Daré Bioscience Reports Third Quarter 2024 Financial Results and Provides Company Update

11-14-2024 at 4:01 PM EST

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

Development Program Highlights and Anticipated Milestones

- **Ovaprene®** hormone-free monthly intravaginal contraceptive candidate – pivotal Phase 3 contraceptive efficacy study recruiting across the United States; foundation grant announced yesterday will provide funding to allow Daré to expand the number of clinical sites to accelerate the development timeline
- **Sildenafil Cream, 3.6%** topical formulation of sildenafil being developed to treat female sexual arousal disorder - continued operational progress toward a planned Phase 3 study, including constructive discussions with FDA; Phase 3 design, development, and collaboration strategy updates
- **DARE-HPV** proprietary, fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert for the treatment of human papillomavirus (HPV)-related cervical diseases – conducting activities necessary to enable submission of an IND application to the FDA for a Phase 2, randomized, placebo-controlled, double-blind clinical study of DARE-HPV for clearance of high-risk HPV infection in women, which will be supported with funding Daré receives as an ARPA-H Sprint for Women's Health $10 million awardee
- **DARE-VVA1** proprietary formulation of tamoxifen for intravaginal administration being developed as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse – conducting activities in preparation for a Phase 2 clinical study of DARE-VVA1 based on Daré's FDA-cleared IND
- **DARE-PTB1** intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for the prevention of preterm birth – conducting activities necessary to enable submission of an IND application to the FDA for a Phase 1 clinical study, which will be supported by a $2 million grant from NICHD
- Foundation grant of up to approximately $10.7 million to fund activities related to the identification and development of a novel non-hormonal intravaginal contraceptive product candidate and to add additional clinical sites to accelerate the ongoing Ovaprene® pivotal study.

SAN DIEGO, Nov. 14, 2024 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, today reported financial results for the quarter ended September 30, 2024 and provided a company update.

"We continue to be excited about the increased attention on the health and wellbeing of women, including by the Advanced Research Projects Agency for Health (ARPA-H) as evidenced by their recent announcement related to the awardees of the ARPA-H Sprint for Women's Health and our announcement of the $10 million award we were selected to receive for DARE-HPV, an innovative investigational treatment for HPV-related cervical diseases. Essentially all cervical cancer cases worldwide are caused by HPV infection. We are also very pleased by the foundation's continued commitment to invest in the development of non-hormonal contraceptive methods as evidenced by the grant we announced yesterday of up to approximately $10.7 million to fund activities related to our identification and development of a novel non-hormonal intravaginal contraceptive product candidate and to add additional clinical sites to accelerate the ongoing Ovaprene® pivotal study."

"We continue to execute on our mission to accelerate development of and bring to market innovative treatments that women want and need by advancing our late-stage candidates – all of which represent a first-in-category opportunity – as we seek to deliver value for all Daré stakeholders. In addition to the continued commercialization by our collaborator Organon of XACIATO ™ (clindamycin phosphate) vaginal gel 2%, the first FDA-approved product to emerge from our portfolio and a treatment for bacterial vaginosis in females aged 12 and older* that is available by prescription nationwide, we continue to advance our first-in-category Phase 3 development candidates with ongoing enrollment in our Phase 3 study of Ovaprene at sites across the U.S., and continued constructive interactions with the FDA focused on aligning on the Phase 3 program for Sildenafil Cream 3.6% in female sexual arousal disorder. Despite its high prevalence, there are currently no FDA-approved treatments for female sexual arousal

disorder and we look forward to advancing this program into Phase 3. Additionally, we are conducting activities in preparation for a Phase 2 clinical study of DARE-VVA1 and a Phase 1 study of DARE-PTB1, which is supported by a $2 million grant from NICHD," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience.

"The progress across our portfolio, along with the $10.7 million grant agreement announced yesterday, the $10 million award from ARPA-H announced in October, the $15 million equity line arrangement we established with Lincoln Park Capital Fund, LLC in October, and the $22 million we secured in the non-dilutive strategic royalty financing in the second quarter, put Daré on track for meaningful milestones in 2025."

**Please see below for important safety and other information.*

Ovaprene® Phase 3 Study
Ovaprene is a novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer HealthCare.

Working with study collaborators at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH) and commercial collaborator Bayer, Daré commenced patient enrollment in the Ovaprene® pivotal Phase 3 clinical study in December 2023. Non-hormonal contraception represents a significant commercial market opportunity, and there are currently no monthly, hormone-free contraceptives approved by the U.S. Food and Drug Administration (FDA). Ovaprene® has potential to be a disruptive product in the contraceptive category and an important option for women who cannot use hormone-based birth control products or prefer not to do so.

