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 30, 2023

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 30, 2023, Daré Bioscience, Inc. issued a press release announcing its financial results for the quarter and fiscal-year ended December 31, 2022, a copy of which 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 30, 2023
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 30, 2023

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

Exhibit 99.1

Daré Bioscience Reports Full Year 2022 Financial Results and Provides a Company Update

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

2022 Daré Key Portfolio Accomplishments:

License Agreement with Organon to Commercialize XACIATO™
Ovaprene® IDE Approval for Pivotal Contraceptive Efficacy Study
Positive Phase 1/2 Data for both DARE-HRT1 and DARE-VVA1
Three Additional Portfolio Programs (DARE-PDM1, DARE-GML and grant-funded DARE-LBT)

2023 Anticipated Milestones:

XACIATO™ First Commercial Sale
Sildenafil Cream, 3.6% for Female Sexual Arousal Disorder Phase 2b Topline Data
Ovaprene Pivotal Contraceptive Efficacy Study Initiaton
DARE-PDM1 Phase 1 Study Topline Data
IND and Clinical Study Initiation Activities for DARE-VVA1 and DARE-HRT1

SAN DIEGO March 30, 2023 (GLOBE NEWSWIRE) — Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the year ended December 31, 2022 and provided a company update.

"Daré announced a number of positive developments related to our existing portfolio since the beginning of 2022 which serve to benefit all of our stakeholders. We entered into an exclusive global license agreement with Organon for commercialization of our first FDA-approved product, XACIATO™. We completed two Phase 1/2 clinical studies in Australia and announced positive topline data for both. We received FDA approval of our IDE application for Ovaprene, allowing us to conduct a single arm, open-label pivotal contraceptive efficacy study and we hosted an investigator meeting. Finally, we completed subject screening for our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6% for female sexual arousal disorder and are targeting the second quarter of 2023 to announce topline data. We seek to continue the progress made over the past fifteen months by moving these candidates forward in development in 2023 and 2024," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience.

"During 2022, we received $24.1 million in non-dilutive funding which included a $10.0 million cash payment upon the the license agreement with Organon for XACIATO becoming effective, $13.3 million received under grants, and a research and development cash rebate of $0.8 million from the Australian government for clinical work performed in Australia in 2021. Daré will continue to explore ways to operate our business efficiently and to fund our portfolio in a manner we believe will be favorable to our shareholders," added Ms. Johnson

“Our focused efforts to deliver differentiated innovation in women’s health have resulted in 12 development programs across 9 distinct indications, with more than 5 milestone events anticipated in 2023, 3 products in or nearing phase 3 development, 2 potentially transformational collaborations with leaders in women’s health product commercialization, Bayer and Organon, and 1 FDA approved product, XACIATO. Strategic additions to our portfolio in 2022 include global rights to a promising, antimicrobial glycerol monolaurate, which has the potential to be a first-in-category multi-target antimicrobial for vaginal administration. We also added two new candidates to our portfolio—DARE-PDM1 and DARE-LBT—that leverage our proprietary vaginal thermosetting hydrogel technology used in XACIATO. We commenced a Phase 1 study in the first quarter of 2023 for DARE-PDM1, a candidate that delivers the NSAID diclofenac vaginally for the treatment of primary dysmenorrhea, and we received grant funding for DARE-LBT to assess our proprietary hydrogel technology’s potential to deliver live biotherapeutics to support vaginal health. The ability to leverage a platform technology that has recently undergone successful preclinical and clinical testing and regulatory review could offer both time and cost advantages in the development of new candidates to address meaningful unmet needs in women’s health.”

2022 Year and Q1 2023 In Review

Period	Portfolio Asset	Development /Outcome
Q1-2022		
March	XACIATO™	Announced exclusive global commercialization agreement with Organon
Q2-2022		
April	DARE-HRT1	Commenced Phase 1/2 study
May	DARE-ADARE 204 & 214	Received $249,000 NIH grant award
June	XACIATO™	Organon global commercialization agreement became effective; $10 M received in July
Q3-2022		
July	DARE-LARC1	Received $8 million of grant funding
August	GML, antimicrobial glycerol monolaurate	Signed exclusive global technology license with Hennepin Life Sciences
August	Sildenafil Cream, 3.6%	Announced expected timing for completion of enrollment of Phase 2b RESPOND clinical study based on interim analysis
Q4-2022		
October	DARE-HRT1	Announced positive topline efficacy data from Phase 1/2 study
October	Ovaprene®	Received IDE approval for pivotal study
November	Sildenafil Cream, 3.6%	Completed subject screening for exploratory Phase 2b RESPOND clinical study
November	DARE-LBT1	Received $585,000 grant funding
November	DARE-VVA1	Announced positive topline data from Phase 1/2 study
December	DARE-LARC1	Received $4.4 million grant funding
December	Ovaprene®	Investigator kick-off meeting with NICHD for pivotal study
Q1-2023		
January	DARE-HRT1	Announced positive topline pharmacokinetic (PK) data from Phase 1/2 study
February	DARE-PDM1	Commenced Phase 1 study

Portfolio Summary

XACIATO™ (clindamycin phosphate) vaginal gel, 2%:

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.

- **3Q-2022:** $10.0 million cash payment received under license agreement with Organon to commercialize XACIATO
- **4Q-2022:** Organon market access team began meeting with customers and preparing for a U.S. launch
- **2Q-2023**: First commercial sale expected, triggering a $2.5 million milestone to Daré

Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 23 million women in the U.S.[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, including pre-term labor and infertility.[1, 2]

Ovaprene®:

A novel, investigational hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer HealthCare.

