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 2, 2019

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.)

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**

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))

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 October 2, 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 October 2, 2019.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate presentation, dated October 2, 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.

Date: October 2, 2019

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

To become the coordinating presence in women's health. We achieve this by identifying, unlocking and advancing innovation that improves health outcomes and promotes a better quality of life for women.

DARÉ

IN ITALIAN, IT MEANS " **TO GIVE.**"
IN ENGLISH, IT MEANS " **TO BE BOLD.**"

To us, Daré means to give women novel treatment options by **boldly addressing existing therapeutic gaps**. And that's exactly our mission.

October 1, 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.

WE ARE **ACCELERATING INNOVATION** IN WOMEN'S HEALTH

We're driven by a mission to accelerate a diverse portfolio of novel therapies for women that **expand treatment options, improve outcomes and facilitate convenience.**

With clinical trials underway, our initial **focus areas include contraception, fertility, and sexual and vaginal health.**

Partnering is key to our value creation strategy. We in-license products that meet a strict profile and drive commercial optionality (launch, partner or co-promote):

- 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

ADVANCING PRODUCTS **WOMEN WANT**

	Pre-Clinical	Phase 1	Phase 2	Phase 3	Regulatory Filing
Bio-Adhesive Gel Clindamycin	DARE-BV1^			Phase 3 Initiation 4Q 2019	Potential First-line Option for Bacterial Vaginc
Barrier IVR Ferrous gluconate	Ovaprene® (PCT)* CDRH / Device Lead			Top line 4Q 2019	First-in-category Hormone-Free, Monthly Contraceptive
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 no obligation to update or review this estimate. "First-in-category" designations are forward looking statements based on currently available, FDA approved therapies.

^505(b)(2) regulatory pathway anticipated.
*Ovaprene Post Coital Test (PCT) is a pre-pivotal clinical study.
‡HRT Phase 1 study to be conducted in Australia by Daré subsidiary.

MOVE THE FIELD FORWARD

EXECUTIVE MANAGEMENT TEAM

Sabrina Martucci Johnson MSc, MIM
President & CEO

David Friend, PhD
Chief Scientific Officer

Lisa Walters-Hoffert
Chief Financial Officer

Mark Walters
Vice President of Operations

Mary Jarosz, RPh, RAC, FTOPRA
Global Head of Regulatory Affairs

Christine Mauck, MD, MPH
Medical Director

John Fair
Chief Business Development Officer

BOARD OF DIRECTORS

William Rastetter, PhD
Chairman

Jessica Grossman, MD

Susan Kelley, MD

Greg Matz

Robin Steele, JD, LLM

Sabrina Martucci Johnson
President & CEO

DARE-BV1 (Formerly MP-101)

Clindamycin 2% gel for Bacterial Vaginosis

DARE-BV1 Overview

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

- QIDP Designation
  - Five-year exclusivity extension added to any exclusivity for which a QIDP qualifies upon FDA approval.
  - Eligible for Fast Track designation and Priority Review.
- 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

DARE-BV1 Proof of Concept - Trial Design

Study Objective: Study the Efficacy and Safety of DARE-BV1 in the Treatment of Bacterial Vaginosis (n = 30)*

Day 1 Baseline Visit	Day 7 - 14 Test-of-Cure Visit	Day 21 - 30 Continued Clinical Response Visit
• Single dose administered	• Patients questioned regarding comfort level & re-examined	• Patients questioned regarding experience & re-examined
Tests Performed: • Physiological symptoms • pH • Saline "wet mount" • 10% KOH "whiff test" • Urine pregnancy (if needed)	Tests Performed: • Physiological symptoms • pH • Saline "wet mount" • 10% KOH "whiff test" • Urine pregnancy (if needed)	Tests Performed: • Physiological symptoms • pH • Saline "wet mount" • 10% KOH "whiff test" • Urine pregnancy (if needed)

- Eligibility: Female subjects 18 years or older with confirmed clinical diagnosis of BV
- Primary Endpoint: Clinical Cure at Test-of-Cure visit (defined as resolution of clinical findings from baseline visit);
- Secondary Endpoints: Proportion of patients with therapeutic and bacteriologic cures,[1,2]
- Safety: Patients were questioned about their comfort level and adverse reactions they experienced.

