



DARÉ BIOSCIENCE.

Daré Bioscience to Present Phase 1 Sildenafil Cream Data at Sexual Medicine Society of North America (SMSNA) Annual Fall Scientific Meeting

10-08-2026 at 9:15 AM EDT

Medical Director Annie Thurman, MD, FACOG to present adverse event and relative bioavailability data comparing topical Sildenafil Cream with oral sildenafil in healthy male adults

SAN DIEGO, Oct. 08, 2026 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real-world solutions, today announced that clinical data from a Phase 1 study that evaluated the Company's proprietary Sildenafil Cream, 3.6% investigational product (Sildenafil Cream) will be presented at the Annual Fall Scientific Meeting of the Sexual Medicine Society of North America (SMSNA), taking place October 8-11, 2026, in Orlando, Florida.

Annie Thurman, MD, FACOG, Medical Director of Daré Bioscience, will present "An Open-Label, Single-Dose, Randomized, Parallel-Cohort Study of the Safety and Relative Bioavailability of Topical Sildenafil Cream, Versus Oral Sildenafil in Healthy Male Adults" during the Innovations in Sexual Medicine Abstracts session on Friday, October 9, 2026. A copy of the presentation will be made available through the Presentations, Events & Webcasts page of the Investors section of the Company's website (darebioscience.com). The poster will be accessible for approximately 30 days after Dr. Thurman's live presentation.

The Phase 1 study evaluated the adverse events and relative bioavailability of Daré Bioscience's proprietary topical Sildenafil Cream compared with oral sildenafil in healthy adult men. The study provides additional clinical evidence supporting further clinical development of the Company's topical formulation and its potential to deliver sildenafil locally while resulting in substantially lower systemic exposure compared with oral administration.

In the study, at the 71 mg topical dose, mean maximum plasma concentration of sildenafil was approximately 187-fold lower compared to the 50 mg oral dose, while systemic exposure measured by area under the curve (AUC) was approximately 33- to 34-fold lower. All treatment-emergent adverse events reported in the study were mild, with no serious adverse events, severe adverse events, deaths or discontinuations due to treatment-emergent adverse events. Findings from the study were recently published in *Sexual Medicine*, an official journal of the International Society for Sexual Medicine. The journal article may be accessed [here](#).

"These findings provide additional clinical evidence supporting the rationale for topical delivery of sildenafil and the potential for substantially lower systemic exposure compared with oral administration," said Annie Thurman, MD, FACOG, Medical Director of Daré Bioscience. "As a physician and clinical researcher focused on women's health, I believe understanding this data on the pharmacokinetic and potential safety profile of our proprietary formulation in men is an important component of advancing Sildenafil Cream as a potential treatment for women with female sexual arousal disorder."

The Phase 1 study in men complements Daré Bioscience's clinical development program evaluating Sildenafil Cream in women with female sexual arousal disorder (FSAD). Daré Bioscience's Sildenafil Cream has been studied in Phase 1, Phase 2a and Phase 2b clinical trials in women. Daré Bioscience is developing Sildenafil Cream as a potential treatment for FSAD, a condition for which there are currently no FDA-approved pharmacological treatments.

Daré Bioscience is continuing activities necessary to advance Sildenafil Cream toward the FDA's 505(b)(2) regulatory pathway* while also making its proprietary formulation available in the U.S. as DARE to PLAY™ Sildenafil Cream, a compounded product manufactured by a 503B outsourcing facility under current Good Manufacturing Practices (cGMP). Compounded drug products are not approved by the U.S. Food and Drug Administration (FDA).**

ABOUT DARÉ BIOSCIENCE, INC.

Daré Bioscience (NASDAQ: DARE) is a purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real-world solutions. Every innovation Daré Bioscience advances is based in advanced science and backed by rigorous, peer-reviewed research. From contraception to menopause, sexual health to fertility, vaginal health to infectious disease, Daré Bioscience is working to close critical gaps in care using science that serves her needs. For decades, women have been told to "wait it out" or "live with it," while innovations that could improve their quality of life languish in the regulatory or funding pipeline. With growing awareness around menopause, sexual health, and vaginal health, the conversation is shifting. However, access to proven solutions is lagging. Daré Bioscience is working to change that. Learn more at darebioscience.com.

