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): **November 27, 2018**

DARÉ BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36395**	**20-4139823**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3655 Nobel Drive, Suite 260
San Diego, CA 92122
(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 8.01 Other Events.

On November 27, 2018, Daré Bioscience, Inc. ("Daré"), issued a press release regarding its product candidate, Sildenafil Cream, 3.6%, a copy of which is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

By filing this report, including the information in Exhibit 99.1 attached hereto, Daré makes no admission as to the materiality of any information in this report. Exhibit 99.1 contains information that is intended to be considered in the context of Daré's filings with the U.S. Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K filed on March 28, 2018 (as amended by the Form 10-K/A filed on April 30, 2018), Quarterly Reports on Form 10-Q filed on May 14, 2018, August 13, 2018 and November 13, 2018, and other public announcements that Daré makes, by press release or otherwise, from time to time. Daré undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as it believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, or through other public disclosure.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued on November 27, 2018

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: November 27, 2018

By: /s/ Sabrina Martucci Johnson
Name: Sabrina Martucci Johnson
Title: President and Chief Executive Officer

Exhibit 99.1

Daré Bioscience, Inc. Announces Enrollment in Thermography Feasibility Study with Sildenafil Cream, 3.6%, a Potential Therapy for Female Sexual Arousal Disorder

Sildenafil Cream, 3.6% has the Potential to Receive the First FDA Approval for Female Sexual Arousal Disorder

SAN DIEGO, Nov. 27, 2018 (GLOBE NEWSWIRE) -- **Daré Bioscience, Inc.** (NASDAQ: DARE), a leader in clinical-stage women's health innovation, today announced that it is currently enrolling patients in an investigational study designed to evaluate the feasibility of using thermography technology to assess the pharmacodynamics of Sildenafil Cream, 3.6% in normal healthy women. Sildenafil, the active ingredient in Sildenafil Cream, 3.6%, is marketed in an oral dosage form under the brand name Viagra® for the treatment of erectile dysfunction in men. Daré Bioscience, in partnership with Strategic Science & Technologies, LLC (SST), is developing Sildenafil Cream, 3.6% as a potential treatment for female sexual arousal disorder (FSAD). During the thermography study, genital temperature, a surrogate for genital blood flow, will be captured and recorded utilizing an infrared camera capable of detecting heat patterns from blood flow in body tissues. The study consists of the screening visit (visit 1), the double-blind dosing of placebo or active cream (visits 2-3) and a safety follow-up.

"We are excited to announce that enrollment is underway in this thermography study," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience. "This study is part of our larger FSAD development program, and reflects capital-efficient activities we are pursuing to enrich and enhance the Phase 2b program. This small exploratory study has the potential to provide greater insight into the physiologic activity and time to effect resulting from the application of Sildenafil Cream, 3.6% externally to the vulva and internally in the vagina, which would further inform and support the design of our Phase 2b at-home study, anticipated to commence in 2019."

Sildenafil Cream, 3.6% is a proprietary cream formulation specifically designed to increase blood flow to the genital tissue in women, leading to a potential improvement in genital arousal response during sexual activity. If successful, Sildenafil Cream, 3.6% has the potential to be the first FDA-approved FSAD treatment option.

"The thermography study is part of a comprehensive clinical development and regulatory strategy that includes an upcoming content validity study to support the implementation of FSAD specific patient reported outcome (PRO) instruments, as well as an at-home dosing study which together constitute our Phase 2b program," said Mary Jarosz, Global Head of Regulatory Affairs for Daré Bioscience.

The principal investigator for the thermography study is Dr. Irwin Goldstein, a recognized leader in the treatment of both male and female sexual disorders and the 2009 recipient of the World Association for Sexual Health Gold Medal award in recognition of lifetime contributions to the field. "We are pleased to be working with SST and Daré on the Sildenafil Cream, 3.6% program, leveraging the known therapeutic

benefit of Viagra® to stimulate increased blood flow to the genital tissue," said Dr. Goldstein. "There are no approved drugs for the treatment of FSAD and Sildenafil Cream, 3.6% has the potential to be an on-demand solution to prepare the body for a more pleasurable sexual experience."