*Investigator Initiated Proof of Principle Study Design

1. Therapeutic cure was a composite endpoint, which required both clinical cure (defined as resolution of all 4 Amsel criteria) and bacteriologic cure (Nugent score < 4). Bacteriologic cure required a Nugent score < 4.
2. Amsel & Gram Stain Criteria: https://www.cdc.gov/std/tg2015/bv.htm

OUR PIPELINE: DARE-BV1

DARE-BV1 Proof of Concept - Trial Results

A single dose of DARE-BV1 demonstrated **high clinical cure rate** compared to other approved products

Product	Clinical (Amsel) Cure	Bacteriologic (Nugent) Cure	Therapeutic Cure
DARE-BV1 novel gel (clindamycin)	**86%**	**57%***	**57%***
Solesec®[1] (secnidazole 2g oral granules)	53-68%	40-46%	35-40%
Clindesse®[2] clindamycin phosphate Vaginal Cream, 2%	41-64%	45-57%	30-42%
Metrogel, 1.3% [3]	37%	20%	17%

* Based on data from 9 evaluable patients

- 28 of 30 women completed the study
- Test-of-Cure Visit (Day 7 – 14)
  - 24 of 28 (86%) women achieved clinical cure based on Amsel criteria
  - 4 of 7 (57%) women had bacteriologic cure and 4 of 7 (57%) had therapeutic cure
- Continued clinical response visit (Day 21 – 30)
  - 22 of 24 (92%) women showed continued clinical cure
  - 7 of 9 women had bacteriologic cure and 6 of 9 had therapeutic cure

1. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=551e43d5-f700-4d6e-8029-026f8a8932ff&type=display. Cure rate range reflects low and high cure rates across multiple studies.
2. http://www.clindesse.com/pdf/PI.pdf. Cure rate range reflects low and high cure rates across multiple studies
3. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf

OUR PIPELINE: DARE-BV1

DARE-BV1-001: Phase 3 Pivotal Study

(Data Required for NDA Filing & FDA Approval)

Study Design:
- N = 250 (age 12 and above)
- Duration = ~30 days per subject
- Diagnosis = Bacterial vaginosis

Study Objective:
- Primary endpoint – assess Clinical Cure at Day 21-30 Visit. Clinical Cure is defined as:
  - Return to normal physiological discharge as confirmed by the investigator;
  - Negative 10% KOH "whiff test";
  - Clue cells < 20% of the total epithelial cells in the saline wet mount.
- Secondary endpoints
  - Proportion of subjects with Clinical Cure at Day 7-14 Visit
  - Proportion of subjects with Bacteriological Cure at Day 7-14 and Day 21-30 Visits. Bacteriological Cure is defined as a Nugent score < 4.
  - Proportion of subjects with Therapeutic Cure at Day 7-14 and Day 21-30 Visits. Therapeutic Cure is defined as both a Clinical Cure and Bacteriological Cure.
- Any subject who fails to meet the Clinical Cure criteria at the Day 7-14 or Day 21-30 Visits will be offered metronidazole vaginal gel (rescue medication).

DARE-BV1-002: Extension Study

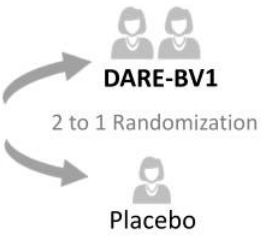
(Value Added Data for Publication & Market Acce

Study Design:
- N = 219
- Duration = 60 days (post DARE-BV1-001)

Study Objective:
- Subjects who meet response criteria at the Day 21-30 DARE-BV1-001 are allowed to enroll in the DARE-BV Extension Study unless the investigator determines th not be good candidates.
- In the Extension Study, subjects enrolled will receive additional treatment and will be evaluated 30 and 60 following enrollment in the DARE-BV1-002 Extension evaluate duration of response of DARE-BV1 and metr vaginal gel (rescue medication).

