Daré Bioscience Reports First Quarter 2022 Financial Results and Provides a Company Update

May 12, 2022

- *$39.3 million in cash and cash equivalents at March 31, 2022*
- *Announced initiation of DARE-HRT1 Phase 1/2 clinical study in April 2022*
- *Organon exclusive global license agreement for XACIATO™(clindamycin phosphate vaginal gel, 2%):*
  - *Expected to close in 2Q-2022*
  - *$10 million cash payment to Daré expected in 2Q-2022*
  - *U.S. commercial launch expected in 4Q-2022*

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

SAN DIEGO, May 12, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the quarter ended March 31, 2022 and provided a company update.

"Our global license agreement with Organon to commercialize XACIATO, an FDA-approved treatment for females 12 years of age and older with bacterial vaginosis, is expected to close this quarter, the second quarter of 2022. Once effective, Daré will receive a $10 million cash payment from Organon. XACIATO is expected to be commercially available in the U.S. in the fourth quarter of 2022. Since announcing our agreement with Organon on March 31, 2022, I have been thrilled with the collaborative spirit between our companies and we continue to believe that Organon's commercial capabilities will ensure that XACIATO reaches the women most impacted by this condition."

Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women.[1] The condition results from an overgrowth of bacteria, which upsets the balance of the natural vaginal microbiome and can lead to symptoms of odor and discharge. In addition to being the most common type of vaginal infection in women of reproductive age and having bothersome symptoms, bacterial vaginosis has been associated with certain increased health risks.[2]

2022 Key Portfolio Objectives

- XACIATO™—U.S. commercial launch in 4Q-2022
- Ovaprene® —Approval of Investigational Device Exemption (IDE) submission by the FDA allowing commencement of pivotal Phase 3 clinical study in 2022
- DARE-VVA1—Phase 1/2 clinical study topline data in 2H-2022
- Sildenafil Cream, 3.6%—Phase 2b RESPOND clinical study interim analysis in 2022 and updated timeframe for topline data
- DARE-HRT1—Phase 1/2 clinical study topline data in 4Q-2022

Portfolio Accomplishments and 2022 Management Expectations

- **XACIATO™(clindamycin phosphate vaginal gel, 2%):**
  A clear, colorless, viscous gel to be administered once intravaginally as a single dose for the treatment of bacterial vaginosis in female patients 12 years of age and older. Please click here for full Prescribing Information.
  - Exclusive global license agreement with Organon announced on March 31, 2022
  - Transaction expected to close 2Q-2022
  - U.S. commercial launch expected 4Q-2022

- **Ovaprene®:**
  A novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer.
  - 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) announced in 3Q-2021
  - IDE review process with the U.S. Food and Drug Administration (FDA) initiated in 1Q-2022
  - Pivotal Phase 3 clinical study in collaboration with NICHD expected to commence in 2022

- **DARE-VVA1:**
  A 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.
  - Phase 1/2 clinical study in Australia initiated in 3Q-2021
  - Topline data expected during 2H-2022

- **DARE-HRT1:**
  A unique, investigational intravaginal ring (IVR) designed to deliver bio-identical estradiol and bio-identical progesterone continuously over a 28-day period for the treatment of menopausal symptoms, including vasomotor symptoms, as part of hormone therapy following menopause.
  - Phase 1/2 clinical study in Australia initiated in 2Q-2022 to evaluate the pharmacokinetics (PK) of lower and higher dose versions of DARE-HRT1 in approximately 20 healthy, post-menopausal women over approximately three consecutive months of use. The study will also collect safety, usability, acceptability and symptom-relief data
  - Topline data expected during 4Q-2022

- **Sildenafil Cream, 3.6%:**
  A proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical administration to treat female sexual arousal disorder (FSAD).
  - Ongoing enrollment in Phase 2b RESPOND clinical study
  - Interim analysis expected to be conducted in 2022 followed by an update on the anticipated timing for announcing topline data

