

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): June 3, 2019

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 x

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. x

Item 8.01 Other Events

Included as Exhibit 99.1 to this report is a presentation about Daré and its product candidates, dated June 3, 2019, which is incorporated herein by reference. Daré intends to use the presentation and its contents in various meetings with investors, securities analysts and others, commencing on June 4, 2019.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Corporate presentation, dated June 3, 2019

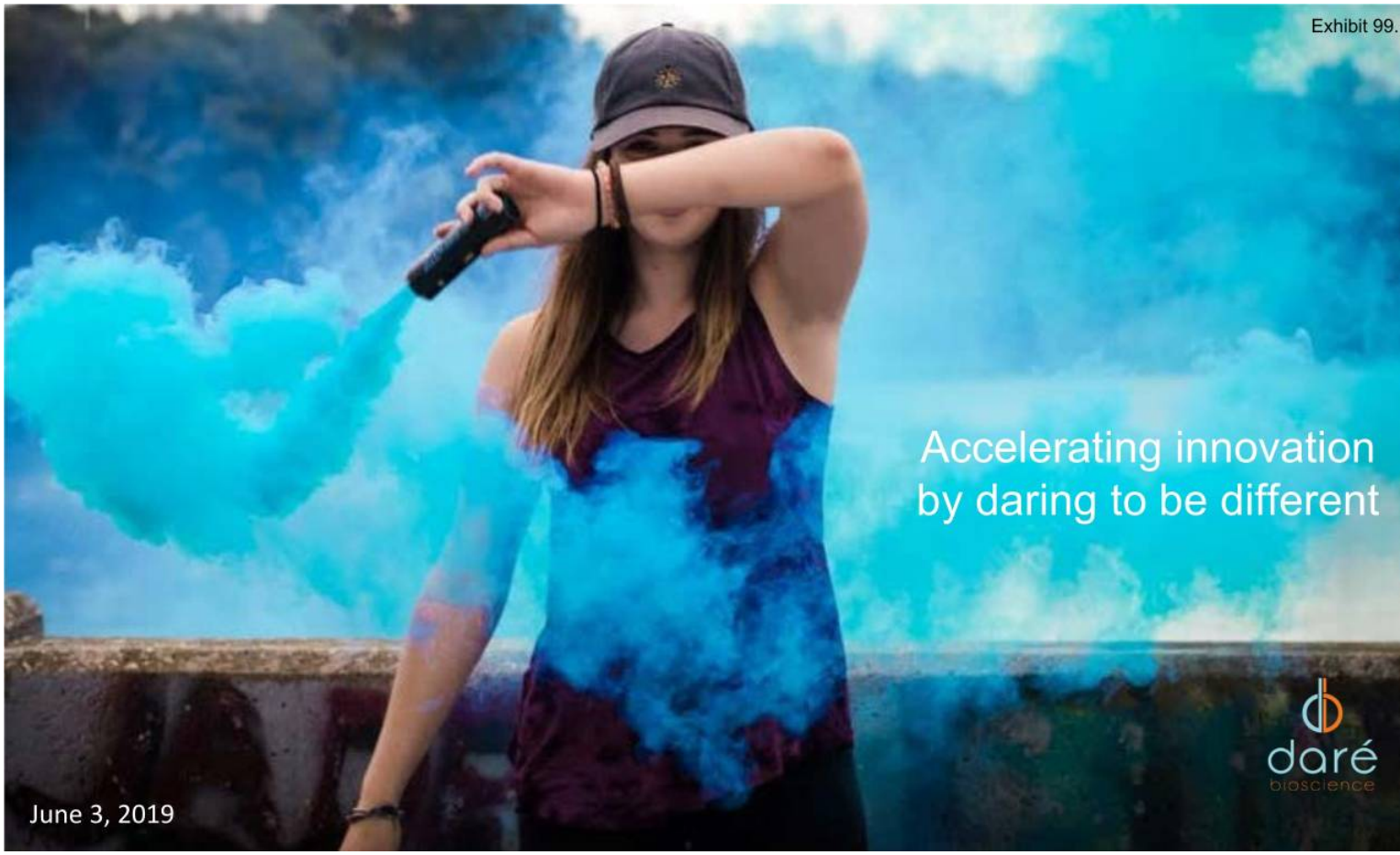
SIGNATURES

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: June 3, 2019

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



Accelerating innovation
by daring to be different



June 3, 2019

Forward Looking Statements

THIS PRESENTATION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OF DARÉ BIOSCIENCE, INC. ("DARÉ" OR THE "COMPANY"). THIS PRESENTATION INCLUDES CERTAIN INFORMATION OBTAINED FROM TRADE AND STATISTICAL SERVICES, THIRD PARTY PUBLICATIONS, AND OTHER SOURCES. DARÉ HAS NOT INDEPENDENTLY VERIFIED SUCH INFORMATION AND THERE CAN BE NO ASSURANCE AS TO ITS ACCURACY.

