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): October 23, 2024

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 October 23, 2024 (the "Effective Date"), Daré Bioscience, Inc. ("Daré," "we," "us," "our" or the "Company") entered into a subaward agreement (the "Agreement") with National Collegiate Inventors and Innovators Alliance, Inc. d/b/a VentureWell (the "CMF"). Pursuant to terms and conditions of the Agreement, we are entitled to receive funding of up to $10.0 million (the "Award Amount") in milestone-based payments to support the advancement of our DARE-HPV development program. DARE-HPV is our investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert being developed as a self-administered at-home treatment for human papillomavirus ("HPV")-related cervical diseases. The CMF is a Consortium Management Firm that received funding from the Advanced Research Projects Agency for Health ("ARPA-H"), an agency within the U.S. Department of Health and Human Services, under an agreement from which funding for the Agreement flows (the "Prime Agreement"). The Agreement was the result of our selection as an awardee of the ARPA-H Sprint for Women's Health program, a funding opportunity announced by First Lady Jill Biden in February 2024 as the first major deliverable of the White House Initiative on Women's Health Research.

The Agreement provides for a 24-month performance period from the Effective Date (the "Performance Period") for us to accomplish specified research activities and objectives relating to advancement of our DARE-HPV program (the "Services"), which include completion of investigational new drug ("IND")-enabling nonclinical studies, clearance by the U.S. Food and Drug Administration ("FDA") of an IND application, clinical supplies manufacturing milestones, and commencement of a Phase 2, randomized, placebo-controlled, double-blind clinical study to evaluate the safety and preliminary efficacy of DARE-HPV for clearance of high-risk HPV infection in women. More than half of the Award Amount will become payable to us during the first 12 months of the Performance Period, subject to our satisfactory performance under the Agreement.

Under the terms of the Agreement, ARPA-H will retain a nonexclusive license to obtain access to and to share research results and data, as well as certain rights, including "march-in" rights, in intellectual property conceived, made, created, developed or reduced to practice in our performance of the Services, pursuant to and in accordance with the Bayh-Dole Act of 1980. During the term of the Agreement and for three years thereafter, we are subject to certain restrictions on foreign access to the intellectual property and other technology developed by or for us in or for the provision of the Services, including restrictions on our sale or other transfer of such technology to a foreign firm or institution (which would include a sale of the Company and a sale or licensing of such technology, but not sales of products or components) without the prior approval of ARPA-H.

The CMF may terminate the Agreement upon 30 days notice to us if the Prime Agreement is materially changed, through no fault of the CMF, in a way that would materially adversely affect the CMF financially. The CMF may also terminate the Agreement in the event of significant, material, chronic and/or regular disagreements or disputes with respect to our performance under the Agreement that cannot be resolved amicably after good faith discussion and escalation. In addition, the Agreement will automatically terminate if the Prime Agreement is terminated.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which we intend to file as an exhibit to our annual report on Form 10-K for the fiscal year ending December 31, 2024, with certain private or confidential provisions or terms omitted.

Item 7.01 Regulation FD Disclosure.

On October 23, 2024, we issued a press release announcing that we were selected as an awardee under the ARPA-H Sprint for Women's Health program. A copy of the press release is furnished as an exhibit to this report and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 to this report, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 7.01 and Exhibit 99.1 shall not be incorporated by reference into any filing under the Exchange Act or the Securities Act, 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 receipt by Daré of payments under the Agreement, the potential timing of Daré's receipt of such payments, and the development of DARE-HPV during the Performance Period. To the extent that statements contained in this report are not descriptions of historical facts, they 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," "target," "objective," 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, without limitation, the risks and uncertainties inherent in the research and development of investigational drug products, including DARE-HPV, Daré's ability to meet the milestones required for receipt of payments under the Agreement, or at all, and Daré's ability to continue as a going concern. 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 Securities and Exchange Commission ("SEC") on March 28, 2024, its quarterly report on Form 10-Q filed with the SEC on August 12, 2024, and its current reports on Form 8-K subsequently 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 October 23, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 23, 2024

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

Exhibit 99.1

Daré Bioscience Selected to Receive $10 Million Award from ARPA-H's Sprint for Women's Health

DARE-HPV is a potential first-in-category treatment for human papillomavirus (HPV)-related cervical disease which could change the treatment paradigm for clinical HPV management.

Essentially all cervical cancer cases worldwide are caused by HPV infection.

SAN DIEGO, October 23, 2024 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, today announced that it has been selected by the Advanced Research Projects Agency for Health (ARPA-H) as an awardee of the Sprint for Women's Health to address critical unmet challenges in women's health, champion transformative innovations, and tackle health conditions that uniquely or disproportionately affect women. Daré will receive $10 million in funding over two years through the Sprint for Women's Health launchpad track for later-stage health solutions.

DARE-HPV is an innovative investigational treatment for HPV-related cervical disease. Essentially all cervical cancers worldwide are caused by HPV infection, and despite the advancements in HPV screening and vaccination, an estimated 100,000 women are still treated for cervical precancer and an estimated 4,000 women still die from cervical cancer in the U.S. every year. Today, cervical precancers are monitored until they reach a late stage, since the most common treatment is a surgery which removes part of the cervix; however, the surgery is associated with an increased risk of preterm birth and sexual dysfunction and therefore is not recommended for patients with fertility concerns.

