Daré Bioscience Reports Full Year 2024 Financial Results and Provides Company Update

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With increasing demand for needed treatments designed for women, Daré is taking action to make its proprietary Sildenafil Cream formulation available via prescription this year

- ***Enables women to access a solution that they want and need***
- ***Creates an opportunity to accelerate revenue generation from this proprietary formulation***
- ***Daré expects to start recording revenue and cash flow in the 4th quarter of this year***

Conference call today at 4:30 p.m. ET to discuss the expanded business strategy to integrate 503B compounding as part of a dual-path approach to bring select Daré proprietary formulations to market as soon as practicable

SAN DIEGO, March 31, 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 year ended December 31, 2024 and provided a company update.

“Daré exists to accelerate innovation in women’s health and our goal is to fulfill the urgent need for access to evidence-based treatment options. We are proud to announce that we are taking action to make our proprietary Sildenafil Cream formulation available via prescription this year as a compounded drug under Section 503B of the FDCA, because we believe women should not have to wait for access to our formulation when an alternative legal path via Section 503B is available while we continue to pursue FDA approval of Sildenafil Cream as a treatment for female sexual arousal disorder. Our proprietary formulation would be produced by a 503B-registered outsourcing facility partner, which is registered with the FDA, subject to FDA inspections and subject to quality standards, including compliance with cGMP regulations,” said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. “After urging on the part of the healthcare community and hearing the demand from women, we are targeting making our proprietary Sildenafil Cream formulation available via one 503B-registered outsourcing facility partner in the fourth quarter of 2025.”

“We believe the diversity of our portfolio, the progress we are making in advancing our product candidates, and the revenue opportunity from our proprietary Sildenafil Cream formulation based on our announcement today, puts Daré on track for meaningful milestones in 2025,” said Ms. Johnson.

Sildenafil Cream and 503B Compounding

"Healthcare providers and women are seeking a formulation of sildenafil that they can trust. Based on the study published in 2024 I am very excited about the availability of Daré’s Sildenafil Cream formulation as an ‘on demand' solution for women," stated Dr. Sheryl Kingsberg, Division Chief of Behavioral Medicine, Department of OBGYN, University Hospitals Cleveland Medical Center, Ohio, and Past President of The International Society for the Study of Women's Sexual Health, as well as co-editor of the Textbook of Female Sexual Function and Dysfunction: Diagnosis and Treatment. “I am thrilled that Daré is taking action to deliver this science-backed formulation—with product consistency from a 503B-registered outsourcing facility, complete toxicology studies, and randomized placebo-controlled studies—to the women who need it without delay."

“As is the case with men, decreased genital blood flow can also compromise a woman's ability to have a pleasurable sexual experience. In January 2020 we published study findings demonstrating that Daré’s Sildenafil Cream elicits a quantifiable, rapid genital response in women within 10-15 minutes using thermography to assess genital temperature changes, a surrogate for genital blood flow,” stated Dr. Irwin Goldstein, the director of San Diego Sexual Medicine and President of The Institute for Sexual Medicine, Inc., and an expert considered a founder of the field of sexual medicine, having been involved with sexual dysfunction research since the late 1970′s and renowned for his work regarding erectile dysfunction as well as female sexual dysfunction. “It is encouraging that Daré is taking action to make this formulation available later this year for the women who need it.”

“Daré is committed to a strategy that optimizes for access to solutions in a fiscally responsible manner. We plan to focus our resources on provider-to-provider education about disease state and our proprietary formulation and do not anticipate needing to invest more than $1 million to support the activities required to make our Sildenafil Cream formulation available via a partner 503B-registered outsourcing facility. We expect to start recording revenue and cash flow in the 4th quarter of this year. We are targeting the second quarter of 2025 to provide an update on the strategic partnerships to achieve these objectives,” added Ms. Johnson. “Like Sildenafil Cream, there are other proprietary formulations in the Daré portfolio that could also be provided via a

prescription through the FDA's 503B framework. We are actively evaluating a dual-path approach for some of our other proprietary formulations as part of our responsibility to women, to the healthcare community, and to our shareholders. In addition, we may also bring to market consumer health products that can be obtained without a physician's prescription. We are also targeting the second quarter of 2025 to provide an update on timing and strategic partnerships to achieve these objectives."

