Daré Bioscience Reports Third Quarter 2025 Financial Results and Provides Corporate Update

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DARE to PLAY™ Sildenafil Cream on Track to Launch Before Year End via 503B Pathway, Paving the Way for Near-Term Product Revenue

Positive Interim DSMB Outcome for Ovaprene® Phase 3 Study Supports Continued Enrollment

Multiple Grant-Funded Programs Advance, Including to Address HPV and Long-Acting as well as Non-Hormonal Contraception

Four Commercially Available Solutions for Women Expected Over the Next Two Years

- ***In addition to DARE to PLAY™ Sildenafil Cream, Commercialization of DARE to RESTORE™ Vaginal Probiotics in the Consumer Health Market Targeted to follow DARE to PLAY Sildenafil Cream availability and DARE to RECLAIM™ Monthly Hormone Therapy via 503B Compounding Pathway Targeted for Early 2027***
- ***DARE to RECLAIM™ Will Establish Entry into the Estimated $4.5 Billion Compounded Hormone Therapy Market While Daré Continues Building Toward FDA-Approval Opportunity***

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

Q3 2025 Highlights; Near-Term Revenue and Long-Term Value Creation Through Dual-Path Execution:

- **DARE to PLAY™ Sildenafil Cream: Near-Term Commercial Opportunity**
  - On track for initial prescription fulfillment in December through a 503B-registered outsourcing facility
  - November 17th webinar to feature leading clinicians discussing clinical data and potential impact in women's sexual health; Registration and Access: https://cvent.me/KO1obd
  - Represents near-term revenue generation opportunity and an important proof point for the Company's 503B compounding strategy
- **Sildenafil Cream, 3.6%**
  - Discussions with FDA ongoing regarding endpoint assessment for Phase 3 clinical studies of Sildenafil Cream, 3.6%
- **Ovaprene®: Investigational Hormone-Free Intravaginal Contraceptive; Positive Interim DSMB Recommendation Highlights Potential**
  - Independent data safety monitoring board (DSMB) reviewed interim safety data in July 2025 and recommended the pivotal Phase 3 multicenter, single-arm, open-label study (ClinicalTrials.gov ID # NCT06127199) continue without modification
  - Interim pregnancy rate of women treated in the study was consistent with the Company's expectations based on prior postcoital test study of Ovaprene
  - Enrollment in the study is ongoing; primary endpoint is assessment of typical use pregnancy rate over 13 menstrual cycles (Pearl Index)
- **DARE-HPV, DARE-NHC, and DARE-LARC1: Progress in Grant-Funded Women's Health Innovation**
  - **DARE-HPV**: Currently funded by an ARPA-H award and NIH grant; in development as a novel intravaginal therapy to treat persistent high-risk genital human papillomavirus (HPV) infections in women and reduce risk of cervical disease
  - **DARE-LARC1**: Preclinical development expected to be fully funded by a foundation grant; investigational long-acting contraceptive intended to offer multi-year protection with remote pause/resume capability; $6 million grant installment received in July 2025 and $4 million grant installment received in October 2025
  - **DARE-NHC**: A preclinical research program that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive product candidate. The grant funding supports activities to de-risk the

development of a novel non-hormonal intravaginal contraceptive, suitable for and acceptable to women in low- and middle-income country settings who need or would prefer to use such a product to avoid an unplanned pregnancy. A $3.6 million installment under a November 2024 grant agreement is anticipated to be received in November 2025.

- **Ongoing Actions to Make Three Additional Solutions Available Commercially**
  - **DARE to RESTORE™**: Targeted for availability in the first quarter of 2026, two non-prescription vaginal probiotics designed to support vaginal microbiome health, intended to be complementary to Daré's prescription offerings
  - **DARE to RECLAIM™:** Proprietary monthly bio-identical estradiol and progesterone intravaginal ring targeted to be available for prescription fulfillment in early 2027 via the 503B compounding pathway to accelerate patient access; Daré is continuing in parallel on pathway to seek FDA approval of DARE-HRT1 for the treatment of moderate-to-severe vasomotor symptoms due to menopause, conducting activities to enable submission of an Investigational New Drug (IND) application to the FDA for a pivotal Phase 3 clinical study.

SAN DIEGO, Nov. 13, 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 reported financial results for the quarter ended September 30, 2025 and provided a company update.

"Daré is executing a disciplined, multi-pronged value creation strategy — preparing to generate revenue from DARE to PLAY ™ Sildenafil Cream beginning in December, while advancing a pipeline that spans both clinical innovation and near-term commercial solutions," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience.

"With four women's health products expected to become commercially available over the next two years, and multiple grant-supported programs, we believe Daré is well positioned to deliver meaningful impact for women and strong value creation for shareholders."

"Women's health remains an underfunded and underserved market — and we believe the coming weeks will represent a historic inflection point for Daré and for women seeking new options. We are proud to lead with science, collaboration, and purpose," stated Johnson.

