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): **January 10, 2020**

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock	**DARE**	**Nasdaq Capital Market**

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 January 10, 2020, Daré Bioscience, Inc. ("Daré"), entered into a license agreement with Bayer HealthCare LLC (“Bayer”) regarding the further development and commercialization of Daré’s investigational contraceptive product, Ovaprene®, in the U.S.

Under the agreement, Daré will receive a $1.0 million upfront payment from Bayer. If Bayer pays an additional $20.0 million to Daré (the “Clinical Trial and Manufacturing Activities Fee”) after Bayer receives and reviews the results of the pivotal clinical trial of Ovaprene, which payment Bayer may elect to make in its sole discretion, the license grant to Bayer to develop and commercialize Ovaprene for human contraception in the U.S. becomes effective. Such license would be exclusive with regard to commercialization and co-exclusive with Daré with regard to development. Daré would also be entitled to receive (a) a milestone payment in the low double-digit millions upon the first commercial sale of Ovaprene in the U.S. and escalating milestone payments based on annual net sales of Ovaprene during a calendar year, totaling up to $310.0 million if all such milestones, including the first commercial sale, are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

Under the agreement, Daré will be responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. Bayer will support Daré in development and regulatory activities by providing up to two full-time equivalents with expertise in clinical, regulatory, preclinical, commercial, CMC and product supply matters in an advisory capacity. After payment of the Clinical Trial and Manufacturing Activities Fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S.

The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of (a) the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S.; or (b) 15 years from the first commercial sale of Ovaprene in the U.S. In addition to customary termination rights for both parties, Bayer may terminate the agreement at any time on 90 days’ notice and the agreement will automatically terminate if Daré does not receive the Clinical Trial and Manufacturing Activities Fee if and when due.

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 Daré intends to file with its annual report on Form 10-K for the year ended December 31, 2019.

Item 7.01 Regulation FD Disclosure

On January 13, 2020, Daré and Bayer issued a joint press release announcing that they entered into the license agreement, a copy of which press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in Item 7.01 of this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in Exhibit 99.1 shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Daré, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Cautionary Statement Regarding Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements relating to the grant of the license to Bayer and the amount of payments Daré may receive under the license agreement. 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. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties. Actual results could differ materially from those anticipated as a result of various factors, including: the risks and uncertainties inherent in the clinical development process; the risks and uncertainties inherent in the regulatory approval process; that Bayer may decide not to pay the Clinical Trial and Manufacturing Activities Fee regardless of the outcome of the pivotal trial for

Ovaprene; that Bayer may terminate the license agreement at any time; the risks and uncertainties inherent in successfully commercializing Ovaprene, if and when it is approved for commercialization in the U.S., including because of competing alternative products that are currently on the market or under development, any of which could impact the commercial potential of Ovaprene and could materially and negatively impact Daré's realization of milestone, royalty and sublicense payments under the license agreement. Additional factors that may affect Daré's strategy, future operations, future financial position, projected costs, prospects, plans and objectives are set forth in its filings with the SEC, including Daré's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are urged to consider these factors carefully in evaluating the forward-looking statements in this report and are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement. Unless otherwise required by law, Daré expressly disclaims any obligation to update publicly any forward-looking statements, whether as result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on January 13, 2020

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: January 13, 2020

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

News Release

Bayer and Daré Bioscience Announce Exclusive Licensing Agreement for U.S. Commercial Rights to Ovaprene®, an Investigational Hormone-Free, Monthly Contraceptive

- Daré may be entitled to up to $310 million in commercial milestone payments plus tiered royalties on net sales in the double-digits
- Daré is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's health

Whippany, NJ and San Diego, CA, Jan. 13, 2020 – Bayer, a leader in women's health, and Daré Bioscience, Inc. (NASDAQ:DARE), a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's health, announced today that the companies have signed a license agreement under which Bayer may commercialize Daré's investigational contraceptive product, Ovaprene® in the United States once approved by the FDA.

Ovaprene is an investigational hormone-free monthly vaginal contraceptive currently in clinical development for the prevention of pregnancy. If approved, it could be the first monthly non-hormonal contraceptive product.

"We believe Bayer is best positioned to maximize the market opportunity for Ovaprene, which has the potential to be a first-in-category product for women, as Bayer has with other first-in-category products," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "This agreement provides Daré the opportunity to immediately benefit from Bayer's expertise in development, regulatory, and commercialization, to unlock the program's full value similar to other innovative contraceptive brands."