ALL STATEMENTS IN THIS PRESENTATION, OTHER THAN STATEMENTS OF HISTORICAL FACT, ARE FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF FEDERAL SECURITIES LAWS. IN SOME CASES, YOU CAN IDENTIFY FORWARD-LOOKING STATEMENTS BY TERMS SUCH AS "MAY," "WILL," "EXPECT," "PLAN," "ANTICIPATE," "STRATEGY," "DESIGNED," "COULD," "INTEND," "BELIEVE," "ESTIMATE," "TARGET," OR "POTENTIAL" AND OTHER SIMILAR EXPRESSIONS, OR THE NEGATIVE OF THESE TERMS. AS USED IN THIS PRESENTATION, "FIRST-IN-CATEGORY" IS A FORWARD-LOOKING STATEMENT REGARDING MARKET POTENTIAL OF A PRODUCT CANDIDATE. FORWARD-LOOKING STATEMENTS INVOLVE RISKS, UNCERTAINTIES AND ASSUMPTIONS THAT MAY CAUSE DARÉ'S ACTUAL RESULTS, PERFORMANCE OR ACHIEVEMENTS TO BE MATERIALLY DIFFERENT FROM THOSE EXPRESSED OR IMPLIED BY THE FORWARD-LOOKING STATEMENTS, INCLUDING, WITHOUT LIMITATION RISKS AND UNCERTAINTIES RELATING TO: THE OUTCOME OR SUCCESS OF CLINICAL TRIALS; DARÉ'S ABILITY TO RAISE ADDITIONAL CAPITAL AS NEEDED; DARÉ'S ABILITY TO OBTAIN AND MAINTAIN INTELLECTUAL PROPERTY PROTECTION FOR ITS PRODUCT CANDIDATES; DARÉ'S ABILITY TO DEVELOP PRODUCT CANDIDATES ON THE TIMELINES SET FORTH HEREIN; AND OTHER RISK FACTORS DESCRIBED IN DARÉ'S MOST RECENT ANNUAL REPORT ON FORM 10-K AND QUARTERLY REPORT ON FORM 10-Q FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

ALL FORWARD-LOOKING STATEMENTS IN THIS PRESENTATION ARE CURRENT ONLY AS OF THE DATE HEREOF AND DARÉ DOES NOT UNDERTAKE ANY OBLIGATION TO UPDATE ANY FORWARD-LOOKING STATEMENT TO REFLECT NEW INFORMATION, FUTURE DEVELOPMENTS OR OTHERWISE, EXCEPT AS REQUIRED BY LAW.

Vision: To become the premier innovation accelerator in women's health.

Mission: We achieve this by identifying, unlocking and advancing candidates with potential to be first-in-category, address persistent unmet needs, and promote a better quality of life for women.

Daring to be different

- A pure play biopharmaceutical company focused on improving the health and well being of women. Our focus areas include:
 - Contraception / Pregnancy Prevention
 - Sexual Health
 - Vaginal Health
 - Fertility
- Partnering is core to our licensing and value creation strategy:
 - Product candidates that are commercially viable and attractive to strategic partners
 - Candidates that have a data package including a proof-of-concept and/or the ability to leverage a 505(b)(2) regulatory pathway
 - Candidates with the potential to be first-in-category that address persistent unmet needs in women's health
 - The ability to deliver products in a more personalized way for women



