
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) February 11, 2018

DARÉ BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36395
(Commission
File Number)

20-4139823
(I.R.S. Employer
Identification No.)

11119 North Torrey Pines Road, Suite 200
La Jolla, CA 92037
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code
(858) 926-7655

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On February 11, 2018, Daré Bioscience, Inc. (“Daré” or the “Company”) entered into a license and collaboration agreement (the “License Agreement”) with Strategic Science and Technologies-D, LLC (“SST”) and Strategic Science Technologies, LLC, which, subject to the Company securing an investment of at least \$10,000,000 by March 31, 2018, which date can be extended by mutual agreement of the parties, will provide the Company with an exclusive, royalty-bearing, sublicensable license to develop and commercialize, in all countries and geographic territories of the world, for all indications for women related to female sexual dysfunction and/or female reproductive health, including treatment of female sexual arousal disorder (the “Field of Use”), SST’s topical formulation of sildenafil citrate as it exists as of the effective date of the License Agreement, or any other topically applied pharmaceutical product containing sildenafil or a salt thereof as a pharmaceutically active ingredient, alone or with other active ingredients, but specifically excluding any product containing ibuprofen or any salt derivative of ibuprofen (the “Licensed Products”).

Under the terms of the License Agreement, the Company retains rights to inventions made by its employees, SST retains rights to inventions made by its employees, and each party shall own a fifty percent (50%) undivided interest in all joint inventions. Each party has agreed to collaborate through a Joint Development Committee (“JDC”) which shall be responsible for determining the strategic objectives for, and generally overseeing, the development efforts of both parties under the License Agreement. Further, the Company has agreed to use commercially reasonable efforts to develop the Licensed Products in the Field of Use in accordance with a development plan contained in the License Agreement, and to commercialize the Licensed Products in the Field of Use.

The License Agreement provides that, in consideration of the rights to be granted to the Company, SST will be eligible to receive tiered royalties based on percentages of annual net sales of Licensed Products in the single digits to the mid double digits, including customary provisions permitting royalty reductions and offset, and a percentage of sublicense revenue. The Company is also responsible for all reasonable internal and external costs and expenses incurred by SST in its performance of the development activities it is required to perform under the License Agreement. Further, the License Agreement provides that Daré shall make milestone payments to SST ranging from \$500,000 to \$150,000,000 contingent on achieving certain clinical, regulatory and commercial milestones.

The term of the License Agreement will begin on the effective date of the License Agreement and will continue, with respect to each Licensed Product, until the later of ten years from the date of the first commercial sale of such Licensed Product (in the last country in which it will be sold) and the expiration of the last valid claim of patent rights covering the Licensed Product in the Field of Use. The License Agreement provides that each party will have customary rights to terminate the License Agreement in the event of material uncured breach by the other party, and, (i) prior to receipt of approval by a regulatory authority necessary for commercialization of a Licensed Product in the corresponding jurisdiction, including NDA Approval, the Company will have the right to terminate the License Agreement without cause upon ninety (90) days prior written notice to SST, and (ii) following receipt of approval by a regulatory authority necessary for commercialization of a Licensed Product in the corresponding jurisdiction, including NDA Approval, Company will have a right to terminate the License Agreement without cause upon one hundred eighty (180) days prior written notice. In addition, the License Agreement provides SST with the right to terminate the License Agreement with respect to the applicable Licensed Product(s) in the applicable country(ies) upon thirty (30) days’ notice to the Company if the Company fails to use commercially reasonable efforts to perform development activities in substantial accordance with the development plan and does not cure such failure within sixty (60) days of receipt of SST’s notice thereof.

Upon expiration (but not termination) of the License Agreement in a particular country, the Company shall have a fully paid-up license under the licensed intellectual property to develop and commercialize the applicable Licensed Products in the applicable country on a non-exclusive basis.

The foregoing summary of the material terms of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement, a copy of which the Company intends to file with the Securities and Exchange Commission on its Yearly Report on Form 10-K for the fiscal year ended December 31, 2017. The Company will seek confidential treatment of certain terms of the License Agreement at such time.

A copy of the press release issued in connection with the parties’ announcement of the License Agreement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Press Release dated February 12, 2018.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DARÉ BIOSCIENCE, INC.

Dated: February 12, 2018

By: /s/ Sabrina Martucci Johnson

Name: Sabrina Martucci Johnson

Title: President and Chief Executive Officer

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

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

SAN DIEGO – February 12, 2018 – 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 Visiongain 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 www.strategicscience.com.

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 www.darebioscience.com.

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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Source: Daré Bioscience