Day 1
Baseline Visit

Tests Performed:
- Signs & symptoms
- pH
- Saline "wet mount"
- 10% KOH "whiff test"



Day 7 – 14
Secondary Endpoint
(Test-of-Cure Visit)

Tests Performed:
- Signs & symptoms
- pH
- Saline "wet mount"
- 10% KOH "whiff test"
- Nugent score

Day 21 – 30
Primary Endpoint
(Test-of-Cure Visit)

Tests Performed:
- Signs & symptoms
- pH
- Saline "wet mount"
- 10% KOH "whiff test"
- Nugent score

Day 60
(Test-of-Cure Visit)

BV-Free Patients
(regardless of treatment or rescue medication)

Day 90
(Test-of Visit)

Ovaprene®

Hormone-Free, Monthly Contraceptive

The global contraceptive category is expected to reach $33 billion by 2023[1]

1. https://www.globenewswire.com/news-release/2017/04/06/955073/0/en/Contraceptives-Market-worth-33bn-by-2023-Global-Market-Insights-Inc.html

MOVE THE FIELD FORWARD

Advances in hormone products have largely focused on reducing the hormone dosage, adjusting or extending the duration of protection and optimizing methods of administration.

Reduction of hormones and convenient product forms are driving new innovation

- Lo Loestrin®
  - Pregnancy prevention with the lowest amount of daily estrogen (10 micrograms) available.
  - 2018 US sales: $527 million (Allergan)[1]
- NuvaRing®
  - Monthly, convenient vaginal ring product form.
  - 2018 worldwide sales: $902 million (Merck)[2]
- Mirena® Product Family
  - Physician inserted, long-acting.
  - Low/locally delivered hormone IUS.
  - 2018 worldwide sales: $1.14 billion (Bayer)[3]

1. https://www.allergan.com/investors/news/thomson-reuters/allergan-reports-fourth-quarter-and-full-year-2018
2. https://investors.merck.com/news/press-release-details/2019/Merck-Announces-Fourth-Quarter-and-Full-Year-2018-Financial-Results/default.aspx
3. https://www.bayer.com/en/bayer-annual-report-2018.pdfx. Includes sales for Mirena®, Kyleena® and Jaydess® / Skyla®

Women's Preferences

1. Effective Pregnancy Prevention
2. Convenient Product Forms
   - Independent surveys revealed that the vaginal ring has many of the features women deemed extremely important.[1]
3. Method Mix
   - >70% of women who practice contraception currently use non-coital (not in the moment) methods.[2]
4. Less Hormones
   - A majority of women prefer a monthly option with a lower hormone dose than the pill.[3]

CONTRACEPTIVE METHOD CHOICE

Most effective method used in the past month by U.S. women, 2014

METHOD	No. of women	% of women aged 15–44	% of women at risk of unintended pregnancy	% c contrac use
Pill	9,572,477	15.6	22.7	25
Tubal (female) sterilization	8,225,149	13.4	19.5	2
Male condom	5,496,905	8.9	13.0	14
IUD	4,452,344	7.2	10.6	1
Vasectomy (male sterilization)	2,441,043	4.0	5.8	6
Withdrawal	3,042,724	5.0	7.2	8
Injectable	1,481,902	2.4	3.5	3
Vaginal ring	905,896	1.5	2.1	2
Fertility awareness-based methods	832,216	1.3	2.0	2
Implant	965,539	1.6	2.3	2
Patch	69,106	0.1	0.2	0
Emergency contraception	69,967	0.1	0.2	0
Other methods*	234,959	0.4	0.6	0
No method, at risk of unintended pregnancy	4,408,474	7.2	10.5	
No method, not at risk	19,302,067	31.4	na	
Total	61,491,766	100.0	100.0	100

*Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream and other methods. NOTE: refers to women who are sexually active; not pregnant, seeking to become pregnant or postpartum; and not noncontra sterile. na=not applicable.

www.guttmache

1. Lessard, L,Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012
2. https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states
3. Hooper, DJ. Clin Drug Investig. 2010;30(11):74963

MOVE THE FIELD FORWARD

Missing from the product mix are monthly, hormone-free alternatives that are effective and easy to us

