

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): November 10, 2022

DARÉ BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36395
(Commission
File Number)

20-4139823
(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
Common stock

Trading Symbol(s)
DARE

Name of each exchange on which registered
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 November 10, 2022, Dare Bioscience, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2022. 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 November 10, 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.

Dated: November 10, 2022

DARÉ BIOSCIENCE, INC.

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



Daré Bioscience Reports Third Quarter 2022 Financial Results and Provides a Company Update

- September 30, 2022: \$40.4 million in cash and cash equivalents
- Ovaprene[®]: IDE approval from FDA for pivotal Phase 3 study; additional study design considerations being reviewed and implemented to further position the study as the single pivotal study for marketing approval
- DARE-HRT1: Positive topline efficacy data from Phase 1/2 clinical study
- Sildenafil Cream, 3.6%: Completion of subject screening for Phase 2b RESPOND clinical study

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

SAN DIEGO, Nov. 10, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reported financial results for the quarter ended September 30, 2022 and provided a company update.

"During the third quarter, we received \$18.0 million in non-dilutive cash to strengthen our balance sheet. Approximately \$8.0 million represented a payment under an existing grant to fund the preclinical development of DARE-LARC1, a novel, investigational long-acting, reversible personal contraceptive system, and \$10.0 million was the upfront payment under our license agreement with Organon to commercialize XACIATO[™], which was revenue we recognized in the second quarter when the agreement became effective. In addition, subsequent to quarter end, we received a research and development cash rebate from the Australian government of approximately \$786,000 for clinical work performed in Australia in 2021. Daré remains committed to exploring ways to operate our business efficiently and to fund our portfolio in a manner we believe will be favorable to our shareholders," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience.

"During the past two months, we had several positive developments related to our clinical-stage candidates. In October, we announced the FDA's approval of our Investigational Device Exemption application allowing us to conduct a single arm, open-label pivotal contraceptive efficacy study of Ovaprene. We are currently reviewing and implementing additional FDA study design considerations to further position the study to serve as the single pivotal study necessary to support a premarket approval submission to the FDA. In October, we also announced positive topline efficacy data from our Phase 1/2 clinical study of DARE-HRT1, an investigational intravaginal ring to provide bio-identical hormone therapy for the treatment of menopausal symptoms with one IVR delivering both bio-identical progesterone and bio-identical estradiol together over 28 days. In November, we announced the completion of 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."

"Finally, the teams at Daré and Organon have been diligently working toward a commercial launch of XACIATO in the U.S. since our license agreement became effective. We are confident in Organon's go-to-market strategy, which will leverage the knowledge and experience of its established NEXPLANON[®] sales team to accelerate XACIATO uptake at launch, and we look forward to the market introduction of this new medication for the treatment of bacterial vaginosis in females 12 years of age and older. Bacterial vaginosis is estimated to affect approximately 21 million women in the U.S.¹ We expect the first commercial sale in the first half of 2023 in the U.S. Our goal is to carry the strong momentum of the final months of 2022 into 2023 so that we can start next year from a position of strength."

2H-2022 Portfolio Accomplishments and 1H-2023 Objectives

- Ovaprene: FDA approved IDE application for pivotal study; investigator meeting for pivotal study to be held in 4Q-2022; initiation of subject recruitment targeted for mid-2023
- DARE-HRT1: Phase 1/2 clinical study topline efficacy data announced 4Q-2022; topline pharmacokinetics (PK) data expected later in 4Q-2022
- DARE-VVA1: Phase 1/2 clinical study topline data expected in 4Q-2022
- Sildenafil Cream, 3.6%: Subject screening completed for Phase 2b RESPOND clinical study in 4Q-2022; topline data targeted for 2Q-2023
- XACIATO: Organon market access team is meeting with U.S. customers now to review XACIATO and obtain competitive coverage in the bacterial vaginosis marketplace; first commercial sale of XACIATO expected in 1H-2023 in the U.S.

