



DARÉ BIOSCIENCE.

Daré Bioscience and Theramex Announce Co-Development and Licensing Agreement for a Potential Biodegradable Long-Acting Contraceptive Implant

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Ongoing Phase 1 study is funded by a foundation grant

Daré received a royalty-free, exclusive license to the US patents

SAN DIEGO and LONDON, Feb. 20, 2025 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, and Theramex, a leading, global specialty pharmaceutical company dedicated to women and their health, announced today that they entered into a co-development and licensing agreement for a potential first-in-category biodegradable contraceptive implant called Casea S recently acquired by Theramex.

"We are thrilled that Theramex selected Daré as its development partner for this potentially disruptive long-acting, minimally-invasive contraceptive candidate. The fully funded ongoing Phase 1 study is external validation of this important technology, and enables Daré and Theramex to make future development decisions based on results of the study," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The in-license of these US patents to add to our portfolio is another example of how we leverage non-dilutive funding to advance first-in-category product candidates, and this collaboration with Theramex is a testament to our development track record in women's health."

"We are excited to partner with Daré to develop Casea S, a potential first-in-category contraceptive candidate for women," said Rob Stewart, CEO of Theramex. "A biodegradable implant for contraception resonates with what we hear from women as does the idea that she can make that choice every 18-24 months as to whether it is right for her. With its innovative design, Casea S would only require a single surgery visit, offering a more convenient, reversible alternative to existing long-acting contraceptive methods that would enable women to take control of their reproductive health with confidence."

Casea S is designed to control release of a well-characterized contraceptive 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.

[FHI 360](#) is conducting a fully-funded Phase 1 trial to investigate pharmacokinetics, removability, safety and tolerability of Casea S with support from a foundation grant ([ClinicalTrials.gov](#) ID: NCT05174884).

Daré received a royalty-free, exclusive, fully paid up, sublicensable license to the US patents Theramex recently acquired for Casea S. Given that the product candidate is in an ongoing Phase 1 study that is funded by a grant, there are no development costs for Daré or Theramex at this time. If Daré determines that the results from the study are positive, it would be responsible for conducting the Phase II study in the US, and funding for such study and for a future Phase III study in the US will be shared by Daré and Theramex on terms to be agreed upon by the parties, taking into account the size of the opportunity for Casea S in their respective markets.

About Daré Bioscience

Daré Bioscience is a biopharmaceutical company committed to advancing innovative products for women's health. The company's mission is to identify, develop and bring to market a diverse portfolio of differentiated therapies that prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious diseases, and menopause.

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 2022. In 2023, Daré's CEO was 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 Bioscience placed #1 in the Small Company category of the San Diego Business Journal's 2023 Best Places to Work Awards.

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.

About Theramex

Theramex is a leading global specialty pharmaceutical company dedicated to women and their health. Theramex supports women of all ages by providing a broad portfolio of innovative and established brands covering contraception, fertility, menopause, and osteoporosis. Theramex's vision is to be a lifetime partner for women and the healthcare professionals who treat them, and is committed to listening to and understanding its patients, serving their needs, and offering effective healthcare solutions that care for and support women through different stages of their lives.

For further information about Theramex, please contact:

info@theramex.com

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," 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 future development of Casea S and its potential to be a first-in-category product, and that funding for future studies of Casea S may be shared between Daré and Theramex. As used in this press release, "first-in-category" is a forward-looking statement relating to the potential of a product candidate if it were to receive marketing approval for the use 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: the risk that the results of the ongoing Phase I study of Casea S may not be positive; 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 inherent uncertainty of outcomes of clinical trials; 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; 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 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 or reimbursement from third-party payers; 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:

Daré Bioscience Investor Relations

innovations@darebioscience.com

Theramex

info@theramex.com

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