



Daré Bioscience Announces Return of Rights to Ovaprene®; Phase 3 Program Ongoing; Positive Interim Data and Grant Funding Position Asset for Value-Maximization

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SAN DIEGO, Dec. 01, 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 all rights to Ovaprene®, the company's first-in-category, investigational, hormone-free monthly intravaginal contraceptive, will be returned to Daré by Bayer HealthCare LLC as a result of Bayer electing to terminate the license agreement between the parties as part of a strategic prioritization. In accordance with the license agreement, the termination will be effective in February 2026. With the Phase 3 program advancing with non-dilutive grant support, the return of rights will provide Daré with full control of a late-stage asset that is differentiated in a large market with significant unmet need.

Late-Stage, First-in-Category Asset

The consolidation of commercialization rights will strengthen Daré's strategic position as Ovaprene advances through its pivotal Phase 3 clinical study. Ovaprene has the potential to become the first FDA-approved hormone-free, monthly intravaginal contraceptive option available to women, representing a meaningful innovation in a category that has seen limited advancement in decades.

"We view the consolidation of commercial rights under Daré at this stage of Ovaprene's development as value-enhancing for our company," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The Phase 3 study is progressing, supported by non-dilutive funding, and the positive interim data announced in July 2025 underscore the asset's potential. We will have maximum strategic flexibility to capture the value of this opportunity."

Positive Interim Results Reinforce Clinical and Commercial Potential

In July 2025, [Daré announced positive interim data](#) from the ongoing open-label Phase 3 trial of Ovaprene ([ClinicalTrials.gov](#) ID: NCT06127199) demonstrating encouraging results including consistent safety and tolerability; no serious safety concerns were identified, and overall tolerability was favorable. The rate of pregnancy in women treated in the study at the time of the interim analysis was consistent with the company's expectations based on the results of the pre-pivotal postcoital test [clinical study](#) of Ovaprene. These interim findings support Ovaprene's potential as a meaningful hormone-free alternative. These fundamentals remain unchanged, and the study is progressing toward anticipated completion of enrollment in 2026.

The ongoing trial is supported by previously announced external grant funding, including the award from the [Gates Foundation announced in 2024](#), and continues without any change to timelines or operations.

Expanded Strategic Optionality

With global commercialization rights consolidated at Daré, the company is now positioned to evaluate partnership structures that best reflect the value of a late-stage, non-hormonal contraceptive with differentiation and relevance. The company believes that Ovaprene will attract broad strategic interest across pharmaceutical and consumer health organizations.

"We believe this development gives us the ability to pursue the most attractive commercial and access pathways for Ovaprene, including partnerships, non-traditional commercialization models, and opportunities to retain greater long-term economics," Johnson added. "This increased optionality, combined with the clinical profile demonstrated to date, positions Ovaprene as one of the most exciting assets in the women's health pipeline."

Clear Path Forward

- Phase 3 study enrollment expected to be completed in 2026
- Continuation of grant funded trial operations
- Premarket approval (PMA) strategy with the FDA's Center for Devices and Radiological Health (CDRH) as lead review division
- Increasing global interest in non-hormonal contraception
- Company will explore partnership and strategic transaction opportunities

About Ovaprene®

Ovaprene is an investigational, hormone-free monthly, intravaginal contraceptive that combines physical and chemical mechanisms. Ovaprene features a proprietary knitted polymer barrier to physically block sperm from entering the cervical canal within a silicone-reinforced ring that releases non-hormonal agent ferrous gluconate to impede sperm motility. Unlike current FDA-approved monthly intravaginal contraceptives, Ovaprene does not contain hormones, but consistent with those monthly intravaginal contraceptives Ovaprene is designed to be a "one size fits most" monthly, self-administered product. It is inserted at the end of one menstrual period and left until the beginning of the next, requiring no action at intercourse. It requires no clinician fitting and a new product is used each month. If approved, Ovaprene would represent the first product of its kind for women seeking new options in non-hormonal contraception.

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 LinkedIn accounts: @Sabrina Johnson and @DareBioscience and 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," "view," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "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 the potential benefits of the return of the rights to Ovaprene to Daré, that Ovaprene will attract broad strategic interest across pharmaceutical and consumer health organizations, the importance of the interim results from the ongoing pivotal Phase 3 trial of Ovaprene to Daré and Ovaprene, Ovaprene's potential as a safe and effective first-in-category, hormone-free, intravaginal monthly contraceptive, Ovaprene's potential to be the first U.S. Food and Drug Administration (FDA)-approved hormone-free, monthly intravaginal contraceptive, the potential market opportunity for Ovaprene, if approved, and that enrollment in the ongoing pivotal Phase 3 clinical study of Ovaprene will be completed in 2026. As used in this press release, "first-in-category" is a forward-looking statement relating to the potential of a product candidate to represent a new category of product if it were to receive marketing approval for the indication for which it is being developed because Daré believes it would address a need in women's health that is not being met by existing FDA-approved products. 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 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, including to conduct clinical and nonclinical studies and manufacture and supply clinical trial material and commercial product; 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 risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates, or that the duration of a study or number of study subjects must be significantly greater than anticipated; 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 the Gates Foundation, or the foundation; the foundation's ability to modify, suspend, discontinue payment of grant funds or terminate a grant agreement in certain circumstances largely in the foundation's discretion; 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 expanded business strategy to bring to market prescription compounded drug products and non-prescription consumer health products; Daré's inexperience, as a company, in and lack of infrastructure for commercializing products; the degree of market demand and acceptance for the products Daré brings to market; competitive product launches; Daré's ability to identify, develop, obtain FDA or foreign regulatory approval for, and commercialize product candidates and to do so on communicated timelines; failure or delay in starting, conducting or completing clinical trials and the inherent uncertainty of outcomes of clinical trials; the loss of, or inability to attract, key personnel; 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 pricing and coverage and reimbursement from third-party payors; 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; 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'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 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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