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): March 31, 2022

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 2.02 Results of Operations and Financial Condition.

On March 31, 2022, Dare Bioscience, Inc. issued a press release announcing its financial results for the year ended December 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this report.

The information under this Item 2.02 and in Exhibit 99.1 is being furnished and is not being filed for purposes of Section 18 of the Securities and Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, regardless of any general incorporation language in any such filing, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on March 31, 2022
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: March 31, 2022

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

Exhibit 99.1

Daré Bioscience Reports Full-Year 2021 Financial Results and Provides a Company Update

Entered into exclusive global license agreement with Organon to commercialize XACIATO™ (clindamycin phosphate vaginal gel, 2%) that includes a $10 million upfront cash payment once effective

U.S. commercial launch of XACIATO expected in 4Q-2022

Initiated communication with the FDA to support a full IDE review for Ovaprene with plans to start the pivotal Phase 3 clinical study in 2022

$51.7 million in cash and cash equivalents at December 31, 2021

Conference Call and Webcast Today at 4:30 p.m. ET

SAN DIEGO, March 31, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the year ended December 31, 2021 and provided a company update.

"We made significant progress across the portfolio during 2021 and into the first quarter of 2022, most notably with XACIATO" said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We filed a new drug application with the FDA for XACIATO in June 2021, were notified by the FDA of its marketing approval in December 2021 and, today, announced that we entered into a global license agreement with Organon to commercialize XACIATO, an FDA-approved medication for the treatment of bacterial vaginosis in females 12 years of age and older. The agreement includes a $10 million cash payment from Organon once it is effective, potential milestone payments of up to $182.5 million and tiered double-digit royalties on net sales. XACIATO is expected to be commercially available in the U.S. in the fourth quarter of 2022. We are excited to be collaborating with one of the premier companies in women's health as we believe that Organon's commercial capabilities will ensure that XACIATO reaches the women most impacted by this condition."

Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women.[1] The condition results from an overgrowth of bacteria, which

upsets the balance of the natural vaginal microbiome and can lead to symptoms of odor and discharge. In addition to being the most common type of vaginal infection in women of reproductive age and having bothersome symptoms, bacterial vaginosis has been associated with certain increased health risks.[2]

"In terms of the rest of the portfolio," said Johnson, "in 2021, we entered into a cooperative research and development agreement with NICHD to conduct the pivotal Phase 3 clinical study of Ovaprene within NICHD's Contraceptive Clinical Trial Network and share the study costs. In 1Q-2022, we initiated the process with the FDA to support the IDE review for Ovaprene and we are targeting commencement of the pivotal Phase 3 study in 2022. Finally, we continue to enroll patients in our Phase 2b RESPOND study of Sildenafil Cream, 3.6%, as well as in our Phase 1/2 clinical study of DARE-VVA1, with plans to have topline data from the DARE-VVA1 study in 2H-2022, and we are initiating a Phase 1/2 clinical study of DARE-HRT1 in Australia during 2Q-2022. We look forward to providing updates on these and other portfolio developments throughout the year."

2022 Key Portfolio Objectives

- XACIATO™: U.S. commercial launch in 4Q-2022
- Ovaprene®: Approval of Investigational Device Exemption (IDE) submission by the FDA allowing commencement of pivotal clinical study in 2022
- DARE-VVA1: Phase 1 /2 clinical study topline data during 2H-2022
- Sildenafil Cream, 3.6%: Phase 2b RESPOND clinical study interim analysis during 2022 and updated timeframe for topline data

Portfolio Accomplishments and 2022 Management Expectations

- **XACIATO™ (clindamycin phosphate vaginal gel, 2%) (f/k/a DARE-BV1):**
  A clear, colorless, viscous gel, to be administered once intravaginally as a single dose for the treatment of bacterial vaginosis in female patients 12 years of age and older. Please click here for full Prescribing Information.
  - FDA marketing approval received on PDUFA date, December 7, 2021
  - FDA granted 5-year exclusivity extension: data exclusivity period expires December 7, 2029
  - Entered into exclusive global license agreement with Organon, March 31, 2022
  - U.S. commercial launch expected 4Q-2022

- **Ovaprene®:**
  Novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer
  - Announced Collaborative Research and Development Agreement (CRADA) for a pivotal Phase 3 study in the U.S. with *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH), in 3Q-2021

- Initiated IDE review process with FDA in 1Q-2022
- Commence pivotal Phase 3 clinical study in collaboration with NICHD in 2022

- **DARE-VVA1:**
  Proprietary, investigational formulation of tamoxifen for intravaginal administration to treat vulvar and vaginal atrophy (VVA) in women with or at risk for hormone-receptor positive breast cancer
  - Initiated a Phase 1/2 clinical study in Australia in 3Q-2021
  - Report topline data of Phase 1/2 study during 2H-2022