Least Effective Methods

[1,2]

Method	Perfect Use	Typical Use
Spermicide* / Vaginal Gels	82.00%	72.00%
Sponge-Parous*	80.00%	76.00%
Sponge-Nulliparous*	91.00%	88.00%
Condom (male)*	98.00%	82.00%
Diaphragm*	94.00%	88.00%
Combined Pill & Progestin only*	99.70%	91.00%
Evra Patch*	99.70%	91.00%
Nuva Ring*	99.70%	91.00%
Depo-Provera*	99.80%	94.00%
IUD- ParaGard (Copper T)*	99.40%	99.80%
IUD- Mirena (LNg)*	99.80%	99.80%
Implanon*	99.95%	99.95%
Female Sterilization*	99.50%	99.50%
Male Sterilization*	99.90%	98.85%

100% Effective = 0% Risk of Pregnancy

Most Effective Methods

Hormone Free Product Landscape[1]

Marketed or in development

Spermicides / Vaginal Gels
- Effectiveness (72% Typical Use)
- Woman controlled
- Used "in the moment"

Condoms
- Effectiveness (82% Typical Use)
- Not woman controlled
- Used "in the moment"

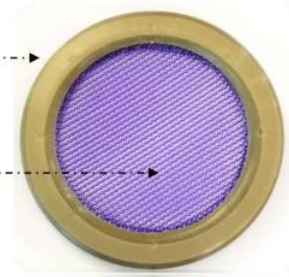
Diaphragms
- Effectiveness (88% Typical Use)
- Woman controlled
- Used "in the moment"

Long-acting IUD
- Effectiveness (99% Typical Use)
- Not woman controlled
- Physician inserted

1. Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.
2. http://www.contraceptivetechnology.org/wp-content/uploads/2013/09/CTFailureTable.pdf

OUR PIPELINE: OVAPRENE®

Ovaprene® Hormone-Free, Monthly Vaginal Contraceptive



Spermiostatic Environment[1]

- Achieved through a contraceptive-loaded silicone ring
- Releasing non-hormonal active Ferrous gluconate.

Physical Barrier[1]

- 3-D, knitted polymer barrier.

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

Ovaprene successfully prevented sperm from reaching the cervical canal in a previous human postcoital test (PCT) clinical study.

- 2009 - Postcoital Assessment:[1]
  - Open-label, single-arm, pilot safety and tolerability study.
  - Published in the Journal of Reproductive Medicine, 2009.
- Patients:
  - N= 20; all women completed one cycle of use.
- Results:
  - Postcoital testing revealed no viable sperm in the cervical mucus.
  - No colposcopic abnormalities, no significant changes in vaginal flora and no serious adverse effects observed.

Birth Control Effectiveness

Method	Perfect Use	Typical
Spermicide* / vaginal gels	82.00%	72.00
Sponge-Parous*	80.00%	76.00
Sponge-Nulliparous*	91.00%	88.00
Condom (male)*	98.00%	82.00
Diaphragm*	94.00%	88.00
Combined Pill & Progestin only*	99.70%	91.00
Evra Patch*	99.70%	91.00
Nuva Ring*	99.70%	91.00
Depo-Provera*	99.80%	94.00
IUD- ParaGard (Copper T)*	99.40%	99.80
IUD- Mirena (LNg)*	99.80%	99.80
Implanon*	99.95%	99.95
Female Sterilization*	99.50%	99.50
Male Sterilization*	99.90%	98.85

In PCT studies of similar size, products (diaphragms) with no motile sperm in the cervical mucus during their PCT assessments demonstrated “typical use” contraceptive effectiveness of 88% in pivotal contraceptive studies evaluating pregnancy rates over time.

