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

08-14-2025 at 4:01 PM EDT

DARE to PLAY™ Sildenafil Cream on Track for Q4 2025 Launch via 503B Compounding Pathway; Positioned for Product Revenue Beginning in Q4 2025

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

Multiple Grant-Funded Programs Advance, Including to Address HPV and Long-Acting Contraception

Four Commercially Available Solutions for Women on the Horizon

- *In addition to DARE to PLAY™ Sildenafil Cream, Commercialization of Vaginal Probiotics in the Consumer Health Market Targeted to follow DARE to PLAY Sildenafil Cream availability and Proprietary Monthly Hormone Therapy via 503B Compounding Pathway Targeted for Late 2026*
- *Creates Entry into the Estimated $4.5 Billion Compounded Hormone Therapy Market*

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

Q2 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 Q4 2025 launch through a 503B outsourcing facility
  - First phase of direct-to-patient campaign launched in collaboration with Rosy Wellness
  - Near-term revenue generation opportunity
- **Sildenafil Cream, 3.6%**
  - Discussions with FDA ongoing regarding endpoint assessment for Phase 3 clinical studies of Sildenafil Cream, 3.6%
- **Ovaprene®: DSMB Recommendation and Positive Interim Phase 3 Results Highlight Potential of Ovaprene, Investigational Hormone-Free Intravaginal Contraceptive**
  - Interim results support Ovaprene's differentiation as a first-in-category, hormone-free, intravaginal monthly contraceptive
  - Independent data safety monitoring board (DSMB) reviewed interim safety data and recommended study continuation without modification
  - No new safety or tolerability concerns and no serious safety concerns were identified
  - Interim pregnancy rate of women treated in the study was consistent with the Company's expectations based on prior postcoital test study of Ovaprene
  - Primary endpoint will assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene
- **DARE-HPV 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

- **Ongoing Actions to Make Three Additional Solutions Available Commercially**
    - Two non-prescription vaginal probiotics designed to support vaginal microbiome health, complementary to Daré's prescription offerings; availability targeted to follow DARE to PLAY Sildenafil Cream availability
    - **DARE-HRT1**: Proprietary monthly intravaginal ring designed to deliver bio-identical estradiol and progesterone; Daré is pursuing both an FDA approval pathway and a 503B compounding opportunity to accelerate patient access while continuing to generate the data necessary to seek FDA approval and support long-term value creation; 503B compounded solution targeted for late 2026

SAN DIEGO, Aug. 14, 2025 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a biopharmaceutical company with a sole focus of closing the gap in women's health between promising science and real solutions, today reported financial results for the quarter ended June 30, 2025 and provided a company update.

"Daré is rapidly transitioning its business model by executing on a dual-path strategy designed to unlock both near-term revenue and long-term value," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "With the anticipated launch of DARE to PLAY™ Sildenafil Cream through a 503B outsourcing facility in Q4, followed by other commercialization efforts including DARE-HRT1 and vaginal probiotics, we intend to build a robust commercial foundation. At the same time, we are advancing a differentiated pipeline through development, with grant-funded programs that target unmet needs in contraception, HPV, and pre-term birth. With four potential on-market solutions and a rich clinical pipeline behind them, we believe this is a pivotal time for investors to take a close look at Daré and the growth potential of our portfolio."

Financial Highlights for the Quarter Ended June 30, 2025

- **Cash Position:** As of June 30, 2025, Daré had approximately $5.0 million in cash and cash equivalents, and a working capital deficit of approximately $12.6 million.
- **Subsequent Capital Raise:** After quarter-end, Daré received approximately $17.6 million in net proceeds from sales of its common stock, primarily through its at-the-market offering program, and a $6.0 million grant installment payment. The additional capital significantly strengthens the company's balance sheet, enhancing the company's ability to execute its dual-path strategy.
- **General and Administrative Expenses:** $2.4 million in Q2 2025 compared to $2.5 million in Q2 2024, with the year-over-year change primarily attributable to decreases in personnel costs, stock-based compensation expense, and general corporate overhead, partially offset by an increase in professional services expense.
- **Research and Development (R&D) Expenses:** $1.4 million in Q2 2025 compared to $4.9 million in Q2 2024, reflecting a decrease of 71%, 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 development costs related to Sildenafil Cream, 3.6%, partially offset by increases in costs related development activities for other clinical- and preclinical-stage R&D programs, including DARE-HPV and DARE-LARC1.

References to Section 503B, 503B, Section 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 June 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, August 14, 2025, at 4:30 p.m. Eastern Time to review its financial results for the quarter ended June 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 2684883. 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 August 28, 2025.

About Daré Bioscience

Daré Bioscience is a biopharmaceutical company driven by a mission to challenge the status quo, making women's health a priority. Daré believes that innovation does not have to start from scratch. The company's goal is to bring to market as soon as practicable innovative evidence-based solutions that address decades of unmet needs in women's health and enhance outcomes and convenience, primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health and menopause. The potential products Daré identifies, in many cases, already have clinical proof of concept or existing safety data for the active ingredient that the company leverages. This provides optionality and flexibility, in many cases, in how Daré seeks to bring solutions to market in ways designed to optimize access for women in a fiscally responsible manner.

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 citrate, the active ingredient in an oral erectile dysfunction drug for men, 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 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," "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 Daré's go-to-market strategies; Daré's plans and timing for making its proprietary formulations available by prescription in the U.S. as compounded drugs via Section 503B and for launching 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 interim results from the ongoing Phase 3 clinical study of Ovaprene to Daré and Ovaprene; potential strategic partnerships and third-party collaborations; expectations regarding existing collaborations; the sufficiency of non-dilutive grant and other financial award funding to advance development of specified product candidates, including through specified milestones; and the impact of post-second quarter-end funding on Daré's ability to execute its business strategy. 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 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 inexperience, as a company, in and lack of infrastructure for commercializing products; 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; 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; the degree of market demand and acceptance for the products Daré brings to market; 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; 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 products or product candidates, if approved, to gain market acceptance or obtain adequate coverage, pricing 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; 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; 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; 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:

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Source: Daré Bioscience, Inc.

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

	Three months ended June 30,	
	2025	**2024**
Revenue		
Royalty revenue	$ (21,172)	$ 22,438
Total revenue	(21,172)	22,438
Operating expenses		
General and administrative	2,377,866	2,448,130
Research and development	1,428,762	4,933,774
Total operating expenses	3,806,628	7,381,904
Loss from operations	(3,827,800)	(7,359,466)
Other income (expense)		
Sale of royalty and milestone rights, net	-	20,379,376
Other income (expense), net	(188,683)	(109,254)
Net income (loss)	$ (4,016,483)	$ 12,910,656
Foreign currency translation adjustments	12,893	14,563
Comprehensive income (loss)	$ (4,003,590)	$ 12,925,219
Income (loss) per common share:		
Basic	$ (0.45)	$ 1.53
Diluted	$ (0.45)	$ 1.52

Weighted average number of shares outstanding:		
Basic	8,871,155	8,411,242
Diluted	8,871,155	8,476,231

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

	June 30, 2025	December 31, 2024
	(unaudited)	
Cash and cash equivalents	$ 5,035,006	$ 15,698,174
Working capital (deficit)	$ (12,618,726)	$ (3,165,204)
Total assets	$ 12,979,525	$ 22,101,131
Total stockholders' equity (deficit)	$ (12,733,260)	$ (6,012,089)

Source: Daré Bioscience, Inc.