Financial Highlights for the Quarter ended March 31, 2022

- Cash and cash equivalents: $39.3 million at March 31, 2022, compared to $51.7 million at December 31, 2021.
- General and administrative expenses: $2.6 million in 1Q-2022, as compared to $1.9 million in 1Q-2021, with the increase primarily attributable to increases in professional services expenses, stock-based compensation expense, personnel costs, and commercial-readiness expenses.
- Research and development expenses: $5.8 million in 1Q-2022, as compared to $5.7 million 1Q-2021, with expenses primarily related to the costs of the ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial, manufacturing and regulatory affairs activities related to Ovaprene®, rent and facilities expenses, and expenses for personnel and stock-based compensation.
- Comprehensive loss: $8.4 million in 1Q-2022, as compared to $7.3 million in 1Q-2021.
- As of May 10, 2022: 84.7 million shares of Daré common stock outstanding.

1 https://www.cdc.gov/std/bv/stats.htm2
2 https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-20352279

Conference Call

Daré will host a conference call and live webcast today at 4:30 p.m. Eastern Time to review financial results for the quarter ended March 31, 2022 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 7961884. 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 7961884. The call and webcast replay will be available until May 26, 2022.

About Daré Bioscience
Daré Bioscience is a 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 first FDA-approved product, XACIATO™ (clindamycin phosphate vaginal gel, 2%), is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older, which is under a global license agreement with Organon. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. Daré’s portfolio also 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®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone therapy following menopause. To learn more about XACIATO™, Daré’s full portfolio of women’s health product candidates, and Daré’s mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product and 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 and 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 in the Investors section of Daré's website.

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," "objective," 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 expectations regarding the closing of the transactions under the exclusive license agreement with Organon (the "XACIATO Agreement") and the payment to Daré in connection therewith, the timing of when XACIATO will be commercially available in the U.S., plans and expectations with respect to Daré's product candidates, including anticipated timing for commencement and conduct of clinical trials and clinical trial data readouts for Daré's product candidates. 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 risks that the XACIATO Agreement may not become fully effective, may be terminated early and that payments to Daré under the agreement may not occur or be significantly less than the anticipated or potential amounts; 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 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 and supply clinical trial material and 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 loss of, or inability to attract, key personnel; the effects of the COVID-19 pandemic, macroeconomic conditions and geopolitical events 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 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 or product candidates less competitive or obsolete; failure to timely establish or maintain third-party partnerships or collaborations to develop and/or commercialize Daré's product candidates, if approved; failure of Daré's product or product candidates, if approved, to gain market acceptance or obtain adequate coverage or reimbursement from third-party payers; Daré's ability to retain its licensed rights to develop and commercialize a product or 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 and 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; product liability claims; governmental investigations or actions relating to Daré's product, product candidates or business activities; 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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Source: Daré Bioscience, Inc.

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

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses		
General and administrative	$ 2,569,987	$ 1,940,328

Research and development	5,805,462	5,728,206
License fees	25,000	25,000
Total operating expenses	8,400,449	7,693,534
Loss from operations	(8,400,449)	(7,693,534)
Other income	1,779	3
Gain on loan extinguishment of note payable	-	369,887
Net loss	$ (8,398,670)	$ (7,323,644)
Net loss to common shareholders	$ (8,398,670)	$ (7,323,644)
Foreign currency translation adjustments	$ (9,150)	$ (6,841)
Comprehensive loss	$ (8,407,820)	$ (7,330,485)
Loss per common share - basic and diluted	$ (0.10)	$ (0.16)
Weighted average number of common shares outstanding:		
Basic and diluted	83,944,119	44,502,582

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

	March 31 2022	Dec 31 2021
	(unaudited)	
Cash and cash equivalents	$ 39,316,911	$ 51,674,087
Working capital	$ 31,422,629	$ 39,243,160
Total assets	$ 49,186,582	$ 55,807,177
Total stockholders' equity	$ 30,878,910	$ 38,754,321

Source: Daré Bioscience, Inc.