1. Journal of Reproductive Medicine 2009; 54: 685-690
2. Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.
3. http://www.contraceptivetechnology.org/wp-content/uploads/2013/09/CTFailureTable.pdf

OUR PIPELINE: OVAPRENE®

U.S. Regulatory Strategy

- PMA with CDRH (Medical Device Division) as lead review division.
- Pathway expected to be based on similar CDRH approvals - Example: Caya® diaphragm.*

Step 1 – Postcoital test (PCT)*

- Patient recruitment completed 2Q 2019.
  - ~25 women to complete a total of 21 visits
- Evaluated over the course of five menstrual cycles.
- Each woman's cervical mucus will be examined at several points during the study:
  - Cycle 1 - Baseline (excludes the use of any product),
  - Cycle 2 - Use of a barrier method (diaphragm),
  - Cycles 3,4 and 5 - Ovaprene vaginal ring.
- Assess progressively motile sperm (PMS) per high powered field (HPF) in the cervical mucus, post coitus (primary endpoint <5 PMS per HPF).
- Safety assessments, PK, acceptability, fit, and ease of use.

- **Data from the study is expected to be available in 4Q 2019.**
  - If the PCT clinical trial demonstrates <5 PMS / HPF in the cervical mucus in most women and that Ovaprene can be safely worn over multiple weeks, the Company intends to prepare and file an Investigational Device Exemption (IDE) with the FDA to commence a pivotal clinical trial to support marketing approvals of Ovaprene in the United States, Europe and other countries worldwide.

Step 2 – Pivotal Study*

- Single pivotal clinical (expected).
- N= ~250 completers over 6 months of use.
  - Primary Endpoints: Safety & Efficacy
    - Pregnancy probability.
  - Secondary Endpoints:
    - Acceptability/product fit/ease of us
    - Assessments of vaginal health.

*Anticipated regulatory pathway and timelines. Daré has not had any communications with the FDA regarding the specific PMA requirements for Ovaprene.

OUR PIPELINE: OVAPRENE®

Features Desired Most in Birth Control:[1-4]	Design Features of Ovaprene:[5,6]
+ Convenience (Easy to Use & Easy to Remember)	Monthly Ring Product Form Women chose monthly rings for the convenience of a non-daily option.
+ Hormone Free	No Hormones in the API Unique dual action MOA (spermiostatic & barrier).
+ Efficacy	Expected Typical Use Effectiveness Comparable to Hormone Contraception (88% vs 91%).
+ Favorable Side Effect Profile	No Colposcopic Abnormalities No significant changes in vaginal flora. No serious adverse effects observed in prior published study.
+ Easily Manage Fertility	No Systemic Activity Inserted and removed without a provider. Immediate return to fertility.

1. https://www.urban.org/urban-wire/women-want-effective-birth-control
2. Lessard, L,Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012
3. Hooper, DJ, Clin Drug Investig. 2010;30(11):74963
4. Ersek, J, Matern Child Health J (2011) 15:497–506
5. Journal of Reproductive Medicine 2009; 54: 685-690
6. Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.

Sildenafil Cream, 3.6%

Female Sexual Arousal Disorder (FSAD)

World market for both male and female sexual dysfunction drugs will reach 7.7 billion in 201

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

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 Opportunity[2]

- 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.

OUR PIPELINE: SILDENAFIL CREAM, 3.6%

Dyspareunia	Vulvar-Vaginal Atrophy	Hypoactive Sexual Desire Disorder (HSDD)	Female Sexual Arousal Disorder (FSAD)
Imvexxy (estradiol vaginal insert) Intrarosa Prasterone 6.5 mg Osphena (ospemifene) tablets 60 mg	ESTRACE CREAM (estradiol vaginal cream, USP, 0.01%) Premarin (conjugated estrogens) vaginal cream	vyleesi addyi (flibanserin)	No Approved Products

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.