Portfolio Review

- 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 million cash payment received under license agreement with Organon to commercialize XACIATO
- 4Q-2022: Organon market access team is meeting with U.S. customers now to review XACIATO and obtain competitive coverage in the bacterial vaginosis marketplace
- 1H-2023: First commercial sale expected

Bacterial vaginosis is the most common cause of vaginitis worldwide. 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 (December): Investigator meeting for the pivotal Phase 3 clinical study
- Mid-year 2023: 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, or the NICHD, part of the National Institutes of Health.

▪ **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 Phase 2b RESPOND clinical study
- 2Q-2023: Topline data announcement targeted for Phase 2b 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 vasomotor symptoms, as part of hormone therapy following menopause.

- 2Q-2022: Phase 1/2 clinical study initiated in Australia to evaluate the pharmacokinetics of two versions of DARE-HRT1 and to collect safety, usability, acceptability and symptom-relief data
- 4Q-2022: Positive topline efficacy data reported from Phase 1/2 clinical study; topline PK data expected later in 4Q-2022

▪ **DARE-VVA1:**

A proprietary, investigational formulation of tamoxifen for vaginal administration to treat vulvar and vaginal atrophy in women with or at risk for hormone-receptor positive breast cancer.

- 3Q-2021: Phase 1/2 clinical study initiated in Australia
- 4Q-2022: Topline data from Phase 1/2 clinical study anticipated

Financial Highlights for the Quarter ended September 30, 2022

- Cash and cash equivalents: \$40.4 million at September 30, 2022, compared to \$51.7 million at December 31, 2021.
- General and administrative expenses: \$2.7 million in 3Q-2022, as compared to \$2.2 million in 3Q-2021, with the current quarter's increase primarily attributable to an increase in professional services expense.
- Research and development expenses: \$4.5 million in 3Q-2022, as compared to \$10.4 million 3Q-2021, with the current quarter's decrease primarily attributable to decreases in expenses related to the ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial, manufacturing and regulatory affairs activities related to Ovaprene, costs related to development activities for XACIATO as a result of the completion of the Phase 3 clinical trial for XACIATO in December 2020, and costs related to development activities for our preclinical programs and Phase 1 and Phase 1-ready programs.
- As of November 9, 2022: 84.8 million shares of common stock outstanding.

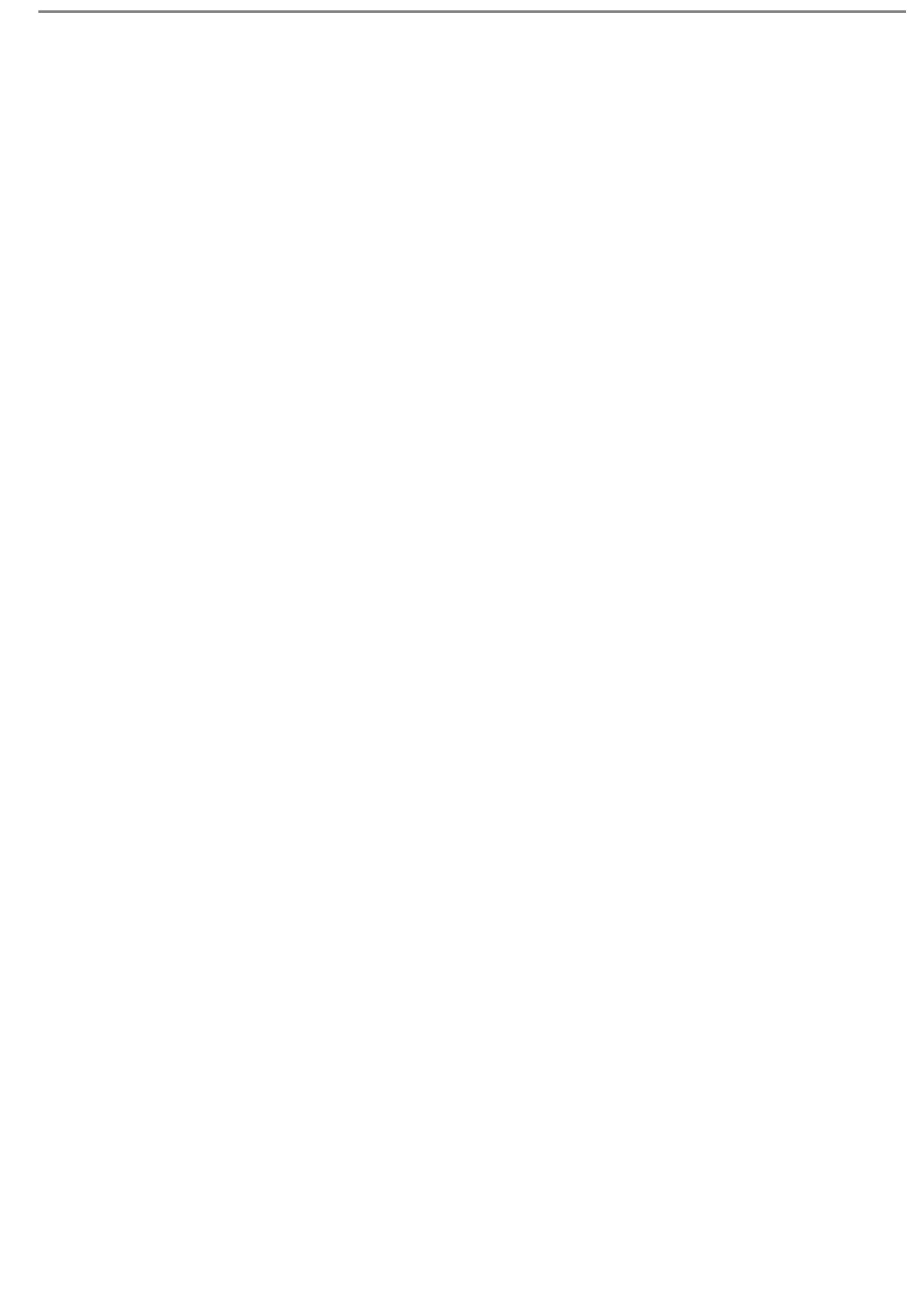
¹ <https://www.cdc.gov/std/bv/stats.htm>

