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

08-09-2022 at 8:00 AM EDT

- June 30, 2022: $32.1 million in cash and cash equivalents
- July 2022: approximately $18.0 million in cash received subsequent to quarter-end:
  - $10.0 million upfront license fee under global license agreement with Organon to commercialize XACIATO™ (clindamycin phosphate) vaginal gel, 2%, and
  - $7.96 million under existing $48.9 million grant to fund DARE-LARC1
- 4Q-2022: expected U.S. commercial launch of XACIATO

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

SAN DIEGO, Aug. 09, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the quarter ended June 30, 2022 and provided a company update.

"In the second quarter, we closed our global license agreement with Organon to commercialize XACIATO, an FDA-approved treatment for females 12 years of age and older with bacterial vaginosis, and recognized our first revenue of $10 million under the agreement. The teams at Daré and Organon have been working diligently and collaboratively toward the targeted commercial launch of XACIATO in the U.S. during the fourth quarter of 2022. Both companies remain highly committed to introducing a new therapeutic option for treating this condition, which is estimated to affect approximately 21 million women,[1]" said Sabrina Martucci Johnson, President and CEO of Daré Bioscience.

Bacterial vaginosis is the most common cause of vaginitis worldwide.[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, including pre-term labor and infertility.[2]

"Also during the second quarter, we continued to advance our other portfolio candidates. Two Phase 1/2 studies are ongoing: DARE-VVA1, our non-hormonal treatment for vulvar and vaginal atrophy for women with or at risk for hormone receptor positive breast cancer, using a novel vaginal administration of tamoxifen; and DARE-HRT1, an intravaginal ring to provide bio-identical hormone therapy for the treatment of menopausal systems with one IVR delivering both progesterone and estradiol together over 28 days. Both studies are being conducted in Australia, allowing us to take advantage of the Australian research and development cash rebate program. Both the DARE-VVA1 and the DARE-HRT1 studies are on track to report topline data in the fourth quarter of 2022. We are advancing the regulatory activities needed to initiate the pivotal Phase 3 study of Ovaprene® planned to commence later this year. Finally, we continue to enroll and treat patients in our ongoing Phase 2b RESPOND clinical study for female sexual arousal disorder, with an interim analysis for study sizing planned for this year. "

2022 Key Portfolio Objectives

- XACIATO: U.S. commercial launch in 4Q-2022
- Ovaprene: Initiation of pivotal Phase 3 clinical study in 4Q-2022
- DARE-VVA1: Phase 1/2 clinical study topline data in 4Q-2022
- DARE-HRT1: Phase 1/2 clinical study topline data in 4Q-2022
- Sildenafil Cream, 3.6%: Phase 2b RESPOND clinical study interim analysis 2H-2022 and updated timeframe for topline data

1H-2022 Portfolio Accomplishments and FY-2022 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.
  - License agreement with Organon to commercialize XACIATO closed and $10.0 million revenue recognized from upfront license fee in 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 HealthCare.
  - Ongoing interactions with FDA and Bayer in 2Q-2022
  - Investigator meeting, the preparative step to commencing the pivotal Phase 3 clinical study, targeted for 4Q-2022
  - Pivotal Phase 3 clinical study will be conducted under Collaborative Research and Development Agreement with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or the NICHD, part of the National Institutes of Health

- **DARE-VVA1:**
  A proprietary, investigational formulation of tamoxifen for vaginal administration to treat vulvar and vaginal atrophy 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 4Q-2022

- **DARE-HRT1:**
  A unique, investigational intravaginal ring designed to deliver bio-identical estradiol and 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 of two versions of DARE-HRT1 and to 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.
  - Ongoing enrollment in Phase 2b RESPOND clinical study
  - Interim analysis for trial sizing expected to be conducted in 2H-2022 followed by an update on the anticipated timing for announcing topline data

Financial Highlights for the Quarter ended June 30, 2022

- Cash and cash equivalents: $32.1 million at June 30, 2022, compared to $51.7 million at December 31, 2021.
- License fee revenue recognition: $10.0 million during 2Q-2022 in connection with the closing under the global license agreement with Organon to commercialize XACIATO, as compared to no revenue in 2Q-2021. Upon the first commercial sale of XACIATO, currently expected in 4Q-2022, we may receive another $2.5 million in license fee revenue.
- General and administrative expenses: $2.8 million in 2Q-2022, as compared to $1.8 million in 2Q-2021, with the current quarter's increase primarily attributable to increases in professional services expenses, commercial-readiness expenses, insurance, rent and facilities expenses, stock-based compensation expense, and personnel costs.
- Research and development expenses: $6.8 million in 2Q-2022, as compared to $7.3 million 2Q-2021. The current quarter's expenses primarily reflect personnel costs, expenses related to the ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial, manufacturing and regulatory affairs activities related to Ovaprene®, and stock-based compensation expense.
- As of August 8, 2022: 84.8 million shares of 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

Subsequent Events from July 1, 2022 through August 8, 2022

- $10.0 million payment received under the license agreement with Organon to commercialize XACIATO, after it became effective on June 30, 2022.
- $7.96 million received under a grant to support the development of DARE-LARC1.

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 June 30, 2022 and to provide a company update.

To access the conference call via phone, dial (800) 715-9871 (U.S.) or (646) 307-1963 (international). The conference ID number for the call is 3817141. 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 (800) 770-2030 (U.S.) or (609) 800-9909 (international). The conference ID number for the replay is 3817141. The call and webcast replay will be available until August 23, 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 timing of when XACIATO will be commercially available in the U.S. and 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: 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 and 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; 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.

Contacts:
Investor Relations
Lee Roth
Burns McClellan
lroth@burnsmc.com
212.213.0006

OR

Media on behalf of Daré Bioscience, Inc.:
Jake Robison
Evoke Canale
jake.robison@evokegroup.com
619.849.5383

Source: Daré Bioscience, Inc.

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

	Three months ended June 30,	
	2022	**2021**
Revenue		
License fee revenue	$ 10,000,000	$ -
Total revenue	10,000,000	-
Operating expenses		
General and administrative	2,792,894	1,797,637
Research and development	6,797,784	7,340,289
License fee expense	25,000	25,000
Total operating expenses	9,615,678	9,162,926
Income (loss) from operations	384,322	(9,162,926)
Other income	29,676	175
Net income (loss)	$ 413,998	$ (9,162,751)
Foreign currency translation adjustments	$ (135,869)	$ (8,880)
Comprehensive income (loss)	$ 278,129	$ (9,171,631)
Income (loss) per common share:		
Basic	$ 0.00	$ (0.18)
Diluted	$ 0.00	$ (0.18)
Weighted average number of shares outstanding:		
Basic	84,682,765	50,436,593
Diluted	85,369,424	50,436,593

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

	June 30, 2022	**December 31, 2021**
	(unaudited)	
Cash and cash equivalents	$ 32,070,612	$ 51,674,087
Accounts receivable	$ 10,000,000	$ -
Working capital	$ 33,575,695	$ 39,243,160
Total assets	$ 51,394,340	$ 55,807,177
Total stockholders' equity	$ 33,033,459	$ 38,754,321

Source: Daré Bioscience, Inc.