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): July 8, 2021

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 July 8, 2021, Daré Bioscience, Inc. ("Daré," “we,” “us,” or “our”) and the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (“NICHD”), part of the National Institutes of Health, entered into a Cooperative Research and Development Agreement (the "CRADA") for the conduct of a multi-center, non-comparative, pivotal Phase 3 clinical study to evaluate the effectiveness of Ovaprene® as a contraceptive device (the “Study”). We anticipate submitting an Investigational Device Exemption (“IDE”) to the U.S. Food and Drug Administration (“FDA”) in the fourth quarter of 2021 to permit the commencement of the Study in 2022.

Pursuant to the terms of the CRADA, the Study will be conducted within NICHD’s Contraceptive Clinical Trial Network with NICHD contractor Health Decisions Inc., a contract research organization, providing clinical coordination and data collection and management services for the Study. We and NICHD will each provide medical oversight and final data review and analysis for the Study and will work together to prepare the final report of the results of the Study. We are responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million in four payments to NICHD to be applied toward the costs of conducting the Study. The first such payment, which is due within 30 days of the effective date of the CRADA, is $250,000. Payment 2, due in the fourth quarter of 2021, is $1.25 million, Payment 3, due in the first quarter of 2022, is $3.5 million, and Payment 4, due in the second quarter of 2023, is $500,000. NICHD will be responsible for the other costs related to the conduct of the Study and will manage the payment of expenses to Health Decisions Inc., the clinical sites, and other parties involved with the Study.

Either party may terminate the CRADA for any reason upon 30 days’ prior written notice to the other party. If the CRADA is terminated before completion of the Study, NICHD will cooperate with us to transfer the data and the conduct of the Study to us or our designee and will continue to conduct the Study for so long as necessary to enable such transfer to be completed without interrupting the Study. If we terminate the CRADA before the completion of any active Study protocol, we generally will be responsible for providing sufficient clinical supplies of Ovaprene to NICHD in order to complete the Study. NICHD may retain and use payments we make under the CRADA for up to one year after expiration or termination to cover costs associated with the conduct of activities described under the research plan in the CRADA that were initiated prior to expiration or termination, and any unused funds will be returned to us.

Under the CRADA, each party granted the other party rights to use their respective background inventions solely to the extent necessary to conduct the activities described in the research plan in the CRADA. Subject to the U.S. government’s nonexclusive, nontransferable, irrevocable, paid-up right to practice any CRADA invention for research or other government purposes, each party will own inventions, data and materials produced by its employees, and both parties will jointly own inventions jointly invented by their employees in performing the research plan. Under the CRADA, we were granted an exclusive option to negotiate an exclusive or nonexclusive development and commercialization license with a field of use that does not exceed the scope of the research plan to rights that the U.S. government may have in inventions jointly or independently invented by NICHD employees for which a patent application is filed. The CRADA also contains customary representations, warranties, and indemnification and confidentiality obligations. The CRADA expires five years from its effective date.

The foregoing description of terms of the CRADA is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which Daré intends to file with its quarterly report on Form 10-Q for the period ending September 30, 2021.

Item 7.01 Regulation FD Disclosure.

On July 12, 2021, we issued a press release announcing the CRADA, a copy of which press release is attached as Exhibit 99.1 to this report.

The information contained in this Item 7.01 and Exhibit 99.1 to this report is being “furnished” and shall not be deemed “filed” for the 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 us, 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 of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements relating to the performance by NICHD and Daré of their respective obligations under the CRADA, including the conduct of the Study, and the anticipated timing of the IDE filing and commencement of the Study. To the extent that statements contained in this report are not descriptions of historical facts, they are forward-looking statements. 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, without limitation, the risks and uncertainties inherent in the research and development of investigational products, such as Ovaprene, 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 timely meet its payment obligations under the CRADA, and NICHD's ability to terminate the CRADA for any reason upon 30-days' notice. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in the forward-looking statements, as well as risks relating to Daré's business in general, please refer to Daré's annual report on Form 10-K filed with the SEC on March 30, 2021, and its current and future periodic reports filed with the SEC. 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 July 12, 2021

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: July 12, 2021

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

Exhibit 99.1

Daré Announces Collaborative Research Agreement (CRADA) for the Pivotal Phase 3 Study of Ovaprene®, an Investigational Hormone-Free Monthly Contraceptive

Funding and Clinical Operations Support will be Provided by the National Institutes of Health's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Under the CRADA

Daré Plans to Submit an Investigational Device Exemption (IDE) to the FDA in the Fourth Quarter of 2021 and Commence the Ovaprene Pivotal Study in 2022

SAN DIEGO, July 12, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced that it entered into a Cooperative Research and Development Agreement (CRADA) with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health (NIH), for the pivotal Phase 3 study of Ovaprene®, an investigational hormone-free monthly intravaginal contraceptive currently in clinical development for the prevention of pregnancy. The agreement will allow Daré to leverage the contraceptive clinical trial expertise of NICHD while also sharing the costs of the Phase 3 pivotal study with NICHD. If Ovaprene® is approved by the U.S. Food and Drug Administration (FDA), it could be the first monthly non-hormonal contraceptive option for women.