Recruitment is currently proceeding at 10 sites across the United States, supported by a central advertising campaign for the study that launched in March 2024. Based on the current average enrollment rate, Daré anticipates that approximately half of its target number of participants to complete the study, or 125 women, will complete approximately 6 months of product use by the end of the second quarter of 2025. The foundation grant announced yesterday will provide funding to allow Daré to expand the number of clinical sites recruiting in the study, which is intended to accelerate the overall development timeline.

Sildenafil Cream, 3.6% Progress toward Phase 3 Study
Sildenafil Cream is a proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical on-demand administration to treat female sexual arousal disorder (FSAD).

Daré completed all study analyses of data from the exploratory Phase 2b RESPOND clinical study and held an end-of-Phase 2 meeting with the FDA in December 2023. In prior quantitative studies, Sildenafil Cream increased genital tissue blood flow, and the Phase 2b at-home study was specifically designed to identify the patient population that experienced the most meaningful improvement from Sildenafil Cream and the questions to ask them that best reflect that improvement. The patient population and the endpoints proposed to the FDA for Phase 3 clinical development were those where Daré's exploratory post-hoc analyses of the Phase 2b study data showed that Sildenafil Cream demonstrated statistically significant and meaningful patient improvement. Ongoing discussions with the FDA are focused on aligning on primary and secondary patient reported outcome endpoints for the Phase 3 studies as well as other data that might be required for a new drug application (NDA) submission. Based on FDA feedback Daré has received, two successful Phase 3 clinical studies of Sildenafil Cream will be required to support an NDA for Sildenafil Cream for the treatment of FSAD, and Daré anticipates that each Phase 3 study will be approximately $15.0 million in direct costs. Daré will take into account its capital resources before initiating a Phase 3 study.

Daré's planned initial Phase 3 study of Sildenafil Cream, 3.6% would be the first ever Phase 3 pivotal study of a therapeutic candidate for the treatment of arousal disorder in women. Daré intends to provide updates on the Phase 3 program, as well as relevant updates on the initial Phase 3 study timing and Daré's collaboration strategy as they become available.

Financial Highlights for the Quarter ended September 30, 2024

- Cash and cash equivalents: $11.2 million at September 30, 2024.
- General and administrative expenses: $2.0 million in 3Q-2024 as compared to $2.7 million in 3Q-2023, with the current quarter's decrease primarily attributable to reduced professional services expense and reduced commercial readiness expenses.
- Research and development expenses: $2.7 million in 3Q-2024 as compared to $6.7 million in 3Q-2023, a 60% decrease compared to Q3-2023, with the current quarter's decrease primarily attributable to a decrease in costs related to development activities for Sildenafil Cream as a result of the Phase 2b RESPOND clinical study completion in June 2023, partially offset by increases in costs related to Ovaprene's development, including the ongoing pivotal Phase 3 clinical trial.

Conference Call

Daré will host a conference call and live webcast today, November 14, 2024, at 4:30 p.m. Eastern Time to review financial results for the quarter ended September 30, 2024 and to provide a company update.

To access the conference call via phone, dial (646) 307-1963 (U.S.) or (800) 715-9871 (toll free). The conference ID number for the call is 6400145. 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. The webcast will be archived under “Presentations, Events & Webcasts” in the Investors section of the company's website at http://ir.darebioscience.com and available for replay until November 28, 2024.

About XACIATO™ (clindamycin phosphate) vaginal gel 2%

XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years and older. A single-dose user-filled disposable applicator delivers 5g of vaginal gel containing 100mg of clindamycin.

Selected Safety Information

XACIATO is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin.

Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile may need to be discontinued.

Polyurethane condoms are not recommended during treatment with XACIATO or for 7 days following treatment. During this time period, polyurethane condoms may not be reliable for preventing pregnancy or for protecting against transmission of HIV and other sexually transmitted diseases. Latex or polyisoprene condoms should be used.

XACIATO may result in the overgrowth of Candida spp. in the vagina resulting in vulvovaginal candidiasis, which may require antifungal treatment.

The most common adverse reactions reported in >2% of patients and at a higher rate in the XACIATO group than in the placebo group were vulvovaginal candidiasis and vulvovaginal discomfort.

XACIATO has not been studied in pregnant women. However, based on the low systemic absorption of XACIATO following the intravaginal route of administration in nonpregnant women, maternal use is not likely to result in significant fetal exposure to the drug.

