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

11-10-2021 at 8:00 AM EST

Significant progress on several key clinical and corporate initiatives with the portfolio during the third quarter, including DARE-BV1 NDA acceptance and Ovaprene NIH CRADA for the pivotal Phase 3

Actively advancing clinical development and strategic partnerships to maximize value of pipeline candidates

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

SAN DIEGO, Nov. 10, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the quarter ended September 30, 2021 and provided a company update.

"We've continued to make significant progress on several key clinical and strategic corporate initiatives with our portfolio during a rather challenging year," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The FDA accepted our NDA for DARE-BV1 for priority review with a PDUFA target date of December 7, 2021, and we entered into a CRADA under which a pivotal Phase 3 clinical study of Ovaprene® will be supported by the NICHD's Contraceptive Development Program and conducted within its Contraceptive Clinical Trial Network. We also initiated a Phase 1/2 clinical study of DARE-VVA1, our intravaginal tamoxifen program. Additionally, we're continuing to enroll patients in our Phase 2b RESPOND study of Sildenafil Cream, 3.6%, and are scoping the development strategy for DARE-HRT1 following the positive topline results of our Phase 1 clinical study reported earlier this year. On the heels of the important milestones achieved thus far in 2021, we are gearing up for an eventful next few months, and I look forward to providing updates as we progress further."

4Q 2021 Key Portfolio Objectives

- DARE-BV1: PDUFA target action date for the NDA of December 7, 2021
- DARE-BV1: Announce U.S. commercialization strategy
- Ovaprene®: Submit Investigational Device Exemption (IDE) to the FDA for pivotal clinical study

Portfolio Accomplishments and 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
  - New Drug Application (NDA) accepted for filing and granted priority review by the FDA in 3Q 2021
  - PDUFA target action date of December 7, 2021
  - Announce U.S. commercialization strategy in 4Q 2021
  - Robust market introduction in 1H 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)
  - Continue Phase 2b RESPOND clinical study in 2021 and 2022

- **Ovaprene®:**
  - Daré innovation: Novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer
  - Announced Collaborative Research and Development Agreement (CRADA) for a pivotal Phase 3 study in the U.S. with *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH), in 3Q 2021
  - Submit IDE to the FDA for a pivotal Phase 3 clinical study in the U.S. in 4Q 2021
  - Commence the pivotal Phase 3 clinical study in 2022

- **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
    - Submit data from the Phase 1 clinical study for publication in a peer-reviewed journal and scope our development strategy for DARE-HRT1.

- **DARE-VVA1:**
    - Daré innovation: Proprietary, investigational formulation of tamoxifen for intravaginal administration to treat vulvar and vaginal atrophy (VVA) in women with or at risk for hormone-receptor positive breast cancer
    - Initiated a Phase 1/2 clinical study in Australia in 3Q 2021
    - Report topline data of Phase 1/2 study in 2022

Financial Highlights for period ended September 30, 2021

- Cash and cash equivalents: $45.6 million at September 30, 2021, compared to $4.7 million at December 31, 2020.
- Net cash from financing activities during the nine months ended September 30, 2021 was approximately $59.8 million, primarily provided by net proceeds from sales of common stock under the company's at-the-market offering programs.
- General and administrative expenses were approximately $2.2 million in 3Q 2021, as compared to $1.4 million in 3Q 2020, with the increase primarily attributable to higher costs and expenses in professional services, commercial readiness, personnel, stock-based compensation and insurance.
- Research and development expenses were approximately $10.4 million in 3Q 2021, as compared to approximately $6.2 million in 3Q 2020. The $4.2 million increase was primarily attributable to the ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial and manufacturing and regulatory affairs activities for Ovaprene®.
- Comprehensive loss for 3Q 2021 was approximately $12.7 million, as compared to approximately $7.6 million for 3Q 2020.

Recent Financial Developments

- As of November 8, 2021, approximately 76.6 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. ET to review the company's financial results for the quarter ended September 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 8459303. 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 8459303. The call and webcast replay will be available until November 24, 2021.

About Daré Bioscience
Daré Bioscience is a clinical-stage biopharmaceutical company committed to advancing 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 prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, fertility, and vaginal and sexual health.

Daré's product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly 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," 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 belief that current clinical development activities and work being done with strategic partners will maximize the value of Daré's product candidates, expectations for Daré's product candidates in 2021 and 2022, including potential FDA approval of the DARE-BV1 NDA, anticipated timing of announcing the commercial strategy for and the commercial launch of DARE-BV1 in the U.S., if approved, anticipated timing for the Ovaprene IDE submission, commencement and conduct of clinical trials, and clinical trial data readouts. 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 develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; failure to timely establish or leverage third-party partnerships or collaborations to commercialize Daré's product candidates, if approved; failure or delay in starting, conducting and completing clinical trials of a product candidate; 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; Daré's dependence on third parties to conduct clinical trials and manufacture clinical trial material, and if any of its product candidates are approved, to manufacture commercial product; Daré's ability to raise additional capital when and as needed to advance its product candidates, execute its business strategy 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; 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 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses				
General and administrative	$ 2,211,334	$ 1,353,069	$ 5,949,299	$ 4,772,382

Research and development expenses	10,432,603	6,203,753	23,501,098	14,131,007
License expenses	25,000	25,000	75,000	58,333
Total operating expenses	12,668,937	7,581,822	29,525,397	18,961,722
Loss from operations	(12,668,937)	(7,581,822)	(29,525,397)	(18,961,722)
Other income (expense)	1,508	(986)	1,686	2,454
Gain on loan extinguishment of note payable	-	-	369,887	-
Net loss	$ (12,667,429)	$ (7,582,808)	$ (29,153,824)	$ (18,959,268)
Deemed dividend from trigger of down round provision feature	-	(6,863)	-	(6,863)
Net loss to common shareholders	$ (12,667,429)	$ (7,589,671)	$ (29,153,824)	$ (18,966,131)
Foreign currency translation adjustments	(63,281)	672	(79,002)	(10,182)
Comprehensive loss	$ (12,730,710)	$ (7,582,136)	$ (29,232,826)	$ (18,976,313)
Loss per common share - basic and diluted	$ (0.18)	$ (0.24)	$ (0.45)	$ (0.69)
Weighted average number of common shares outstanding:				
Basic and diluted	70,775,508	31,588,152	64,196,162	27,381,508

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

	September 30, 2021	December 31, 2020
	(unaudited)	
Cash and cash equivalents	$ 45,570,781	$ 4,669,467
Working capital (deficit)	$ 32,336,068	$ (676,689)
Total assets	$ 48,811,476	$ 7,550,712
Total stockholders' equity (deficit)	$ 31,888,591	$ (1,151,733)

Source: Daré Bioscience, Inc.