"DARE-HPV has the potential to be the first FDA-approved pharmaceutical intervention that could treat both late-stage cervical lesions as well as earlier stage HPV-related cervical infections, which could change the paradigm around how HPV-related cervical diseases are clinically managed today," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We are thrilled that ARPA-H shares our vision for this product candidate's potential to transform the management of HPV-related cervical diseases with this at-home strategy to control the virus that causes cervical cancer."

ARPA-H sought solutions within six topics of interest in women's health, and received an unprecedented response of submissions. ARPA-H launched the Sprint for Women's Health in February, with First Lady Jill Biden announcing the funding as the first major deliverable from the White House Initiative on Women's Health Research.

The ARPA-H Sprint for Women's Health is conducted in collaboration with the Investor Catalyst Hub of ARPANET-H, the agency's nationwide health innovation network that connects people, innovators, and institutions to accelerate better health outcomes for everyone. Daré will work with an ARPA-H Program Manager and the Investor Catalyst Hub over two years to develop DARE-HPV, receiving milestone-based payments aligned to research activities and performance objectives.

The ARPA-H launchpad program accelerates transformative health solutions' path to impact by providing funding and market transition support. As a launchpad performer, Daré will also work with an Entrepreneur-in-Residence and participate in Launchpad Accelerator, which includes customized curriculum, virtual events, and in-person workshops to support performer market transition.

About HPV-Related Cervical Diseases and DARE-HPV

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. Essentially all cervical cancers worldwide are caused by infection with one of 14 carcinogenic, or “high-risk” HPV types (hrHPV). While some HPV infections are transient, persistent hrHPV infection can progress to cervical cancer through the persistence and progression of cervical lesions.

DARE-HPV is an investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert with the potential to be a first-in-category treatment for HPV-related cervical diseases. There currently are no U.S. Food and Drug Administration (FDA)-approved, non-surgical pharmaceutical interventions to treat high-grade cervical lesions (also called high-grade squamous intraepithelial lesions (HSIL) or high-grade cervical intraepithelial neoplasia (CIN 2/3)) and no FDA-approved treatments for HPV infection. DARE-HPV has the potential to be the first FDA-approved pharmaceutical intervention for the treatment of CIN and other HPV-related cervical pathologies.

In the U.S., about 10% of women with HPV infection on their cervix will develop long-lasting HPV infections that put them at risk for cervical cancer. The American Cancer Society estimates that approximately 13,820 new cases of invasive cervical cancer will be diagnosed and more than 4,000 women will die from the disease in the U.S. in 2024. Additionally, each year in the U.S., an estimated 100,000 people are treated for cervical precancer, of which approximately 74% are between the ages of 18–39 years, during prime childbearing and childrearing years.

About Daré Bioscience

Daré Bioscience is a biopharmaceutical company committed to advancing 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 prioritize women’s health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility.

The first FDA-approved product to emerge from Daré’s portfolio of women’s health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older, which is under a global license agreement with Organon. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023. Daré’s portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, 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, the active ingredient in Viagra®, to treat female sexual arousal disorder (FSAD); and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. To learn more about XACIATO, Daré’s full portfolio of women’s health product candidates, and Daré’s mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré Bioscience leadership has been named on the Medicine Maker’s Power List and Endpoints News’ Women in Biopharma 2022. In 2023, Daré’s CEO was honored as one of Fierce Pharma’s Most Influential People in Biopharma for Daré’s contributions to innovation and advocacy in the women’s health space.

Daré Bioscience placed #1 in the Small Company category of the San Diego Business Journal's 2023 Best Places to Work Awards.

Daré may announce material information about its finances, product and 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 and 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 X (formerly Twitter) accounts: @SabrinaDareCEO and @DareBioscience. Any updates to the list of social media channels the company may use to communicate information will be posted in the Investors section of Daré's 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," "objective," 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 Daré's expectation that it will receive $10 million in funding from ARPA-H, DARE-HPV's potential as a safe and effective treatment for HPV-related cervical diseases, the potential for DARE-HPV to be the first FDA-approved pharmaceutical intervention for treatment of late-stage cervical lesions and other HPV-related cervical pathologies, and the potential market opportunity for DARE-HPV, if approved. As used in this press release, the description of a product candidate as "first-in-category" is a forward-looking statement relating to the potential of the candidate to represent a new category of product if it were to receive marketing approval for the indication for which Daré is developing it. 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, risks and uncertainties related to: Daré's ability to achieve the product development and other milestones required for it to receive payments under its ARPA-H funding award; Daré's ability to raise additional capital when and as needed to advance its product candidates, execute its business strategy and continue as a going concern; Daré's ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; failure or delay in starting, conducting and completing clinical trials of a product candidate; 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; Daré's dependence on third parties to conduct clinical trials and manufacture and supply clinical trial material and commercial product; 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 development of a product candidate requires more clinical or nonclinical studies than Daré anticipates; the loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; the risk that developments by competitors make Daré's product or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; failure of Daré's product or product candidates, if approved, to gain market acceptance or obtain adequate coverage or reimbursement from third-party payers; Daré's ability to retain its licensed rights to develop and commercialize a product or 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 and product candidates; 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; product liability claims; governmental investigations or actions relating to Daré's product or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; cybersecurity incidents 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.

Contacts:

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Source: Daré Bioscience, Inc.