FORWARD-LOOKING STATEMENTS

Daré Bioscience 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,” “prepare,” “progress,” “seek,” “should,” “would,” “build” 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 significance of data from the Phase 1 clinical study in men for Daré Bioscience’s Sildenafil Cream program; Daré Bioscience’s plans regarding further clinical development and pursuing FDA approval of Sildenafil Cream; the potential of Sildenafil Cream as a safe and effective treatment for FSAD; the potential of Sildenafil Cream to be the first FDA-approved pharmacological treatment for FSAD; the market opportunity for Sildenafil Cream; and the availability of DARE to PLAY.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Daré Bioscience’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 Bioscience’s ability to obtain additional capital when and as needed to execute its business strategy and continue as a going concern; potential suspension and delisting of Daré Bioscience’s common stock from The Nasdaq Capital Market; failure or delay in commencing, conducting or completing clinical trials and the inherent uncertainty of outcomes of clinical trials; 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; Daré Bioscience’s ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; the risk that Daré Bioscience’s product candidates may fail to demonstrate acceptable safety and tolerability or sufficient efficacy in clinical trials; Daré Bioscience’s dependence on third parties to conduct clinical trials and manufacture and supply clinical trial material and commercial product; the potential that a product candidate in clinical development may never advance into or through a pivotal clinical study or obtain FDA or foreign regulatory approval; the risk that the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré Bioscience’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 Bioscience anticipates; the risk that the FDAs 505(b)(2) pathway may not be available for a product candidate as Daré Bioscience anticipates; difficulties establishing and sustaining relationships with development and/or commercial collaborators; failure of Daré Bioscience’s products or product candidates, if approved, to gain market acceptance or obtain adequate coverage, pricing and reimbursement from third-party payors; Daré Bioscience’s reliance on Section 503B-registered outsourcing facilities and other third parties to bring DARE to PLAY Sildenafil Cream and other solutions to market as compounded drugs or as consumer health products and facilitate access to such products and the risk that those third parties do not perform as expected; difficulties in establishing and sustaining relationships with third-party collaborators; the risk that the FDA could stop permitting Section 503B-registered outsourcing facilities to compound the drug substances in the proprietary formulations Daré Bioscience intends to bring or brings to market or changes the conditions under which those drug substances may be used in compounding or the compounded products may be distributed; the ability of outsourcing facilities for Daré Bioscience’s compounded products to maintain their registration with the FDA under Section 503B; the timing of establishing, and ability to maintain, state-required licensure or registration to enable fulfillment of prescriptions for DARE to PLAY Sildenafil Cream and other solutions brought to market via the Section 503B pathway; Daré Bioscience’s inexperience, as a company, in and limited infrastructure for commercializing products; the degree of market demand and acceptance for the products Daré Bioscience brings to market; competitive product launches; greater than expected costs to bring compounded drug products to market and marketing costs; shifts in consumer spending or behavior; the risk that developments by competitors make Daré Bioscience’s products or product candidates less competitive or obsolete; Daré Bioscience’s ability to retain its licensed rights to develop and commercialize a product or product candidate; Daré Bioscience’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 products and product candidates; Daré Bioscience’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 Bioscience’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 Bioscience’s products or product candidates or the business activities of Daré Bioscience, its commercial collaborators or other third parties on which Daré Bioscience relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; the effects of macroeconomic conditions, geopolitical events, and major changes and disruptions in U.S. government policies and operations on Daré Bioscience’s ability to raise additional capital or on Daré Bioscience’s operations, financial results and condition, and ability to achieve current plans and objectives; and cybersecurity incidents or similar events that compromise Daré Bioscience’s technology systems and/or significantly disrupt Daré Bioscience’s business or those of third parties on which Daré Bioscience relies.

Daré Bioscience’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 Bioscience’s risks and uncertainties, you are encouraged to review its documents filed with the U.S. Securities and Exchange Commission (SEC), including Daré Bioscience’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 Bioscience 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.

*Reference to the FDA's 505(b)(2) regulatory pathway refers to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), which enables an applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of the applicant's new drug application (NDA), providing an alternate path to FDA approval for new or improved formulations or new uses of previously approved drugs.

**The term DARE to PLAY describes a 503B compounded drug product. Compounded drug products are not approved by the FDA. The FDA does not evaluate compounded drug products for safety, effectiveness, or quality. References to Section 503B, 503B, 503B compounding, 503B compounded product, and similar terms refer to Section 503B of the FDCA and the production and supply of compounded drugs by Section 503B-registered outsourcing facilities without patient-specific prescriptions in accordance with Section 503B. Section 503B-registered outsourcing facilities are subject to FDA inspection and required to compound drug products under current Good Manufacturing Practice (cGMP) regulations to ensure quality, strength and consistency.

Contact:

Daré Bioscience Investor Relations

innovations@darebioscience.com

Source: Daré Bioscience, Inc.