2024 Highlights and Anticipated 2025 Milestones – 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 November 2024 supports addition of 5 new investigator sites.
- Currently, there are 15 active sites from within the Eunice Kennedy Shriver National Institute of Child Health and Human Development's Contraceptive Clinical Trials Network following enrolled participants in the study. Enrollment is currently proceeding at five study sites that were initiated in 2025, funded by the grant received in 2024 to accelerate the overall study timeline. Daré anticipates that approximately 125 women, which is half of the target number of participants to complete the study, will complete approximately six months of Ovaprene use by the end of the second quarter of 2025. This is a designated check point for 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.
- 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 Viagra®, for topical on-demand administration to treat female sexual arousal disorder (FSAD).*

- Continued operational progress toward a planned Phase 3 study, including constructive discussions with FDA; Phase 3 design, development, and collaboration strategy updates expected throughout 2025.
- In December 2024, Daré announced plans for a Phase 3 study of Sildenafil Cream reflecting FDA feedback for safety and efficacy evaluations to support the indication of treatment of FSAD in premenopausal women.
- Daré plans to submit the protocol and statistical analysis plan for an adequate and well-controlled Phase 3 clinical study, reflecting the FDA's recommendations, to the FDA in the second quarter of 2025, pending review of additional forthcoming recommendations from the FDA that impact Daré's statistical analysis plan.

DARE-HPV, *a proprietary, 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.

DARE-VVA1, *an investigational proprietary formulation of tamoxifen for intravaginal administration being developed as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse.*

- Conducting activities in preparation for a Phase 2 clinical study of DARE-VVA1 based on FDA-cleared IND.

DARE-PTB1, *an investigational intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for the prevention of preterm birth.*

- Conducting activities necessary to enable the IND and a Phase 1 clinical study.
- Supported by a $2 million grant from NICHD.
- A Phase 1 study would also serve to support safety and PK for this progesterone intravaginal ring to also be investigated for luteal phase support as part of an IVF regimen.

Casea S, *an investigational biodegradable contraceptive implant. Casea S is designed to control release of a well-characterized contraceptive, etonogestrel, for a set period of time (18-24 months) before dissolving.*

- It is designed to provide women with a long-acting, minimally-invasive contraceptive method that will not require surgical removal by a healthcare provider, which would improve convenience and could eliminate one of the barriers to use associated with existing implanted contraceptives.
- Casea S is being tested in a single-center, two-part Phase 1 clinical study to evaluate the PK of etonogestrel, removability, safety, and tolerability of Casea S pellets inserted subdermally in healthy women of reproductive age (ClinicalTrials.gov ID: NCT05174884).
- The ongoing Phase 1 study is being conducted by FHI 360, a nonprofit organization, with support from a foundation grant. There are no development costs to Daré at this time.

- Casea S was recently acquired by Theramex. In February 2025, Daré entered into a co-development and licensing agreement with Theramex for the development of Casea S in the U.S. If Daré determines that the results from the Phase 1 study are positive and elects to proceed with development, Daré would be responsible for conducting a Phase 2 study in the U.S. In accordance with the agreement, the costs of such Phase 2 study would be shared by Daré and Theramex on terms to be agreed upon, taking into account the size of the opportunity for Casea S in the respective markets.

DARE-LARC1, a *novel, long-acting, reversible personal contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option; development supported with an up to $49 million foundation grant.*

- DARE-LARC1's woman-centered design seeks to offer the benefits of traditional long-acting reversible contraceptives with the added flexibility and convenience for the user to pause and resume release of levonorgestrel, depending on her desire for fertility or contraceptive protection.
- Under a grant agreement entered into in June 2021, Daré may receive up to approximately $49.0 million, payable over approximately five years, to advance development of the technology through nonclinical proof of principle studies to enable an IND submission.
- $3.5 million in grant funding received in 2024, bringing the total received to date to $31.8 million.

