Daré Bioscience Reports First Quarter 2025 Financial Results and Provides Company Update

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In addition to its proprietary Sildenafil Cream formulation, Daré is taking action to make three other solutions for women available commercially, two vaginal probiotics in 2025 and its proprietary monthly hormone therapy in 2026

- ***Creates commercial opportunity in the estimated up to $4.5 billion compounded hormone therapy market, enabling women to access an evidence-based solution***
- ***Four on-market products will accelerate revenue generation and provide path to profitability***
- ***Daré expects to start recording revenue in the 4th quarter of this year***

Conference call today at 4:30 p.m. ET to discuss the further expanded business strategy to commercialize multiple solutions in 2025 and 2026

2025 and 2026 Milestones

- **Sildenafil Cream, 3.6%** an investigational topical formulation of sildenafil being developed to treat female sexual arousal disorder, targeting availability via prescription as a Section 503B compounded drug this year
- **DARE-HRT1** an investigational monthly intravaginal hormone therapy being developed to treat the vasomotor symptoms of menopause, targeting availability via prescription as a Section 503B compounded drug next year
- **Vaginal probiotics,** designed to restore a healthy vaginal microbiome, targeting availability as branded consumer health products this year
- **Ovaprene®**, a novel, investigational hormone-free monthly intravaginal contraceptive; enrollment ongoing in pivotal Phase 3 contraceptive efficacy study; data safety monitoring board interim assessment scheduled for July 2025

SAN DIEGO, May 13, 2025 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a biopharmaceutical company driven by a mission to challenge the status quo, making women's health a priority, today reported financial results for the quarter ended March 31, 2025 and provided a company update.

“The first quarter of 2025 has been marked by distractions and disruptions for the overall healthcare and biotech sector. I am proud that Daré is uniquely positioned to cut through the noise and deliver value to all of our stakeholders – women, healthcare providers, and investors. Today, biopharmaceutical companies with relatively low risk assets, a competitive advantage and a path toward near-term revenue are positioned to offer upside. We believe that is Daré today,” said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. “Women's health is ripe for returns because it has been underfunded and fragmented – and with our recently announced expanded business strategy, we believe we are uniquely positioned to deliver value and returns to all of our stakeholders, with a business model that is nimble, allowing us to rapidly commercialize multiple products via multiple channels. We are no longer only seeking FDA approval; we are leveraging a dual path strategy where we commercialize via 503B compounding while continuing to seek FDA approval. We are also taking steps toward launching certain solutions as branded consumer health products that do not require a prescription.”

“To our knowledge, we are the only publicly traded company focused solely on developing therapeutic products for a broad range of conditions affecting women – contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health and menopause. And, to our knowledge, we are the only publicly traded company leveraging all available paths to bring evidence-based solutions to market, reflecting where and how women are getting and paying for their care – as an FDA-approved treatment, as a compounded product, as a consumer health product that does not require a prescription – available via telehealth, online, or via an in-person visit with her healthcare provider. Our portfolio is compelling and over the next months we look forward to providing updates regarding strategic partnerships and collaborations to facilitate access to Daré on-market brands for women across multiple channels,” said Ms. Johnson.

Therapeutic Development Pipeline Highlights

Ovaprene®, a *novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer HealthCare.*

- Pivotal Phase 3 contraceptive efficacy study ongoing across the United States; an up to $10.7 million foundation non-dilutive grant announced in November 2024 supported addition of 5 new investigator sites in the first quarter of 2025.
- Review of interim data by the study's data safety monitoring board, an independent group of experts which evaluates the safety and integrity of the study, scheduled for July 2025.
- The primary objective of the study is to assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene. Secondary objectives are to assess Ovaprene's 13-cycle use cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and assessments of vaginal health. If successful, Daré expects the study to support the submission of a premarket approval application for Ovaprene to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

Sildenafil Cream, 3.6%, *a proprietary, investigational cream formulation of sildenafil, the active ingredient in an oral erectile dysfunction drug for men, for topical on-demand administration to treat female sexual arousal disorder (FSAD).*

- Continued interactions with the FDA regarding planned Phase 3 study; Phase 3 study design, development, and collaboration strategy updates expected throughout 2025.
- Daré is targeting submission of additional information requested by the FDA, along with the protocol and statistical analysis plan for the Phase 3 study, to the FDA by the end of the second quarter of 2025.

