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 30, 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 1.01 Entry Into a Material Definitive Agreement.

On December 5, 2018, Daré Bioscience, Inc. ("Daré") entered into an Assignment Agreement (the "Assignment Agreement") with Hammock Pharmaceuticals, Inc. ("Hammock") and a First Amendment to License Agreement (the "License Amendment") with TriLogic Pharma, LLC ("TriLogic") and MilanaPharm LLC ("MilanaPharm," and, together with TriLogic, the "Licensors"), both of which relate to the Exclusive License Agreement among Hammock and the Licensors dated as of January 9, 2017 (the "MilanaPharm License Agreement"). Under the Assignment Agreement and the MilanaPharm License Agreement, as amended by the License Amendment, Daré acquired an exclusive, royalty-bearing, worldwide license, including the right to grant sublicenses, under certain patents, patent applications, other patent rights and know-how controlled by either of the Licensors or their respective affiliates, to research, develop, make, have made, use, offer for sale, sell, import and commercialize products or processes for the diagnosis, treatment and prevention, or supportive care of human diseases, disorders, conditions, symptoms, or state of health or wellness in or through any intravaginal or urological applications, pathways or routes of administration. The licensed intellectual property relates to the Licensors' hydrogel drug delivery platform known as TRI-726.

The following is a summary of the material terms of the MilanaPharm License Agreement, as amended by the License Amendment:

- License Fees. Daré paid $25,000 to MilanaPharm in connection with the execution of the License Amendment and must pay $200,000 to MilanaPharm (the "MilanaPharm Deferred Fee") within 15 days of the first to occur of December 5, 2019 or the closing of an equity financing in which Daré raises aggregate proceeds of at least $10.0 million. The MilanaPharm Deferred Fee may be paid, in Daré's discretion, either in cash or with shares of Daré's common stock.

- Milestone Payments. Daré must make potential future development milestone payments to MilanaPharm of up to $300,000. Daré is also required to make milestone payments to MilanaPharm of up to $500,000 upon the first commercial sale in the United States of the first licensed product or process for each vaginal use and urological use, and up to $250,000 upon the first commercial sale in the United States of successive licensed products or processes for vaginal or urological use. In addition, upon achievement of $50 million in cumulative worldwide net sales of licensed products and processes, Daré must make a one-time payment of $1.0 million to MilanaPharm.

- Foreign Sublicense Income. Daré will pay MilanaPharm a low double-digit percentage of all income received by Daré or its affiliates in connection with any sublicense granted to a third party for use outside of the United States, subject to certain exclusions.

- Royalty Payments. During the royalty term, Daré will pay MilanaPharm high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes. The royalty term, which is determined on a country-by-country basis and licensed product-by-product basis (or process-by-process basis), begins with the first commercial sale of a licensed product or process in a country and terminates on the latest of (a) the expiration date of the last valid claim of the licensed patent rights that cover the method of use of such product or process in such country, or (b) 10 years following the first commercial sale of such product or process in such country. Royalty payments are subject to reduction in certain circumstances, including as a result of generic competition, patent prosecution expenses incurred by Daré, or payments to third parties for rights or know-how that are required for Daré to exercise the licenses granted to it under the MilanaPharm License Agreement or that are strategically important or could add value to a licensed product or process in a manner expected to materially generate or increase sales.

- Efforts. Daré must use commercially reasonable efforts and resources consistent with those undertaken by it in pursuing development and commercialization of other pharmaceutical products, taking into account program-specific factors, (a) to develop and commercialize at least one licensed product or process in the United States and at least one licensed product or process in at least one of Canada, the United Kingdom, France, Germany, Italy or Spain, and (b) following the first commercial sale of a licensed product or process in any jurisdiction, to continue to commercialize that product or process in that jurisdiction.

- Term. Unless earlier terminated, the term of the MilanaPharm License Agreement will continue until (a) on a licensed product-by-product (or process-by-process basis) and country-by-country basis, the date of expiration of the royalty term with respect to such licensed product in such country, and (b) the expiration of all applicable royalty terms under the MilanaPharm License Agreement with respect to all licensed products and processes in all countries. Upon expiration of the term with respect to any licensed product or process in a country (but not upon earlier termination of the MilanaPharm License Agreement), the licenses granted to Daré under the MilanaPharm License Agreement will convert automatically to an exclusive, fully paid-up, royalty-free, perpetual, non-terminable and irrevocable right and license, with the right to grant sublicenses, under the licensed intellectual property. The MilanaPharm License Agreement is subject to customary termination rights in favor of both Daré and the Licensors, and in addition MilanaPharm may terminate the license granted to Daré solely with respect to a licensed product or process in a country if, after having launched such product or process in such country, (i) Daré, or its affiliates or sublicensees, as applicable, discontinues the sale of such product or process in such country and MilanaPharm notifies Daré of such termination within 60 days of having first been notified by Daré of such discontinuation, or (ii) Daré, or its affiliates or sublicensees, as applicable, (A) discontinues all commercially reasonable marketing efforts to sell, and discontinues all sales of, such product or process in such country for nine months or more for reasons unrelated to force majeure, (B) fails to resume commercially reasonable marketing efforts with the intent to sell such product or process in such country within 120 days of having been notified of such failure by MilanaPharm, (C) fails to reasonably demonstrate a strategic justification for the discontinuation and failure to resume to MilanaPharm under the circumstances set forth in the MilanaPharm License Agreement, and (D) MilanaPharm gives 90 days' notice to Daré.