FSAD is characterized primarily by an inability to attain or maintain sufficient physical sexual arousal; it is also characterized by distress or interpersonal difficulty.*

- Estimated 23-33% of women suffer from arousal disorder:
  - Meta-analysis of 95 studies from 2000-2014 indicated the prevalence of Female Sexual Dysfunction in premenopausal women worldwide is 40.9%, and difficulty with arousal alone is 23%.[1]
  - 33% of women in the U.S. age 21 to 60 (approximately 20 million women), experience symptoms of low or no sexual arousal.[2,3]
  - 10 million women are considered distressed and actively seeking treatment.[2]

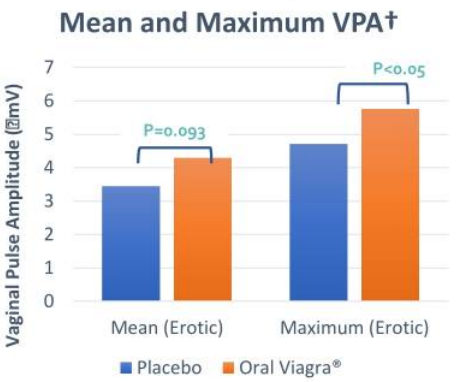
*Diagnostic and Statistical Manual 4th Edition Text Revision (DSM IV TR), defines female sexual arousal disorder as a persistent or recurrent inability to attain or to maintain until completion of the sexual activity, an adequate lubrication-swelling response of sexual excitement. The diagnostic criteria also state that the inability causes marked distress or interpersonal difficulty, is not better accounted for by another Axis I disorder (except another sexual dysfunction), and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

1. McCool et al. Sex Med Rev 2016;4:197-212.
2. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.
3. Based on US Census projections for 2016.

Increased blood flow and clinical efficacy with oral sildenafil (Viagra®) in women:

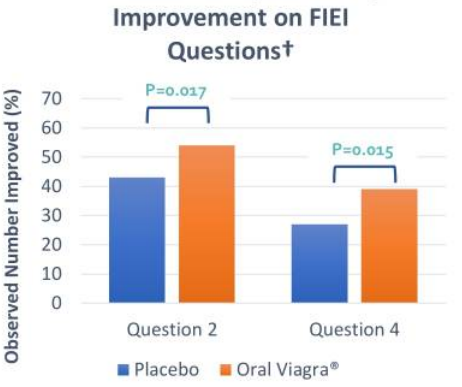
- Statistically significant increases in Vaginal Pulse Amplitude (VPA)[1]
- Statistically significant improvement in genital stimulation (FIEI)[2]

Pfizer VPA Clinical Lab Study – Oral Viagra



† Twelve healthy premenopausal women were studied.

Pfizer Clinical Field Study – Oral Viagra



Female Intervention Efficacy Index (FIEI)

† Question #2 – "After taking study medication, the sensation/feeling in my genital (vaginal, labia, clitoris) area during intercourse or stimulation (foreplay) seemed to be: (a) more than before, (b) less than before, or (c) unchanged". Question #4 – "After taking the study medication, intercourse and/or foreplay was: (a) pleasant and satisfying; better than before taking the study medication, (b) unpleasant; worse than before taking study medication, (c) unchanged; no difference, or (d) pleasant; but still not like it used to be or I would like it to be." 202 postmenopausal women with FSAD who had protocol specified estradiol and free testosterone concentrations, and/or were receiving estrogen and/or androgen replacement therapy were studied.

Key Takeaways of Viagra s

- Oral sildenafil (same active Viagra) demonstrated statis significant activity
- Side effects of the oral form led to the investigation of a topical route of administr

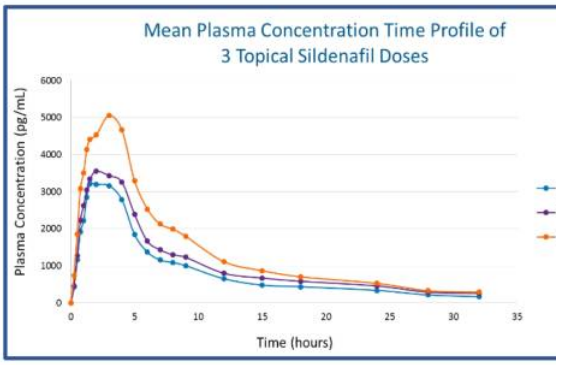
1. The Enhancement of Vaginal Vasocongestion by Sildenafil in Healthy Premenopausal Women. Journal of Women's Health & Gender-Based Medicine. Vol. 11, No. 4. 2002
2. Safety and Efficacy of Sildenafil Citrate for the Treatment of FSAD: A Double-Blind, Placebo Controlled Study. The Journal of Urology. Vol 170, 2333-2338, December 2003.