- **DARE-HRT1:**
  Unique, investigational 28-day intravaginal ring (IVR) containing bio-identical estradiol and bio-identical progesterone for the treatment of vasomotor symptoms and genitourinary syndrome associated with menopause
  - Commencing Phase 1 /2 study in Australia in 2Q-2022 to evaluate the PK of the lower and higher dose versions of DARE-HRT1 in approximately 20 healthy, post-menopausal women over approximately three consecutive months of use. The study will also collect safety, usability, acceptability and symptom-relief data

- **Sildenafil Cream, 3.6%:**
  Proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical administration to treat female sexual arousal disorder (FSAD)
  - Continue enrollment in Phase 2b RESPOND clinical study
  - Interim analysis in 2022 followed by an update on the timeframe for announcing topline data

Financial Highlights for the Year ended December 31, 2021

- Cash and cash equivalents: $51.7 million at December 31, 2021, compared to $4.7 million at December 31, 2020.
- Net cash from financing activities: $75.8 million in 2021, primarily from sales of common stock under the company's at-the-market offering programs.
- General and administrative expenses: $8.4 million in 2021, as compared to $6.5 million in 2020, with the increase primarily attributable to increases in personnel costs, commercial-readiness expenses, and stock-based compensation expense.
- Research and development expenses: $30.6 million in 2021, as compared to $20.8 million in 2020, with the increase primarily attributable to the costs of the ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial, manufacturing and regulatory affairs activities related to Ovaprene® and Phase-1 and Phase 1-ready programs, and expenses for personnel and stock-based compensation.
- Comprehensive loss: $38.8 million in 2021, as compared to $27.4 million in 2020.

- As of March 30, 2022: 83.9 million shares of Daré common stock outstanding.

1 https://www.cdc.gov/std/bv/stats.htm2
2 https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-20352279

Conference Call

Daré will host a conference call and live webcast today at 4:30 p.m. ET to review financial results for the year ended December 31, 2021 and to provide a company update.

To access the conference call via phone, dial (844) 831-3031 (U.S.) or (443) 637-1284 (international). The conference ID number for the call is 1185595. The live webcast can be accessed under "Presentations, Events & Webcasts" in the Investors section of the Company's website at http://ir.darebioscience.com. Please log in approximately 5-10 minutes prior to the call to register and to download and install any necessary software. To access the replay, please call (855) 859-2056 (U.S.) or (404) 537-3406 (international). The conference ID number for the replay is 1185595. The call and webcast replay will be available until April 14, 2022.

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, fertility, and vaginal and sexual health.

Daré's first FDA-approved product, XACIATO™ (clindamycin phosphate), is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. The Company's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly 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®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone therapy following menopause. 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 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 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 plans and expectations with respect to XACIATO and Daré's product candidates, including potential activities and payments under the exclusive license agreement with Organon (the "XACIATO Agreement"), the expected data exclusivity period for XACIATO, commencement of a pivotal Phase 3 clincial study of Ovaprene, and anticipated timing for commencement and conduct of clinical trials and clinical trial data readouts for Daré's other product candidates. 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 risks that the XACIATO Agreement may not become fully effective, may be terminated early and that payments to Daré under the agreement may not occur or be significantly less than the anticipated or potential amounts; Daré's dependence on Organon to commercialize XACIATO and its lack of control over the efforts and resources that Organon devotes to commercialization of XACIATO; Daré's dependence on third parties for commercial supplies of XACIATO and its components; 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 clinical trial material, and if any of its product candidates are approved, to manufacture commercial product; 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; the loss of, or inability to attract, key personnel; the effects of the COVID-19 pandemic, macroeconomic conditions and geopolitical events 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 to fulfill their contractual obligations to Daré; 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 or product candidates less competitive or obsolete; failure to timely establish or maintain third-party partnerships or collaborations to develop and/or commercialize Daré's product candidates, if approved; 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; 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 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 liabilty claims; governmental investigations or actions relating to our product, product candidates or business activities; 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.

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Source: Daré Bioscience, Inc.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,	
	2021	2020
Operating expenses		
General and administrative	$ 8,350,945	$ 6,549,508
Research and development	30,617,567	20,769,416
License fees	100,000	83,333
Total operating expenses	39,068,512	27,402,257
Loss from operations	(39,068,512)	(27,402,257)
Other income	2,520	1,514
Gain on extinguishment of note payable	369,887	-
Net loss	$ (38,696,105)	$ (27,400,743)
Deemed dividend from trigger of round down provision feature	-	(6,863)
Net loss to common shareholders	(38,696,105)	(27,407,606)
Foreign currency translation adjustments	(63,585)	11,237
Comprehensive loss	$ (38,759,690)	$ (27,396,369)
Loss per common share - basic and diluted	$ (0.63)	$ (0.91)
Weighted average number of common shares outstanding:		
Basic and diluted	61,154,157	30,091,469

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets Data

	December 31,	
	2021	2020
Cash and cash equivalents	$ 51,674,087	$ 4,669,467
Working capital (deficit)	$ 39,243,160	$ (676,689)
Total assets	$ 55,807,177	$ 7,550,712
Total liabilities	$ 17,052,856	$ 8,702,445
Total stockholders' equity (deficit)	$ 38,754,321	$ (1,151,733)