The pivotal Phase 3 study will be supported by the NICHD's Contraceptive Development Program (CDP). The CDP oversees the Contraceptive Clinical Trial Network (CCTN), which was established in 1996 to conduct studies of investigational contraceptives, and the Phase 3 study will be conducted within the CCTN with the NICHD contractor Health Decisions Inc. Daré will be responsible for providing clinical supplies of Ovaprene® and coordinating interactions with and preparing and submitting supportive regulatory documentation to the FDA. Daré and NICHD will each provide medical oversight for the trial and final data review and analysis, and will work together to prepare the final report of the trial results.

Under the CRADA, Daré has also agreed to contribute $5.5 million toward the total estimated cost to conduct the pivotal Phase 3 study, which will be payable in four payments. The first payment is due within 30 days of the effective date of the CRADA and the final payment is due by April 1, 2023. NICHD will be responsible for the other costs related to the conduct of the pivotal study and will manage the payment of expenses to Health Decisions, the clinical sites, and other parties involved with the study.

"We are thrilled to continue our work with NICHD to advance Ovaprene® through this pivotal study," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience, Inc. "Grant funding previously provided by NICHD supported the conduct of our pre-pivotal clinical study of Ovaprene. With this CRADA, we have the opportunity to leverage NICHD's experience in the design and execution of contraceptive studies, as well as continued funding to support the development of Ovaprene. We look forward to collaborating with NICHD, along with our partner Bayer®, to advance the development of additional non-hormonal contraceptive options for women."

Bayer and Daré entered into an exclusive licensing agreement for U.S. commercial rights to Ovaprene® in January 2020. Under the agreement, Daré receives access to Bayer's extensive

clinical and market capabilities while retaining control over Ovaprene's development and regulatory approval process. Bayer has 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 and the NICHD. If Bayer, in its sole discretion, makes payment to Daré of $20 million, which Daré intends to apply to reimbursement of its portion of the clinical study and manufacturing 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.

"This collaboration between Daré and NICHD marks an important milestone in Women's Healthcare Innovation. Women are at the center of everything we do and we are so pleased to continue to partner with Daré in support of our mission *We're For Her* to provide women with education and access to contraceptive options," said John Berrios, Bayer's Head of Women's Healthcare.

The multi-center, single arm, non-comparative, pivotal Phase 3 contraceptive study of Ovaprene® will evaluate its effectiveness as a contraceptive device along with its safety and usability. Daré plans to file an IDE for Ovaprene in the forth quarter of 2021 and, pending the FDA's review and clearance of the IDE, to initiate the pivotal study of Ovaprene in 2022. If successful, Daré expects the pivotal study to support marketing approvals of Ovaprene in the U.S. and other countries.

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 novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer; 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 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 the Investors section of its 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 in the Investors section of its website 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 Daré's website mentioned above.

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. In this press release, forward-looking statements include, but are not limited to, statements relating to the conduct and funding of a Phase 3 pivotal clinical study of Ovaprene by the NICHD, anticipated timing of submission of the IDE and commencement of the Phase 3 study, Ovaprene's potential to become the first first monthly non-hormonal contraceptive approved by the FDA, the potential for regulatory approval to market Ovaprene in the U.S. and other countries based on a single pivotal study, and potential payments to Daré under its agreement with Bayer. 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: the NICHD's ability to timely enroll, conduct and report results of the Phase 3 study of Ovaprene; the NICHD's ability to terminate the CRADA for any reason upon 30-days' notice; Daré's ability to raise additional capital when and as needed to advance its product candidates and continue as a going concern; the effects of the COVID-19 pandemic on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on Daré's ability to timely enroll, conduct and report results of its clinical trials and on the ability of third parties on which Daré relies to assist in the conduct of its business, including its clinical trials, to fulfill their contractual obligations to Daré, including the NICHD under the CRADA; Daré's ability to develop, obtain regulatory approval for, and commercialize its product candidates; 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 design and conduct 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 early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; the risk that developments by competitors make Daré's product candidates less competitive or obsolete; failure of Daré's product candidates, if approved, to gain market acceptance or obtain adequate coverage from third-party payers; 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; the risks that the license 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; Daré's failure to timely establish or leverage third-party partnerships or collaborations to commercialize its product candidates, if approved; 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; cyber attacks, security breaches or similar events that compromise Daré's technology systems or those of third parties on which it relies and/or significantly disrupt Daré's business; 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.

Contact

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