The following is a summary of the material terms of the Assignment Agreement:

- Assignment; Technology Transfer. Hammock assigned and transferred to Daré all of Hammock's right, title and interest in and to the MilanaPharm License Agreement and agreed to cooperate to transfer to Daré all of the data, materials and the licensed technology in its possession pursuant to a technology transfer plan to be agreed upon by the parties, with a goal for Daré to independently practice the licensed intellectual property as soon as commercially practical in order to develop and commercialize the licensed products and processes. Hammock will be solely liable for any obligations arising from any breach under the MilanaPharm License Agreement prior to the December 5, 2018.

- Fees. Daré paid $250,000 to Hammock in connection with the execution of the Assignment Agreement and must pay $250,000 to Hammock (the "Hammock Deferred Fee") within 15 days of the first to occur of December 5, 2019 or the closing of an equity financing in which Daré raises aggregate proceeds of at least $10.0 million. The Hammock Deferred Fee may be paid, in Daré's discretion, either in cash or with shares of Daré's common stock.

- Milestone Payments. Daré must make potential future development milestone payments to Hammock of up to $1.1 million.

- Term. The Assignment Agreement will terminate upon the later of (a) completion of the parties' technology transfer plan, and (b) payment to Hammock of the last payment to which it may be entitled under the Hammock Deferred Fee and development milestone payment provisions.

The foregoing summary of the material terms of the MilanaPharm License Agreement, as amended by the License Amendment, and the Assignment Agreement does not purport to be complete and is qualified in its entirety by reference to the MilanaPharm License Agreement, the License Amendment and the Assignment Agreement, a copy of each of which is expected to be filed with Daré's annual report on Form 10-K for the year ending December 31, 2018. Daré expects to seek confidential treatment of certain terms of the MilanaPharm License Agreement, the License Amendment and the Assignment Agreement at the time they are filed.

Item 3.01 Notice of Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On November 30, 2018, Daré received a letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market ("Nasdaq") notifying Daré that, for the last 30 consecutive business days, the closing bid price for Daré's common stock was below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Nasdaq letter has no immediate effect on the listing of Daré's common stock on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, Daré has been provided an initial period of 180 calendar days, or until May 29, 2019 (the "Compliance Date"), to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180-day period, the closing bid price of Daré's common stock is at least $1.00 for a minimum of 10 consecutive business days, unless the Staff exercises its discretion to extend such 10-day period, the Staff will provide Daré written confirmation of compliance with the Minimum Bid Price Requirement and the matter will be closed. If Daré does not regain compliance by the Compliance Date, Daré may be eligible for an additional 180 calendar day compliance period. To qualify for such additional compliance period, Daré would have to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the Minimum Bid Price Requirement, and Daré would need to provide written notice of its intention to cure the deficiency during the additional compliance period, by effecting a reverse stock split, if necessary. If Daré is not eligible for the additional compliance period or it appears to the Staff that Daré will not be able to cure the deficiency or if the Staff exercises its discretion to not provide such additional compliance period, the Staff will provide written notice to Daré that its common stock will be subject to delisting. At that time, Daré may appeal the Staff's delisting determination to a Nasdaq Hearing Panel.

Daré will monitor the closing bid price of its common stock and will consider options to regain compliance with the Minimum Bid Price Requirement. There can be no assurance that Daré will regain compliance with the Minimum Bid Price Requirement or maintain compliance with any of the other Nasdaq continued listing requirements.

Item 8.01 Other Events.

On December 6, 2018, Daré issued a press release announcing the acquisition of the licenses under the MilanaPharm License Agreement, as amended by the License Amendment, pursuant to the Assignment Agreement, a copy of which is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued on December 6, 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: December 6, 2018

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

Exhibit 99.1

Daré Bioscience, Inc. Announces Licensing and Global Rights to Novel Phase III Product Candidate for the Treatment of Bacterial Vaginosis

Bacterial vaginosis affects nearly 20 million women in the U.S. every year

SAN DIEGO, Dec. 6, 2018 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a leader in clinical-stage women's health innovation, today announced that it has entered into definitive agreements with Hammock Pharmaceuticals, Inc., TriLogic Pharma LLC and MilanaPharm LLC under which Daré acquired the global rights to MP-101 for the treatment of bacterial vaginosis (BV), as well as the rights to utilize the underlying proprietary hydrogel drug delivery technology for any vaginal or urological application in humans.