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 quarter ended September 30, 2022 and to provide a company update.

To access the conference call via phone, dial (800) 715-9871 (U.S.) or (646) 307-1963 (international). The conference ID number for the call is 8044477. 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 November 24, 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) 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 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 sources of funding the Company's operations, 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:

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Source: Daré Bioscience, Inc.

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Revenue				
License fee revenue	\$ —	\$ —	\$ 10,000,000	\$ —
Total revenue	—	—	10,000,000	—
Operating expenses				
General and administrative	\$ 2,651,543	\$ 2,211,334	\$ 8,014,424	\$ 5,949,299
Research and development	4,462,250	10,432,603	17,065,497	23,501,098
License fee expense	25,000	25,000	75,000	75,000
Total operating expenses	7,138,793	12,668,937	25,154,921	29,525,397
Loss from operations	(7,138,793)	(12,668,937)	(15,154,921)	(29,525,397)
Other income	118,950	1,508	150,406	1,686
Gain on extinguishment of note payable	\$ 0	\$ 0	0	369,887
Net loss	\$ (7,019,843)	\$ (12,667,429)	\$ (15,004,515)	\$ (29,153,824)
Foreign currency translation adjustments	\$ (230,748)	\$ (63,281)	\$ (375,767)	\$ (79,002)
Comprehensive loss	\$ (7,250,591)	\$ (12,730,710)	\$ (15,380,282)	\$ (29,232,826)
Loss per common share - basic and diluted	\$ (0.08)	\$ (0.18)	\$ (0.18)	\$ (0.45)
Weighted average number of shares outstanding:				
Basic and diluted	84,822,516	70,775,508	85,553,134	64,196,162

Daré Bioscience, Inc. and Subsidiaries
 Condensed Consolidated Balance Sheets Data

	September 30, 2022	December 31, 2021
	(unaudited)	
Cash and cash equivalents	\$ 40,389,546	\$ 51,674,087
Working capital	\$ 26,759,012	\$ 39,243,160
Total assets	\$ 50,376,432	\$ 55,807,177
Total stockholders' equity	\$ 26,343,772	\$ 38,754,321



