Daré Bioscience Reports Second Quarter 2021 Financial Results and Provides a Company Update

08-12-2021 at 8:00 AM EDT

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

SAN DIEGO, Aug. 12, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the quarter ended June 30, 2021 and provided a company update.

"This has been, and continues to be, an incredibly productive year for Daré," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Consistent with our guidance, we submitted our New Drug Application for DARE-BV1, a potential new first-line treatment for bacterial vaginosis, to the FDA in June. Our NDA was accepted for filing and received Priority Review with a PDUFA target date of December 7, 2021. This year we also commenced the Phase 2b RESPOND study of Sildenafil Cream, 3.6%, a potential first-in-category product in development to treat female sexual arousal disorder, a physiological condition for which there are no FDA approved products. In June, we announced positive topline results from our Phase 1 study of DARE-HRT1, a novel intravaginal ring designed to deliver bio-identical hormones which is being developed to treat vasomotor symptoms and the genitourinary syndrome commonly associated with menopause. And finally, we reported two new sources of non-dilutive funding for two of our programs – first, a grant intended to support the continued development of DARE-LARC1 over more than five years through the non-clinical proof of principle work, and second, a collaboration with the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development providing financial and operational support for the conduct of a pivotal Phase 3 clinical trial of Ovaprene®, an investigational hormone-free monthly contraceptive whose U.S. commercial rights are under a license agreement with Bayer."

Portfolio Accomplishments and Management Expectations for 2021-2022

- **DARE-BV1:**
  - Daré innovation: Novel, investigational thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% as a first-line, single-administration treatment for bacterial vaginosis.
  - **4Q 2020**: Successfully completed DARE-BVFREE Phase 3 clinical study.
  - **June 2021**: Submitted New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA).
  - **2021 Prescription Drug User Fee Act (PDUFA) goal date**: NDA accepted and received Priority Review with a PDUFA target date of December 7, 2021.
  - **2021**: Execute and announce commercialization strategy for DARE-BV1 in the U.S. to support a robust market introduction in 2022, if approved.
- **Sildenafil Cream, 3.6%:**
  - Daré innovation: Proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical administration to treat female sexual arousal disorder (FSAD).
  - **1Q 2021**: Commenced Phase 2b RESPOND clinical study.
  - **2021**: Ongoing enrollment in Phase 2b RESPOND clinical study.
  - 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 significant 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.
- **DARE-HRT1:**
  - Daré innovation: 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.
  - **June 2021**: Reported positive topline data of Phase 1 clinical study.

- **Ovaprene:**
  - Daré innovation: Novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer.
  - **3Q 2021**:
    - Announced a Collaborative Research and Development Agreement (CRADA) for a pivotal Phase 3 clinical study of Ovaprene in the U.S.
    - The CRADA is with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health.
    - The CRADA will allow Daré to leverage the contraceptive clinical trial expertise of NICHD while also sharing the costs of the Phase 3 clinical study with NICHD. Daré agreed to contribute $5.5 million toward the total estimated cost to conduct the study and to provide clinical supplies of Ovaprene.
  - **4Q 2021**: Submit Investigational Device Exemption (IDE) to the FDA for a pivotal Phase 3 clinical study in the U.S.
  - **2022:** Commence the pivotal Phase 3 clinical study.
- **DARE-VVA1:**
  - Daré innovation: 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.
  - **2H 2021:** Initiate Phase 1 clinical study in Australia.

Financial Highlights for period ended June 30, 2021

- Cash and cash equivalents: $9.1 million at June 30, 2021, compared to $4.7 million at December 31, 2020.
- Net cash from financing activities during the six months ending June 30, 2021 was approximately $24.6 million and included net proceeds from sales of common stock under the company's at-the-market offering program and equity line and warrant exercises.
- General and administrative expenses were approximately $1.8 million in 2Q 2021, as compared with $1.6 million in 2Q 2020, with the increase reflecting higher personnel costs and stock-based compensation expense.
- Research and development expenses were approximately $7.3 million in 2Q 2021, as compared to approximately $5.5 million in 2Q 2020. The $1.8 million increase was due primarily to increases in expenses related to clinical trial and other development and regulatory affairs activities for Sildenafil Cream, 3.6%, DARE-BV1, Ovaprene and DARE-HRT1.
- Comprehensive loss for 2Q 2021 was approximately $9.2 million, as compared to approximately $7.1 million for 2Q 2020.

Recent Financial Developments

- Between July 1, 2021 and August 10, 2021, Daré received additional cash of approximately $25.4 million (net of fees) from sales of common stock under the company's at-the-market offering program.
- In July 2021, Daré received an initial cash payment of $11.45 million in non-dilutive grant funding to support the non-clinical development of DARE-LARC1. The entire grant award is for up to $48.95 million and future payments are contingent upon the DARE-LARC1 program's achievement of specified development and reporting milestones.
- As of August 10, 2021, approximately 70.5 million shares of Daré common stock were outstanding.

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, 2021 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 5286254. 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 5286254. The call and webcast replay will be available until August 26, 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, hormone-free monthly contraceptive candidate 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 the market opportunity and commercial potential for Daré's product candidates and management's expectations for Daré's product candidates in 2021 and 2022, including anticipated timing for the conduct of clinical trials, topline and other clinical trial data readouts, IDE submissions, potential FDA review and approval, and a potential commercial launch of DARE-BV1. 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; Daré's failure to timely establish or leverage third-party partnerships or collaborations to commercialize its product candidates, if approved; 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

Lisa Walters-Hoffert, Chief Financial Officer
Daré Bioscience, Inc.
lwalters@darebioscience.com

858.926.7655

Source: Daré Bioscience, Inc.

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

	Three Months Ended June 30, 2021	
	2021	**2020**
Operating expenses:		
General and administrative	$ 1,797,637	$ 1,557,548
Research and development expenses	7,340,289	5,547,450
License fees	25,000	20,833
Total operating expenses	9,162,926	7,125,831
Loss from operations	(9,162,926)	(7,125,831)
Other income	175	1,618
Net loss	$ (9,162,751)	$ (7,124,213)
Foreign currency translation adjustments	$ (8,880)	$ 12,090
Comprehensive loss	$ (9,171,631)	$ (7,112,123)
Loss per common share - basic and diluted	$ (0.18)	$ (0.27)
Weighted average number of common shares outstanding:		
Basic and diluted	50,436,593	26,710,750

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheet Data

	June 30, 2021 (unaudited)	December 30, 2021
Cash and cash equivalents	$ 9,111,741	$ 4,669,467
Working capital (deficit)	$ 8,054,330	$ (676,689)
Total assets	$ 14,822,410	$ 7,550,712
Total stockholders' equity (deficit)	$ 7,744,004	$ (1,151,733)

Source: Daré Bioscience, Inc.