DARE-HPV, *a proprietary, investigational fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert for the treatment of human papillomavirus (HPV)-related cervical diseases.*

- Conducting activities necessary to enable submission of an IND application to the FDA for a Phase 2, randomized, placebo-controlled, double-blind clinical study of DARE-HPV for clearance of high-risk HPV infection in women.
- Supported with up to $10 million milestone-based non-dilutive award announced October 2024.

Financial Highlights for the Quarter ended March 31, 2025

- Cash position: at March 31, 2025, cash and cash equivalents of approximately $10.3 million, and working capital deficit of approximately $9.4 million.
- General and administrative expenses: $2.3 million in 1Q-2025 as compared to $2.7 million in 1Q-2024, with the current quarter's decrease primarily attributable to decreases in stock-based compensation expense, professional services expense and personnel costs.
- Research and development expenses: $2.3 million in 1Q-2025 as compared to $3.4 million in 1Q-2024, a 31% decrease compared to Q1-2024. The current quarter's decrease is primarily attributable to decreases in manufacturing costs related to Ovaprene, costs related to development activities for Sildenafil Cream, and costs related to development activities for preclinical stage programs.

We encourage investors to review the more detailed discussion of our financial statements, our financial condition, liquidity, capital resources, and risk factors in our quarterly report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC today.

Conference Call
Daré will host a conference call and live webcast today, May 13, 2025, at 4:30 p.m. Eastern Time to review financial results for the quarter ended March 31, 2025 and to provide a company update.

To access the conference call via phone, dial (646) 307-1963 (U.S.) or (800) 715-9871 (toll free). The conference ID number for the call is 3461324. 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 May 27, 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, 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, product 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, product 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," "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 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 of Federal Food, Drug, and Cosmetic Act (FDCA) 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 and that such sales will provide a path to profitability for Daré; 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; potential strategic partnerships and third-party collaborations; expectations regarding existing collaborations; and the amount and timing of Daré's receipt of funds under grant agreements. 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; the risk of delisting of Daré's common stock from Nasdaq; 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 enter into and maintain third-party collaborations to facilitate access to the solutions Daré intends to bring to market as compounded drugs or consumer health products and Daré's reliance on those third parties; the performance of Section 503B-registered outsourcing facilities and other third parties on which Daré will rely to execute its expanded business strategy; 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 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 achieve the product development and other milestones required for it to receive payments under its subaward and grant agreements; the potential for termination of the subaward and grant agreements before Daré receives additional payments; the limits on Daré's ability to sell stock under its equity line arrangement at times it may desire to raise additional capital; 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; 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 product 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 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
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Revenue		
Royalty revenue	$ 25,427	$ 9,302
Total revenue	25,427	9,302
Operating expenses		
General and administrative	2,309,164	2,670,581
Research and development	2,297,381	3,353,520
Royalty expense	-	7,674
Total operating expenses	4,606,545	6,031,775
Loss from operations	(4,581,118)	(6,022,473)
Other income (expense)	202,811	(732,883)
Net loss	$ (4,378,307)	$ (6,755,356)
Foreign currency translation adjustments	13,090	(39,227)
Comprehensive loss	$ (4,365,217)	$ (6,794,583)
Loss per common share - basic and diluted	$ (0.50)	$ (0.81)
Weighted average number of shares outstanding:		
Basic and diluted	8,759,053	8,376,189

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

	March 31, 2025 (unaudited)	**December 31, 2024**
Cash and cash equivalents	$ 10,329,967	$ 15,698,174
Working capital deficit	$ (9,365,525)	$ (3,161,150)
Total assets	$ 18,618,941	$ 22,101,131
Total stockholders' deficit	$ (9,563,701)	$ (6,012,089)

Source: Daré Bioscience, Inc.