

# Daré Bioscience, Inc. Enters into License and Collaboration Agreement for a Product with the Potential to Receive the First FDA Approval for Female Sexual Arousal Disorder

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Company enters into license agreement with Strategic Science & Technologies, LLC to develop Topical Sildenafil, now in Phase 2 clinical studies

SAN DIEGO, Feb. 12, 2018 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a clinical-stage, women's biopharmaceutical company, today announced it has entered into an agreement to license SST-6007 (5% Topical Sildenafil Citrate Cream), a potential treatment for Female Sexual Arousal Disorder ("FSAD"), from Strategic Science & Technologies, LLC ("SST"). FSAD is characterized primarily by an inability to attain or maintain sufficient physical sexual arousal that causes distress or interpersonal difficulty. SST-6007 incorporates sildenafil, the same active ingredient in Viagra®, in a proprietary cream formulation that is specifically designed to locally increase blood flow to the vulvar-vaginal tissue in women, leading to a potential improvement in genital arousal response and overall sexual experience. If approved, Daré believes SST-6007 would be the first FDA approved treatment for FSAD.

SST-6007 is the second product in Daré's growing portfolio of novel therapeutic candidates that address unmet needs in women's reproductive and sexual health. Daré's first product candidate undergoing clinical development in the United States is Ovaprene™, a non-hormonal contraceptive ring with the potential to be the first non-hormonal product to provide monthly contraceptive protection.

"We look forward to working closely with SST to bring SST-6007 to the market for women, leveraging SST's deep knowledge of FSAD and our experience developing innovative women's health products and readying them for U.S. commercialization. Driven by a mission to identify unmet needs in women's health and mining the globe for unique assets that would serve these needs, we are confident that SST-6007 has the potential to significantly impact women with Female Sexual Arousal Disorder, an area that has long been studied but for which there are currently no FDA approved treatments," said Sabrina Martucci Johnson, President and CEO, Daré Bioscience.

"While increased attention has been focused on female sexual dysfunctions over the past several years, no pharmacologic options have yet been FDA approved for Female Sexual Arousal Disorder (FSAD), a condition which significantly compromises a woman's ability to have a pleasurable sexual experience," commented Dr. Sheryl Kingsberg, Division Chief, OB/GYN Behavioral Medicine, UH Cleveland Medical Center. "I am very excited about the potential for Topical Sildenafil to address this critical unmet need in women's sexual health. Leveraging the known therapeutic benefit of Viagra® to stimulate increased blood flow to the genital tissue, Topical Sildenafil may offer these women a safe, effective and 'on demand' solution to difficulties with sexual arousal allowing for a more intense and enjoyable sexual experience."

In a Phase 2 study, SST-6007 demonstrated an increase in blood flow to the vaginal tissue in both pre- and postmenopausal women with FSAD. Daré plans to pursue the 505(b)(2) regulatory pathway for SST-6007 in the U.S. and leverage the existing data and established safety profile of the Viagra® brand. Daré anticipates commencing a Phase 2b clinical trial in the second half of 2018.

With the potential introduction of SST-6007 as the first FDA approved product for FSAD, Daré is poised to create a new market category within the female sexual dysfunction space. A report by <u>Visiongain</u> forecasts that the world market for both male and female sexual dysfunction drugs will reach \$7.7 billion in 2019.

## About Strategic Science & Technologies, LLC

Strategic Science & Technologies, LLC (SST) is a clinical-stage biotechnology company with an innovative topical drug delivery technology. The company's patented delivery technology provides targeted local delivery of known drugs at therapeutic levels. SST's product portfolio includes Topical Ibuprofen and Topical Sildenafil, both in clinical development. SST is headquartered in Cambridge, MA and remains privately funded by its original investors. For more information please visit <a href="https://www.strategicscience.com">www.strategicscience.com</a>.

#### **About Daré Bioscience**

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's reproductive health. The company is driven by a mission to identify, develop and bring to market a diverse portfolio of novel therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. Daré's lead product candidate, Ovaprene, is a non-hormonal, monthly contraceptive ring that is currently in clinical studies. The company is headquartered in San Diego. For more information please visit <a href="https://www.darebioscience.com">www.darebioscience.com</a>.

### **Forward-Looking Statements**

This press release contains "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995 regarding matters that are not historical facts, including statements relating to Daré's expectations regarding the anticipated market demands for its products, the safety and effectiveness of its products, market acceptance of Daré's products and the qualifications and expertise of Daré's management team. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements as a result of various important factors, including the uncertainties inherent in the initiation and completion of clinical trials; availability and timing of data from ongoing and future clinical trials and the results of such trials; whether preliminary results from a clinical trial will be predictive of the

final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals; claims of infringement and other risks relating to Daré's owned and licensed intellectual property rights, and other factors discussed in the "Risk Factors" section of Daré's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 13, 2017. Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements is contained in Daré's reports to the Securities and Exchange Commission, including Daré's reports on Forms 10-Q, 8-K and 10-K. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. Daré specifically disclaims any obligation to update any forward-looking statements included in this press release.

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