



DARÉ BIOSCIENCE.

DARE to PLAY™ Sildenafil Cream Now Available for Pre-Order by Prescription: First Evidence-Based Topical Arousal Cream for Women Begins Commercial Rollout in Select States via 503B Outsourcing Facility

12-10-2025 at 8:00 AM EST

Developed and evaluated specifically for women, DARE to PLAY™ Sildenafil Cream is a first-of-its-kind female arousal cream, a non-hormonal topical cream shown in clinical studies to increase genital blood flow in 10–15 minutes, and improve arousal sensations based on clinically-validated endpoints. Market introduction of DARE to PLAY™ is expected to mark a breakthrough in women's sexual health and represents important progress toward closing one of medicine's most persistent gender gaps.

SAN DIEGO, Dec. 10, 2025 (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 providers in select states can now begin prescribing DARE to PLAY™ Sildenafil Cream, a proprietary topical arousal cream designed specifically for women to enhance genital blood flow and arousal response.

DARE to PLAY™ represents the first and only evidence-backed sildenafil cream formulation for women. Its commercial availability through a 503B outsourcing facility will mark the first time a topical sildenafil formulation manufactured in accordance with cGMP requirements and supported by clinical data will be accessible to women.

DARE to PLAY™ uses sildenafil, the same active ingredient found in Viagra®, to improve genital blood flow. Applied topically, it's designed for use as needed, to enhance the body's natural arousal response without systemic effects, providing women with a new, evidence-based tool to take charge of their sexual health.

"When Viagra was approved in 1998, it revolutionized sexual medicine for men. But for women, comparable progress on enhancing the natural arousal sensations has stalled for nearly three decades," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We believe DARE to PLAY™ represents a long overdue correction, giving women an option to reconnect with their own bodies, their pleasure, and their confidence, using science that finally recognizes their needs."

Existing products promoted for arousal lean heavily on marketing language, consumer reviews, and lifestyle branding without real evidence. DARE to PLAY™ is the first and only topical formulation of sildenafil developed specifically for women and [backed by](#):

- Toxicology studies covering oral, anal, vaginal, and reproductive health;
- Multiple clinical trials in women, including a randomized placebo-controlled study with 200 women and their sexual partners; and
- Published, peer-reviewed research in medical journals such as The Green Journal, the official publication of the American College of Obstetrics and Gynecology (ACOG) and the Journal of Sexual Medicine, the official publication of the International Society for the Study of Women's Sexual Health (ISSWSH).

"As more women speak openly about their sexual health, the need for research-backed solutions has never been greater," said Dr. Irwin Goldstein, Director of San Diego Sexual Medicine and a founder of ISSWSH. "Daré's commitment to both clinical integrity and timely access ensures women who need it don't have to wait to benefit from this innovation."

While continuing activities necessary to seek U.S. Food and Drug Administration (FDA) approval of its proprietary sildenafil cream formulation in the future, Daré Bioscience is making DARE to PLAY™ available as a Section 503B compounded product, manufactured in an outsourcing facility subject to FDA inspection and under current Good Manufacturing Practice (cGMP) regulations to ensure quality, strength and consistency. Compounded drug products are not FDA approved. The FDA does not evaluate compounded drug products for safety, effectiveness, or quality.

DARE to PLAY™ can now be prescribed for pre-order by licensed healthcare providers for prescription fulfillment in these states: CT, FL, IN, MO, NH, NJ, OR, PA, RI, and UT, and will ship within 45 days of order placement during the pre-order phase. DARE to PLAY™ prescriptions are being accepted through the DARE Health Hub, managed by Medvantx. DARE to PLAY™ will be available in other states throughout December and early 2026. Visit <https://daretoplaybio.com/> for more information on DARE to PLAY™, including how to access a prescription and to sign up for an alert on when it is available in your state.

Market Opportunity

An estimated 20 million women in the United States experience challenges related to genital arousal, yet there are no FDA-approved therapeutics to address this need. The availability of DARE to PLAY™ through a cGMP 503B facility provides this large, underserved community of women access to a product uniquely supported by clinical evidence and scientific rigor.