Financial Highlights for the Quarter Ended September 30, 2025

- **Cash Position:** As of September 30, 2025, Daré had approximately $23.1 million in cash and cash equivalents, and working capital of approximately $3.8 million.
- **General and Administrative Expenses:** $2.5 million in Q3 2025 compared to $2.0 million in Q3 2024, with the year-over-year change primarily attributable to increases in professional services expense and commercial-readiness expenses driven by execution against the Company's expanded business strategy, which includes earlier market access for select proprietary solutions via 503B compounding and bringing to market non-prescription consumer health products.
- **Research and Development (R&D) Expenses:** $1.2 million in Q3 2025 compared to $2.7 million in Q3 2024, reflecting a decrease of 56%, primarily due to an increase in contra R&D expenses (reductions to R&D expenses due to non-dilutive funding awards), as well as decreases in manufacturing costs related to Ovaprene and in personnel costs, partially offset by increases in costs related development activities for other clinical- and preclinical-stage R&D programs, including DARE-HPV, DARE-LARC1, Sildenafil Cream, 3.6%, DARE to PLAY Sildenafil Cream, and DARE-PTB1.

References to Section 503B, 503B, 503B compounding, 503B compounding pathway, 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. Daré encourages investors to review the more detailed discussion of its financial condition, results of operations, liquidity, capital resources, and risk factors included in its Form 10-Q for the quarter ended September 30, 2025, filed today with the U.S. Securities and Exchange Commission (SEC).

Conference Call

Daré will host a conference call and live webcast today, November 13, 2025, at 4:30 p.m. Eastern Time to review its financial results for the quarter ended September 30, 2025 and to provide a company update.

To access the conference call via phone, dial (646) 307-1963 or (800) 715-9871 (toll free). The conference ID number for the call is 5794075. 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 the same section of the company's website and available for replay until November 27, 2025.

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," "positioned," "pursue," "seek," "execute," "prepare," "should," "would," "target," "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 Daré's go-to-market strategies; Daré's plans and timing for making solutions for women available by prescription in the U.S. as compounded drugs via Section 503B or without a prescription as branded consumer health products; the market opportunity for those products and their ability to gain market acceptance; expected timing of revenue from sales of those products; Daré's intent to continue to pursue an FDA approval pathway for those product candidates it brings to market under Section 503B; plans and expectations with respect to Daré's product candidates, including clinical development plans, trial design, timelines, costs, milestones, targeted indications, clinical trials and results, regulatory strategy, and U.S. Food and Drug Administration (FDA) communications, submissions and review of applications; the clinical potential of and market opportunities for Daré's product candidates; Ovaprene's potential to be the first FDA-approved hormone-free intravaginal monthly contraceptive; the importance of the DSMB's recommendation and the interim results from the ongoing Phase 3 clinical study of Ovaprene to Daré and Ovaprene; expectations regarding existing collaborations; the sufficiency of non-dilutive grant and other financial award funding to advance development of specified product candidates or programs, including through specified milestones; Daré's ability to meaningfully impact women and create value for its shareholders; and the potential impact of DARE to PLAY Sildenafil Cream for Daré and women. 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 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 intends to bring or brings to market or changes the conditions under which those drug substances may used in compounding or the compounded products may be distributed; the ability of Daré's outsourcing facility partners 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'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; 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 reliance on third parties to manufacture and conduct clinical trials and preclinical studies of its product candidates and commercialize XACIATO™ (clindamycin phosphate) vaginal gel 2% and future FDA-approved products, if any; the risk that the current regulatory pathway known as the FDA's 505(b)(2) pathway for drug product approval in the U.S. is not available for a product candidate as Daré anticipates; 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 and the inherent uncertainty of outcomes of clinical trials; 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; 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; the loss of, or inability to attract, key personnel; product pricing and coverage and reimbursement from third-party payors; 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; disputes or other developments concerning Daré'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 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 it 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.

Contacts:

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Source: Daré Bioscience, Inc.

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

	Three months ended September 30,	
	2025	**2024**
Revenue		
Royalty revenue	$ 2,262	$ 41,691
Total revenue	2,262	41,691
Operating expenses		
General and administrative	2,499,242	2,041,268
Research and development	1,175,168	2,681,772
Total operating expenses	3,674,410	4,723,040
Loss from operations	(3,672,148)	(4,681,349)
Other income (expense)	109,382	(21,152)
Net loss	$ (3,562,766)	$ (4,702,501)
Foreign currency translation adjustments	6,860	22,935
Comprehensive loss	$ (3,555,906)	$ (4,679,566)
Loss per common share - basic and diluted	$ (0.28)	$ (0.55)
Weighted average number of shares outstanding:		
Basic and diluted	12,755,112	8,534,433

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

	September 30, 2025	**December 31, 2024**
	(unaudited)	
Cash and cash equivalents	$ 23,075,261	$ 15,698,174
Working capital (deficit)	$ 3,787,786	$ (3,165,204)
Total assets	$ 30,748,574	$ 22,101,131
Total stockholders' equity (deficit)	$ 2,857,903	$ (6,012,089)

Source: Daré Bioscience, Inc.