (3,393,078)	\$ (2,574,475)	\$(10,397,367)	\$(13,822,263)
Deemed dividend from trigger of down round provision feature	-	-	(789,594)	-
Net loss to common shareholders	\$ (3,393,078)	\$ (2,574,475)	\$(11,186,961)	\$(13,822,263)
Foreign currency translation adjustments	\$ (15,378)	\$ (18,721)	\$ (15,674)	\$ (59,952)
Comprehensive loss	\$ (3,408,456)	\$ (2,593,196)	\$(11,202,635)	\$(13,882,215)
Loss per common share - basic and diluted	\$ (0.20)	\$ (0.23)	\$ (0.76)	\$ (1.32)
Weighted average number of common shares outstanding:				
Basic and diluted	16,683,411	11,422,161	14,756,213	10,499,982

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
	(unaudited)	
Cash and cash equivalents	\$ 2,435,120	\$ 6,805,889
Working capital	\$ 1,354,635	\$ 6,148,967
Total assets	\$ 3,882,018	\$ 7,827,387
Total stockholders' equity	\$ 1,809,992	\$ 6,726,620



Source: Dare Bioscience, Inc.