There are no data on the effect of clindamycin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for clindamycin and any potential adverse effects on the breastfed child from clindamycin or from the underlying maternal condition.

Please see the Prescribing Information, Patient Information, and Instructions for Use.

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, sexual health, pelvic pain, fertility, infectious diseases, and menopause.

The first FDA-approved product to emerge from Daré’s portfolio of women’s health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, 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. Visit www.xaciato.com for information about XACIATO. Daré’s portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil, the active ingredient in Viagra®, to treat female sexual arousal disorder (FSAD); and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. 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 Bioscience leadership has been named on the Medicine Maker’s Power List and Endpoints News’ Women in Biopharma 2022. In 2023, Daré's CEO was honored as one of Fierce Pharma’s Most Influential People in Biopharma for Daré’s contributions to innovation and advocacy in the women’s health space. Daré Bioscience placed #1 in the Small Company category of the San Diego Business Journal’s 2023 Best Places to Work Awards.

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 X (formerly 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,” “project,” “target,” “objective,” “on track,” 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 plans and expectations with respect to Daré’s product candidates, including clinical development plans, trial design, timelines, costs, milestones, targeted indications, anticipated regulatory approval pathways, and potential alignment with the FDA on requirements for a successful NDA submission, the potential for FDA approval of Ovaprene based on a single pivotal clinical study, the expectation that a product candidate, if approved, could be a first-in-category product, the potential market size and opportunity for a product candidate, if approved, the amount and timing of Daré’s receipt of funds under the recently announced foundation grant agreement, Daré’s anticipated use of funds it receives and Daré’s expectations with respect to the impact of such grant funding on its Ovaprene development program, the expectation that Daré will receive $10 million in funding under ARPA-H’s Sprint for Women’s Health, Daré’s ability to access $15 million in additional capital under its equity line arrangement with Lincoln Park Capital Fund at times and in amounts it desires to help advance development of its investigational products, and the potential for Daré’s product candidates to demonstrate they are safe and effective for their respective target indications. As used in this press release, the description of a product candidate as “first-in-category” is a forward-looking statement relating to the potential of the candidate to represent a new category of product if it were to receive marketing approval for the indication for which Daré is developing it. 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, risks and uncertainties related to: 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; Daré’s ability to achieve the product development and other milestones required for it to receive payments under its ARPA-H funding award and grant agreements with the foundation; the limits on Daré’s ability to sell stock to Lincoln Park Capital Fund under the purchase agreement at times it may desire to raise additional capital; 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 ability to add new clinical study sites to the Ovaprene pivotal study and the ability of such additional sites to enroll subjects in a manner that accelerates the study timeline; Daré’s dependence on third parties to conduct clinical trials and manufacture and supply clinical trial material and commercial product; 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 the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré’s interpretation of or conclusions regarding data from clinical studies of its product candidates; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates; the loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré’s operations, financial results and condition, and ability to achieve current plans and objectives; the risk that developments by competitors make Daré’s product or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; 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 or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; cybersecurity incidents 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:

Daré Bioscience Investor Relations
innovations@darebioscience.com

Source: Daré Bioscience, Inc.

Daré Bioscience, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three months ended September 30,	
	2024	**2023**
Revenue		
License fee revenue	$ -	$ 1,000,000
Royalty revenue	41,691	-
Total revenue	41,691	1,000,000
Operating expenses		
General and administrative	2,041,268	2,696,779
Research and development	2,656,772	6,674,636
License fee expense	25,000	25,000
Total operating expenses	4,723,040	9,396,415
Loss from operations	(4,681,349)	(8,396,415)
Other income (expense)	(21,152)	97,319
Net loss	$ (4,702,501)	$ (8,299,096)
Foreign currency translation adjustments	$ 22,935	$ (15,030)
Comprehensive loss	$ (4,679,566)	$ (8,314,126)
Loss per common share:		
Basic	$ (0.55)	$ (1.09)
Diluted	$ (0.55)	$ (1.09)
Weighted average number of shares outstanding:		
Basic	8,534,433	7,587,637
Diluted	8,534,433	7,587,637

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

	September 30, 2024	**December 31, 2023**
	(unaudited)	
Cash and cash equivalents	$ 11,232,609	$ 10,476,056
Working capital (deficit)	$ 1,790,546	$ (2,936,897)
Total assets	$ 18,058,801	$ 21,282,215
Total stockholders' deficit	$ (1,484,483)	$ (5,047,640)

Source: Daré Bioscience, Inc.