Section 503B

References to Section 503B, 503B, 503B compounding, 503B compounded product, and similar terms refer to Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) and the production and supply of compounded drugs by Section 503B-registered outsourcing facilities without patient-specific prescriptions in accordance with Section 503B.

About Daré Bioscience

Daré Bioscience 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 advances is based in advanced science and backed by rigorous, peer-reviewed research. From contraception to menopause, pelvic pain to fertility, vaginal health to infectious disease, Daré 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 real, evidence-based solutions continues to lag. Daré was founded to change that. As a female-led health biotech company, Daré is accelerating the development of credible, science-based solutions that meet the high standards of clinical rigor – randomized, controlled trials; validated endpoints; peer-reviewed publications; and current Good Manufacturing Practice (cGMP) requirements.

To learn more about Daré's mission to deliver differentiated therapies for women and its innovation pipeline, please visit www.darebioscience.com.

Daré Bioscience leadership has been named on the Medicine Maker's Power List and Endpoints News' Women in Biopharma and Daré's CEO has been 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 may announce material information about its finances, products 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, products 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,” “seek,” “should,” “would,” “project,” “target,” “explore” “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 timing for commercial availability of DARE to PLAY™ Sildenafil Cream in states in the U.S., production of the compounded drug product in accordance with cGMP requirements, the ability of the product to enhance genital arousal response in women without systemic effects, the market opportunity for the product, its market position, its impact in women's sexual health, and its ability to gain market acceptance, and Daré's plans to seek FDA approval of its sildenafil cream formulation, pending additional development activities. 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 reliance on a Section 503B-registered outsourcing facility, a licensed dispensing pharmacy with an online platform, and other third parties to bring DARE to PLAY™ Sildenafil Cream to market and facilitate access to the product 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 FDA could stop permitting Section 503B-registered outsourcing facilities to manufacture and fulfill orders for compounded sildenafil products or change the conditions under which sildenafil may be used in compounding or compounded sildenafil products may be distributed; the ability of Daré's outsourcing facility partner to maintain its registration with the FDA under Section 503B of the Federal Food, Drug, and Cosmetic Act; the timing of establishing, and ability to maintain, state-required licensure or registration to enable fulfillment of prescriptions for DARE to PLAY™ Sildenafil Cream; Daré's inexperience, as a company, in and lack of infrastructure for commercializing products; the degree of market demand and acceptance for DARE to PLAY™ Sildenafil Cream; competitive product launches; greater than expected costs to bring compounded drug products to market and marketing costs; shifts in consumer spending or behavior; Daré's ability to raise additional capital when and as needed to execute its business strategy and continue as a going concern; Daré's dependence on grants and other financial awards from governmental entities and a private foundation; limitations on Daré's ability to raise additional capital through sales of its common stock or other equity

securities due to restrictions under SEC and Nasdaq rules and regulations or contractual limitation; 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 products and product candidates; Daré's ability to adequately protect or enforce its, or its licensor's, intellectual property rights; disputes or other developments concerning Daré's intellectual property rights; product liability claims; governmental investigations or actions relating to Daré's products or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; changes in healthcare, pharmaceutical, consumer protection or privacy laws and regulatory policies; increased scrutiny from regulators; 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, completing or conducting clinical trials of a product candidate and the inherent uncertainty of outcomes of clinical trials; the risks 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 and that interim data or results from a particular clinical study do not necessarily predict the final results for that study; 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 effects of macroeconomic conditions, geopolitical events, and major changes and disruptions in U.S. government policies and operations on Daré's ability to raise additional capital or on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; Daré's ability to maintain compliance with Nasdaq's continued listing requirements and continue to have its common stock listed on The Nasdaq Capital Market; and cybersecurity incidents or similar events that compromise Daré's technology systems and/or significantly disrupt Daré's business or those of third parties on which Daré relies. 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 U.S. Securities and Exchange Commission, 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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