Bio-Adhesive Gel Clindamycin	DARE-BV1 [^]	Phase 3 Initiation 4Q 2019	Potential First-line Option for BV
Barrier IVR Ferrous gluconate	Ovaprene [®] (PCT)* <small>CDRH / Device Lead</small>	Top line 2H 2019	First-in-category Non-Hormonal, Monthly Contraception
Topical Cream Sildenafil	Sildenafil Cream, 3.6% [^]	Top line 4Q 2020	First-in-category for Treatment of Female Sexual Arousal Disorder
IVR Bio-identical Estradiol + Bio-identical progesterone	DARE-HRT1 [†]		First-in-category Sustained-Release Hormone Replacement Therapy
Vaginal Insert SERM (tamoxifen)	DARE-VVA1 [^]		First-in-category Treatment for VVA for ER/PR+ Breast Cancer Patients
IVR Bio-identical progesterone	DARE-FRT1 [^]		First-in-category Sustained Release Progesterone for Pregnancy Maintenance
Injectable Etonogestrel	ORB 204/214 [^]		First-in-category 6 & 12 Month Injectable Contraception
Ca2+ Target	DARE-RH1		First-in-category Male or Female Contraceptive Target

Accelerating early-stage clinical programs with collaborations and non-dilutive funding whenever possible

Timeline reflects management's current estimates and constitutes a forward looking statement subject to qualifications elsewhere in the presentation. Actual development timeline may be substantially longer, and Daré is under obligation to update or review this estimate. "First-in-category" designations are forward looking statements based on currently available, FDA approved therapies.



DARE-BV1
Clindamycin 2% gel for Bacterial Vaginosis



DARE-BV1 Overview

Bacterial Vaginosis (BV)

Successful Proof of Concept

- Vaginal application of DARE-BV1 (clindamycin phosphate 2%) demonstrated effectiveness against BV in a proof-of-concept investigator initiated study in women (n=30):¹
- 86% of evaluable subjects met clinical cure endpoint at Test-of-Cure visit after single dose administered
- Favorable efficacy profile over currently approved treatments

505(b)(2) Regulatory Pathway

- Single Phase 3 clinical trial planned for FDA approval

Attractive Market Opportunity

- BV is the most common vaginal infection in women ages 15-44 ²
- U.S. prevalence estimated to be ~21 million among women ages 14-49 ²
- Approved prescription drugs have less than optimal clinical cure rates (37-68%) ³
- Opportunity for significant upside and market expansion

Patent Coverage

- Patents covering the licensed technology have been granted with terms through 2028
- Additional patents pending would have terms through 2035

1. Data on file

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

3. BV Product Data: <http://www.clindesse.com/pdf/PI.pdf>; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf



Contraception

Expected to be a \$33 billion global category by 2023¹



1. Global Market Insights, <https://globenewswire.com/news-release/2016/05/19/841462/0/en/Contraceptives-Market-size-to-exceed-33-Billion-by-2023-Global-Market-Insights-Inc.html>

Ovaprene[®] Overview

New Contraceptive Option

Successful Proof of Concept Study

- Ovaprene demonstrated effectiveness in preventing sperm from entering the cervical canal in a proof-of-concept study in women (n=20):¹
 - No viable sperm in the cervical mucus
 - No colposcopic abnormalities

CDRH (Device) Regulatory Pathway

- Single pivotal clinical trial expected for FDA approval

Attractive Market Opportunity

- >\$6 billion in US Rx sales of contraceptive products (2016).²
- 40 million women of reproductive age currently use a contraceptive method.³

Patent Coverage

- Patents covering the licensed technology have been granted with terms through 3Q 2028
- Opportunity for Patent Term Extension (PTE) and potential new patents

1. Journal of Reproductive Medicine 2009; 54: 685-690
2. IMS NSP through Dec 2016
3. www.guttmacher.org, contraceptive fact sheet



Women's Sexual Health & Wellness Female Sexual Arousal Disorder (FSAD)

World market for both male and female sexual dysfunction drugs will reach 7.7 billion in 2019¹



1. <https://www.visiongain.com/sexual-dysfunction-drugs-market-will-reach-7-7bn-in-2019-predicts-a-new-visiongain-study/>

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream, 3.6%

Successful Proof of Concept

- Sildenafil Cream, 3.6% improved genital blood flow in a proof-of-concept study (n=31):¹
 - Efficacy signal observed in both pre and postmenopausal patients
 - Excellent systemic/local safety and tolerability profile

505(b)(2) Regulatory Pathway

- Ability to leverage the safety profile of sildenafil (Viagra[®]) for FDA submission package

Attractive Market Opportunity²

- 33% of females in the U.S. (21 to 60 years old) experience symptoms of low or no sexual arousal
- 16% (~10m women) are considered distressed and are seeking a solution to improve their condition

Patent Coverage

- Patents covering the licensed technology have been granted with terms through 2031 (through June 2029 in the U.S.)
- No ANDA route: ANDA is not currently an option for topicals that result in low systemic uptake

1. Data on file

2. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC. Based on US Census projections for 2016.