- **4Q-2022:** FDA approved an Investigational Device Exemption (IDE) application for a single arm, open-label pivotal contraceptive efficacy study over 12-months (13 menstrual cycles) and provided additional study design considerations
- **4Q-2022**: Investigator meeting held (with the NICHD) for the pivotal Phase 3 clinical study
- **Mid-2023:** Anticipated initiation of subject recruitment for the pivotal Phase 3 clinical study

The planned pivotal Phase 3 clinical study will be conducted under a Collaborative Research and Development Agreement with 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 (NIH).

Sildenafil Cream, 3.6%:

A proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical administration to treat female sexual arousal disorder.

- **4Q-2022:** Completed subject screening for exploratory Phase 2b RESPOND clinical study
- **2Q-2023:** Topline data announcement targeted for Phase 2b RESPOND clinical study

DARE-HRT1:

A unique, investigational intravaginal ring (IVR) designed to deliver bio-identical estradiol and progesterone continuously over a 28-day period for the treatment of menopausal symptoms, including moderate to severe vasomotor symptoms, as part of a menopausal hormone therapy regimen.

- **4Q-2022:** Positive topline efficacy data reported from Phase 1/2 clinical study
- **1Q-2023:** Positive topline PK data reported from Phase 1/2 clinical study, and anticipated plans to progress to a single Phase 3 study announced

DARE-VVA1:

A proprietary, investigational formulation of tamoxifen for intravaginal administration to treat vulvar and vaginal atrophy in women without the use of hormones.

- **3Q-2021:** Phase 1/2 clinical study initiated in Australia
- **4Q-2022:** Positive topline safety, tolerability, PK and pharmacodynamics data reported from Phase 1/2 clinical study

Financial Highlights for the Year ended December 31, 2022

- Cash and cash equivalents: $34.7 million at December 31, 2022, compared to $51.7 million at December 31, 2021.
- General and administrative expenses: $11.2 million in fiscal 2022 as compared to $8.4 million in the prior year, with the current year's increase primarily attributable to an increase in professional services expenses, stock-based compensation expense, personnel costs, general corporate overhead expenses, and expenses related to commercial-readiness activities for XACIATO.
- Research and development expenses: $30.0 million in fiscal 2022 as compared to $30.6 in the prior year. The current year's R&D activities across our entire portfolio of 12 development candidates primarily reflected expenses related to the ongoing Sildenafil Cream, 3.6% exploratory Phase 2b RESPOND clinical trial, manufacturing and regulatory affairs activities related to Ovaprene, costs related to development activities for XACIATO, and costs related to development activities for our preclinical programs and Phase 1 and Phase 1-ready programs.

[1] https://www.cdc.gov/std/bv/stats.htm and https://www.census.gov/data/datasets/2017/demo/popproj/2017-popproj.html

[2] https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-2035227

Conference Call

Daré will host a conference call and live webcast today at 4:30 p.m. Eastern Time to review financial results for the year ended December 31, 2022 and to provide a company update.

To access the conference call via phone, dial (800) 715-9871 (U.S. & Canada) or (646) 307-1963 (international). The conference ID number for the call is 7242530. 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. The webcast will be archived under “Presentations, Events & Webcasts” in the Investors section of the Company’s website at http://ir.darebioscience.com and available for replay until April 14, 2023.

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.

Daré’s first FDA-approved product, XACIATO™ (clindamycin phosphate) vaginal gel, 2% is 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. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. 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 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 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 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 Daré's product candidates, including anticipated timing for commencement and conduct of clinical trials and clinical trial data readouts and the potential for FDA approval of a product candidate based on a single pivotal clinical study, and expectations regarding the commercial launch of XACIATO in the U.S., including the strategy, efforts and capabilities of Daré's commercial collaborator and the timing of the first commercial sale of XACIATO. 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 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; 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; 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; 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.

Contacts:

Investors on behalf of Daré Bioscience, Inc.:
Lee Roth
Burns McClellan
lroth@burnsmc.com
212.213.0006

OR

Media on behalf of Daré Bioscience, Inc.:
Jake Robison
Evoke Canale
jake.robison@evokegroup.com
619.849.5383

Source: Daré Bioscience, Inc.

Dare Bioscience, Inc. and Subsidiaries
Consolidated Statement of Operations and Comprehensive Loss

	Years Ended December 31,	
	2022	**2021**
Revenue		
License fee revenue	$ 10,000,000	$ -
Total revenue	10,000,000	-
Operating expenses		
General and administrative	11,243,271	8,350,945
Research and development	30,042,217	30,617,567
License fee expense	100,000	100,000
Total operating expenses	41,385,488	39,068,512
Loss from operations	(31,385,488)	(39,068,512)
Other income	437,750	2,520
Gain on extinguishment of note payable	-	369,887
Net loss	$ (30,947,738)	$ (38,696,105)
Foreign currency translation adjustments	(196,338)	(63,585)
Comprehensive loss	$ (31,144,076)	$ (38,759,690)
Loss per common share - basic and diluted	$ (0.37)	$ (0.63)
Weighted average number of common shares outstanding:		
Basic and diluted	84,571,805	61,154,157

Dare Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets Data

	December 31,	
	2022	**2021**
Cash and cash equivalents	$ 34,669,605	$ 51,674,087
Working capital	$ 11,414,826	$ 39,243,160
Total assets	$ 43,826,383	$ 55,807,177
Total liabilities	$ 32,714,273	$ 17,052,856
Total stockholders' equity	$ 11,112,110	$ 38,754,321