About Sildenafil Cream, 3.6% and 3Q2018 Type C Meeting with the FDA

Sildenafil Cream, 3.6% has the potential to be the first FDA-approved FSAD treatment option. Unlike other female sexual disorders, FSAD is characterized primarily by an inability to attain or maintain sufficient physical sexual arousal that causes distress or interpersonal difficulty. It is the closest analog in women to erectile dysfunction in men. While increased attention has been focused on female sexual dysfunction over the past several years, no pharmacologic options have yet been U.S. Food and Drug Administration (FDA) approved for FSAD. In a Phase 2a trial, Sildenafil Cream, 3.6% increased measurable blood flow to the vaginal tissue in both pre- and postmenopausal women with FSAD compared to placebo.

During the third quarter of 2018, we had a Type C meeting with the FDA regarding the Phase 2b program for Sildenafil Cream, 3.6%. The objective of this meeting was to align with the agency on key aspects of the Phase 2b and the overall clinical program to support the planned New Drug Application, or NDA, including the screening assessments used to accurately diagnose FSAD, the PRO instruments to be used as primary efficacy endpoints for pivotal clinical studies, study duration, and the target patient population to be studied.

Based on the outcome of this meeting, in the fourth quarter of 2018, we will commence Phase 2b related activities for Sildenafil Cream, 3.6% with the initiation of a content validity PRO study to demonstrate that the FSAD symptoms we plan to assess in our Phase 2b and our pivotal studies are the most important and relevant to our target patient population and are also acceptable efficacy endpoints for the FDA. After the content validity PRO study is completed and before the Phase 2b at-home trial is initiated, we plan to request another Type C meeting to obtain the FDA's guidance on whether it agrees that the PRO instruments are content valid for the target population.

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's reproductive and sexual health. The company's mission is to identify, develop and bring to market a portfolio of novel, differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's product portfolio includes two potential first-in-class candidates in clinical development: Ovaprene®, a non-hormonal, monthly contraceptive vaginal ring, and Sildenafil Cream, 3.6%, a potential treatment for female sexual arousal disorder utilizing the same active ingredient as Viagra®. To learn more about Daré's full portfolio of women's health products, and mission to deliver novel therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product candidates, clinical trials and other matters using its investor relations website (http://ir.darebioscience.com), SEC filings, press releases, public conference calls and webcasts. Daré uses these channels to communicate with its investors and the public about the company and other company-related matters. The information Daré posts on its investor relations website may be deemed to be material information. Daré encourages investors, the media, and others interested in the company to review the information Daré posts on its investor relations 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," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the potential of Sildenafil Cream, 3.6% to be the first FDA-approved FSAD treatment option, the usefulness of the thermography study to clinical development and potential regulatory approval of Sildenafil Cream, 3.6% for FSAD, the timing of initiation or completion of the company's clinical studies, and the company's ability to advance its product candidates through clinical development and regulatory approval. 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, risk and uncertainties related to: our ability to raise additional capital when and as needed; our ability to develop and commercialize our product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for our product candidates in a timely manner; our ability to conduct and design 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 efficacy of our product candidates; our ability to retain our licensed rights to develop and commercialize a product candidate; our ability to satisfy the monetary obligations and other requirements in connection with our exclusive, in-license agreements covering the critical patents and related intellectual property related to our product candidates; developments by our competitors that make our product candidates less competitive or obsolete; our dependence on third parties to conduct clinical trials; our ability to adequately protect or enforce our, or our licensor's, intellectual property rights; the lack of patent protection for the active ingredients in certain of our product candidates which could expose our products to competition from other formulations using the same active ingredients; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; and disputes or other developments concerning our intellectual property rights. Our forward-looking statements are based upon our 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 our risks and uncertainties, you are encouraged to review our documents filed with the SEC including our 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.

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