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream, 3.6%

Dyspareunia

Vulvar-Vaginal
Atrophy

Hypoactive Sexual
Desire Disorder
(HSDD)

Female Sexual
Arousal Disorder
(FSAD)

 **Intrarosa**
Prasterone USP, 6.5 mg

ESTRACE CREAM
(estradiol vaginal cream, USP, 0.01%)

addyi
(flibanserin)

No Approved
Products

 **Invexxy**
(estradiol vaginal insert)

 **Osphena**
(ospemifene) tablets
60mg

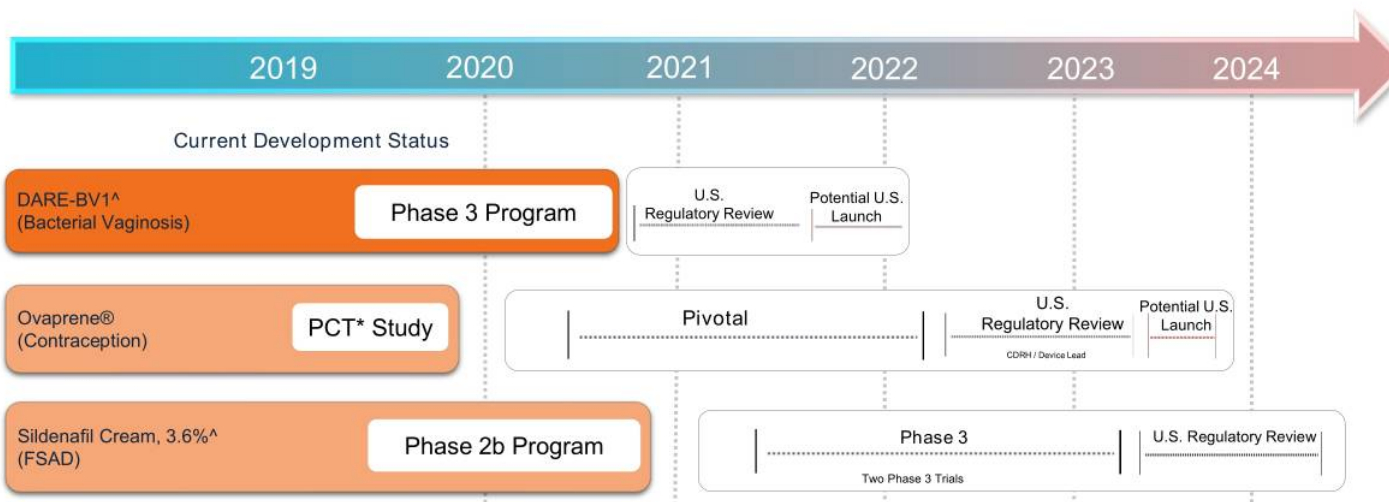
 **Premarin**
(conjugated estrogens)
vaginal cream

With its approval of Addyi®, FDA has now acknowledged and formally classified the distinct and separate disorders that comprise Female Sexual Dysfunction.

Where HSDD is characterized primarily by a lack of sexual desire, FSAD is characterized primarily by an inability to attain or maintain sufficient physical sexual arousal.

- INTRAROSA is a registered trademark of Endoceutics, Inc.
- Invexxy is a trademark of TherapeuticsMD, Inc.
- Osphena is a registered trademark of Duchesnay USA, Pennsylvania, USA.
- ESTRACE® is a registered trademark of Allergan Pharmaceuticals International Limited.
- Premarin is a registered trademark of Pfizer Inc.
- Addyi is a registered trademark of Sprout Pharmaceuticals, Inc.

Portfolio Timeline Overview



Timeline reflects management's current estimates and constitutes a forward looking statement subject to qualifications elsewhere in the presentation. Actual development timeline may be substantially longer, and Daré is under no obligation to update or review this estimate.

[^]505(b)(2) regulatory pathway anticipated.

*Ovaprene Post Coital Test (PCT) is a pre-pivotal clinical study.

Corporate & Investor Communications

NASDAQ: DARE
Trading as DARE since July 20, 2017



www.darebioscience.com