Bacterial vaginosis is a type of vaginal inflammation caused by the overgrowth of bacteria naturally found in the vagina, which upsets the natural balance and is characterized by vaginal discharge, vaginal odor, vaginal itching, and burning during urination.

The proprietary *in-situ* gel system, which consists of a combination of a tri block copolymer and a natural polysaccharide, is designed to take advantage of body temperature to undergo solution-to-gel transition, enabling transformation into a bioadhesive gel formulation featuring extended release of the incorporated drug following application at the site of action. In MP-101 this proprietary technology is formulated with clindamycin, an antibiotic used to treat certain bacterial infections including BV, and has been engineered to produce a dual release pattern after vaginal application, providing maximum duration of exposure to clindamycin at the site of infection. Daré expects to commence a Phase III clinical study of MP-101 in approximately 250 women in the second half of 2019, and if the study is successful, to be in a position to file a new drug application with the U. S. Food and Drug Administration (FDA) in 2020. Based on MilanaPharm's discussions with the FDA, Daré believes that one Phase III study with sufficient power and size may be sufficient for marketing approval in the U.S.

Current BV therapies typically have a success rate of less than 70%. In an investigator initiated pilot study treating 30 women, MP-101 demonstrated an 88% cure rate with just one administration.

"We believe this Phase III program will allow us to move into a leadership position in an area of great concern for both women and healthcare providers," said Sabrina Martucci Johnson, President and CEO of Daré. "Studies suggest that nearly 20 million women in the U.S. experience BV and many suffer from episodes of recurrence. Current standard of care is oral antibiotics taken either once or over the course of several days, which can have systemic side effects, or antibiotics delivered vaginally in creams or gels, typically over the course of several days. If a cure rate consistent with the pilot study is demonstrated in the Phase III program, MP-101 has the potential to provide a significant improvement in efficacy over currently marketed BV therapies and enhanced convenience for women."

"Hammock is excited to announce our partnership with Daré Bioscience. The transaction allows Hammock to focus on our OTC products and to potentially recognize value from MP-101 and the novel hydrogel technology. We look forward to working with the Daré and MilanaPharm teams on the transition and the lead product candidate and possibly other product candidates incorporating the hydrogel technology," said William R. Maichle, CEO of Hammock Pharmaceuticals.

Under the agreements with Hammock and TriLogic/MilanaPharm, Daré received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the technology, paid one-time upfront fees of $275,000 and will pay one-time deferred fees of $450,000 within one year. In addition, Daré agreed to make potential future milestone payments through the term of the license based on clinical, regulatory, commercial launch and sales events, and to pay royalties based on commercial sales. Patents covering the licensed technology have been granted with terms through 2028 and additional patents pending would have terms through 2035.

Destum Partners advised Hammock Pharmaceuticals on the transaction.

About Hammock Pharmaceuticals

Hammock Pharmaceuticals is an international branded, specialty pharmaceutical and consumer health company focused on the commercialization of differentiated brands and high value generic products.

About MilanaPharm

MilanaPharm is a specialty pharmaceutical company built upon a proprietary drug delivery platform for numerous active compounds. MP-101 is part of the company's hydrogel platform which is designed to deliver drugs that remain in place over periods ranging from several hours to several days, depending on the desired delivery profile, in order to achieve an effective treatment outcome.

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 MP-101 to significantly improve treatment outcomes in BV compared to currently marketed products, the potential for MP-101 to receive marketing approval for the treatment of BV following a single Phase III clinical study in approximately 250 subjects, the potential application of the licensed drug delivery platform for indications other than BV, Daré's ability to advance MP-101 into Phase III development, to successfully conduct the planned Phase III clinical study, and to achieve FDA acceptance of a new drug application for MP-101 in BV on its anticipated timelines or at all, and the potential for marketing exclusivity in BV and other inidications based on issued patents and pending patent applications. 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: Daré's ability to raise additional capital when and as needed, to advance its product candidates; Daré's ability to develop and commercialize product candidates, including MP-101; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré's product candidates in a timely manner; Daré's 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 its product candidates; Daré's ability to retain our licensed rights to develop and commercialize a 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 candidates; developments by Daré's competitors that make its product candidates less competitive or obsolete; Daré's dependence on third parties to conduct clinical trials; 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; 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 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:

Investors on behalf of Daré Bioscience, Inc.:
Ami Bavishi
Burns McClellan
abavishi@burnsmc.com
212-213-0006

OR

Media on behalf of Daré Bioscience, Inc.:
Amanda Guisbond
Canale Communications
amanda@canalecomm.com
781-405-8775

Source: Daré Bioscience, Inc.