OUR PIPELINE: SILDENAFIL CREAM, 3.6%

Phase 1 Study of SST-6007 (Sildenafil Cream, 3.6%)[1]

- Normal healthy postmenopausal women were dosed with escalating doses of Sildenafil Cream, 3.6%, using a cross-over study design.
- Topical sildenafil had significantly lower systemic exposure compared to a 50 mg oral sildenafil dose
  - AUC – 3-6%
  - C_{max} – 1-2%
- Safe and very well tolerated at clinically relevant doses (1-2g)
- Favorable product characteristics as self reported by subjects
  - Easy to use
  - Readily absorbed

Treatment	N	Sildenafil Single Dose	C_{max} (ng/ml)	T_{max} (hr)	A (h
Topical Sildenafil 1 g of cream	20	35 mg	3.4	2.37	
Topical Sildenafil 2 g of cream	20	71 mg	3.8	2.27	
Topical Sildenafil 4 g of cream	19	142 mg	5.3	2.22	



Phase 2a Study of SST-6007 (Sildenafil Cream, 3.6%)[1]

- Demonstrated increased blood flow in the genital tissue compared to placebo (mean change in VPA analysis) in 31 women (pre and postmenopausal) ~30 minutes post dosing

1. Data on file. Sildenafil Cream, 3.6% was previously known as SST-6007.

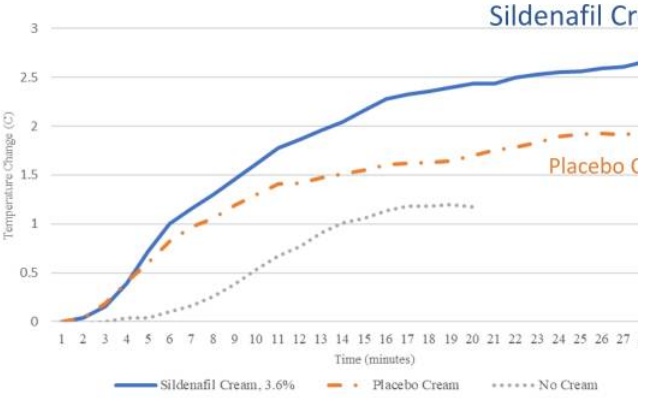
Positive Data - Thermography Study

"The results from the first six subjects to complete all assessments indicate the utility of thermography technology to detect statistically meaningful differences in genital temperature changes, a surrogate for genital blood flow, and support the ongoing evaluation of Sildenafil Cream as a treatment for FSAD."

Dr. Tuuli Kukkonen, C.Psych., an Associate Professor in the Department of Family Relations and Applied Nutrition at the University of Guelph in Ontario, Canada

- Thermography utilizes sensitive cameras capable of detecting and recording temperature variations over time.
  - Genital temperature changes are a surrogate for genital blood flow.
- Study Design & Methodology (N=6)[1]
  - This is a Phase 1, single-dose, double-blind, placebo-controlled, 2-way crossover study evaluating the feasibility of using thermography to assess the pharmacodynamics of Sildenafil Cream, 3.6% in normal healthy women.
  - The study consists of three phases, Screening Phase (Visit 1), the Double-Blind Dosing Phase (Visits 2-3) and a Safety Follow-up Phase (Phone Call).
- Findings:
  - The thermography study yielded positive findings for Sildenafil Cream, 3.6% (blue line), as shown in Figure 1.
  - Positive cognitive arousal responses were noted.
  - Significantly greater increases in genital temperature after application of Sildenafil Cream compared to placebo cream and no cream.
  - Significantly greater self-reported arousal responses reported during Sildenafil Cream visits compared to placebo cream visits.

Figure 1. Clitoral temperature change during the sexually explicit film



1. Data on file.

OUR PIPELINE: SILDENAFIL CREAM, 3.6%

Content Validity
Completed (3Q 2019)

- A content validity study is designed to help ensure the concepts we plan to measure are the most important and relevant to our target population.
- This is a non-interventional study – participants were not asked to use or evaluate any products.