Financial Highlights

- Cash position: at December 31, 2024, cash and cash equivalents of approximately $15.7 million, and working capital deficit of approximately $3.2 million.
- General and administrative expenses: approximately $9.2 million for 2024, which is a 24% decrease compared to the prior year due primarily to reduced commercial readiness expenses and reduced headcount.
- Research and development (R&D) expenses: approximately $14.2 million for 2024, which is a 34% decrease compared to the prior year. R&D expenses in 2024 primarily reflected the costs of manufacturing activities and ongoing enrollment in the Phase 3 study of Ovaprene. Currently, Daré's only active clinical study is the Phase 3 study of Ovaprene.

We encourage investors to review the more detailed discussion of our financial statements, our financial condition, liquidity, capital resources, and risk factors in our annual report on Form 10-K for the year ended December 31, 2024, filed with the SEC today.

Conference Call
Daré will host a conference call and live webcast today, March 31, 2025, at 4:30 p.m. Eastern Time to review financial results for the year ended December 31, 2024 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 9767621. 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 in the same section of the company's website and available for replay until April 14, 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. We believe that innovation does not have to start from scratch. Our 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 we identify, in many cases, already have clinical proof of concept or existing safety data for the active ingredient that we leverage. This gives us optionality and flexibility, in many cases, in how we seek 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 Viagra®, 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 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 FDA communications, submissions and review of applications; the clinical potential of and market opportunities for Daré's product candidates; Daré's go-to-market strategies; Daré's plans and timing for making its proprietary formulation of Sildenafil Cream available by prescription in the U.S. as a compounded drug via Section 503B of Federal Food, Drug, and Cosmetic Act, the anticipated amount needed to invest to support the activities required to make its proprietary formulation of Sildenafil Cream available in such manner, its market opportunity and ability to gain market acceptance, and the expected timing of revenue and cash flow from sales; the potential future development of Casea S and that funding for future studies of Casea S may be shared between Daré and Theramex; potential third-party collaborations; expectations regarding existing collaborations; 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 advance its product candidates, execute its business strategy and continue as a going concern; the risk of delisting of Daré's common stock from Nasdaq; developments impacting U.S. federal government contracting and funding of research and development activities; the degree of market demand and acceptance for Daré's proprietary formulation of Sildenafil Cream provided as a compounded drug; 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 performance of Section 503B-registered outsourcing facilities on which Daré will rely; the risk that the FDA could stop permitting Section 503B-registered outsourcing facilities to compound sildenafil citrate; 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 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 risk 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; 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 effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; 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 product 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.

Dare Bioscience, Inc. and Subsidiaries
Consolidated Statement of Operations and Comprehensive Loss

	December 31,	
	2024	**2023**
Revenue		
License fee revenue	$ -	$ 1,000,000
Milestone revenue	-	1,800,000
Royalty revenue	9,784	7,885
Total revenue	9,784	2,807,885
Operating expenses		
General and administrative	9,156,061	12,109,691
Research and development	14,205,208	21,538,074
License fee expense	100,000	100,000
Total operating expenses	23,461,269	33,747,765
Loss from operations	(23,451,485)	(30,939,880)
Other income (expense)		
Sale of royalty and milestone rights, net of transaction costs	20,379,676	-
Other (expense) income	(981,490)	778,489
Net loss	$ (4,053,299)	$ (30,161,391)
Net loss to common shareholders	(4,053,299)	(30,161,391)
Foreign currency translation adjustments	(67,913)	(9,585)
Comprehensive loss	$ (4,121,212)	$ (30,170,976)
Loss per common share - basic and diluted	$ (0.48)	$ (4.15)
Weighted average number of common shares outstanding:		
Basic and diluted	8,497,459	7,275,308

Dare Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets Data

	December 31,	
	2024	**2023**
Cash and cash equivalents	$ 15,698,174	$ 10,476,056
Working capital (deficit)	$ (3,161,150)	$ (2,936,897)
Total assets	$ 22,101,131	$ 21,282,215
Total liabilities	$ 28,113,220	$ 26,329,855
Total stockholders' deficit	$ (6,012,089)	$ (5,047,640)

Source: Daré Bioscience, Inc.