Under the agreement, Daré will receive an upfront payment and access to Bayer's extensive clinical and market capabilities while retaining control over Ovaprene's development and regulatory approval process. Bayer receives the right to obtain exclusive rights to commercialize the product in the U.S. following completion of the pivotal clinical trial being undertaken by Daré. If Bayer, in its sole discretion, makes payment to Daré of $20 million, which Daré intends to apply to reimbursement of clinical

study costs, then the exclusive license to commercialize Ovaprene in the U.S. will become effective. Daré will also be entitled to receive commercial milestone payments potentially totaling $310 million, in addition to double digit tiered royalties on net sales.

“Both Daré and Bayer share an intense passion of developing products and medicines that enhance the lives of women,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer’s Pharmaceuticals Division and Head of Research and Development. “Low or no hormones in contraceptives is something many women prefer, and we are proud to collaborate with a partner who shares a similar commitment to bringing products to market that can make a meaningful impact for women, their families and communities.”

Daré plans to file an Investigational Device Exemption (IDE) for Ovaprene in the first half of 2020 and, pending the U.S. Food and Drug Administration’s review and clearance of the IDE, to initiate a pivotal contraceptive effectiveness and safety clinical study of Ovaprene in the second half of 2020. If successful, Daré expects that study to support marketing approvals of Ovaprene in the U.S., Europe and other countries worldwide.

The Pharmaceuticals Business Development & Licensing team of Bayer facilitated this collaboration.

About Ovaprene®

Ovaprene is an investigational hormone-free, intravaginal ring currently in clinical development for pregnancy prevention. Ovaprene releases a locally acting, non-hormonal agent which impedes sperm motility and features a proprietary knitted polymer barrier to physically block sperm from entering the cervical canal.

Ovaprene recently completed a successful postcoital test (PCT) clinical study where, in all women and across all cycles evaluated, it prevented virtually all sperm from entering the cervical canal, a surrogate marker for contraceptive effectiveness.[1] The topline results from the PCT clinical study support continued clinical development of Ovaprene and its potential to be the first hormone-free, monthly contraceptive option for women.

[1] https://ir.darebioscience.com/news-releases/news-release-details/dare-bioscience-announces-positive-findings-postcoital-test

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of 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 expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's product portfolio includes potential first-in-category candidates in clinical development: Ovaprene, a hormone-free, monthly vaginal contraceptive; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder utilizing the active ingredient in Viagra®, DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause. 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 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 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 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 on its investor relations website (https://darebioscience.gcs-web.com/) and to follow these Twitter accounts: @SabrinaDareCEO and @DareBioscience. Any updates to the list of social media channels the company may use to communicate information will be posted on the investor relations page of the company's website mentioned above.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2018, the Group employed around 117,000 people and had sales of 39.6 billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 billion euros. For more information, go to www.bayer.com.

About Gynecology at Bayer

Bayer is committed to delivering Science For A Better Life by advancing a portfolio of innovative treatments. Women's health, including family planning and menopause management, has been at the center of Bayer's gynecology franchise for many years. Today, Bayer's research efforts focus on finding new treatment options for gynecological diseases with a high medical need, and includes several investigational compounds in various stages of pre-clinical and clinical development. Together, these projects reflect the company's approach to research, which prioritizes targets and pathways with the potential to alter the way that gynecological diseases are treated.

Daré 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 potential payments and non-monetary benefits to Daré under its agreement with Bayer, the potential for Ovaprene to become the first FDA-approved hormone-free, monthly contraceptive option, the success and timing of a contraceptive effectiveness and safety clinical study of Ovaprene, and the potential for regulatory approval to market Ovaprene in the U.S., Europe and other countries based on a single successful contraceptive effectiveness and safety clinical study. 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 and continue as a going concern; Daré’s ability to develop, obtain regulatory approval for, and commercialize its product candidates; the risks that the agreement with Bayer may not become effective and, if it becomes effective, that future payments to Daré under the agreement may be significantly less than the anticipated or potential amounts; 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 safety and efficacy of its product candidates; the risk that positive findings in pre-pivotal clinical studies of a product candidate may not be predictive of success in pivotal clinical studies of that candidate; the risk that a product candidate may fail to demonstrate equivalent or superior efficacy and/or safety in a pivotal clinical study compared to results from a pre-pivotal study or studies; Daré’s ability to retain its 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 and manufacture clinical trial material; 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.

Bayer Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Our online press service is just a click away: media.bayer.com
Find more information at www.bayer.com.

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