Planned Type C Meeting
2019

- Type C meeting to get feedback on whether the agency agrees that the patient reported outcomes (PRO) instruments are content valid for the target population.
- Explore additional clinical and non-clinical work that might be valuable or required to support the overall program.

At Home Study
2b At Home Study Initiation Anticipated 2019
Topline Data – 4Q 2020

- The Phase 2b at-home study will allow patients to use the investigational product and placebo in their home setting.
- The FDA is agreeable to a 12-week Phase 2b for Sildenafil Cream, 3.6% to assess reasonable safety and preliminary efficacy.
- The 2016 Draft Guidance reflects expectations regarding Phase 3 study length and patient population.

Key Takeaways:

- Pending alignment with the FDA, the output of the content validity study is intended to be used as the basis for the PRO efficacy endpoint and screening criteria for the Phase 2b and Phase 3 clinical trials.

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Imvexxy (estradiol vaginal insert) Osphena (ospemifene 60mg)	Premarin (conjugated estrogens) vaginal cream	vyleesi	*Upon Approval*

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Financial Profile

NASDAQ: DARE

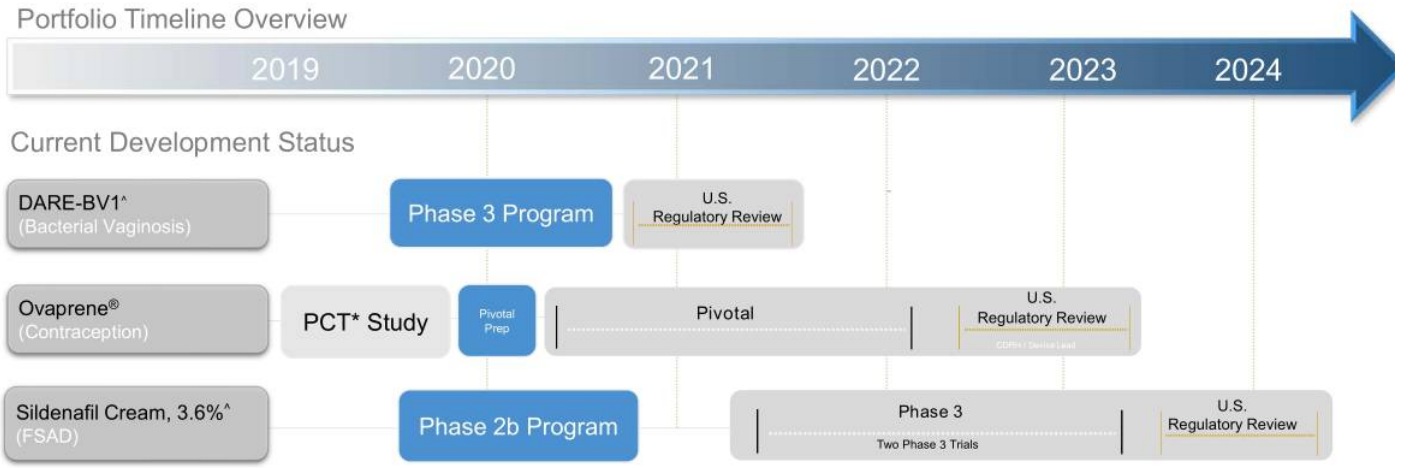
Balance Sheet, June 30, 2019:

- Cash: $5.6 million
- Common shares: 16.7 million
- Common stock warrants: 3.75 million
- No debt

March 2019: Second Notice of Award under non-dilutive NIH SBIR grant:

- Grant providing up to $1.9 million in the aggregate for Ovaprene research from the Eunice Kennedy Shriver Natio Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH). T Company received award payments totaling $224,665 in 2018.
- Second Notice of Award, for an additional $982,851, followed the NIH's review of a data analysis and other result the first phase of research supporting Ovaprene. These funds are being used to offset certain costs related to the postcoital test clinical trial.

WE ARE **ACCELERATING INNOVATION** IN WOMEN'S HEALTH



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.

darébio

NASDAQ: DARE
www.darebioscience.com