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): July 22, 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.)

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 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 July 22, 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 July 22, 2019.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate presentation, dated July 22, 2019

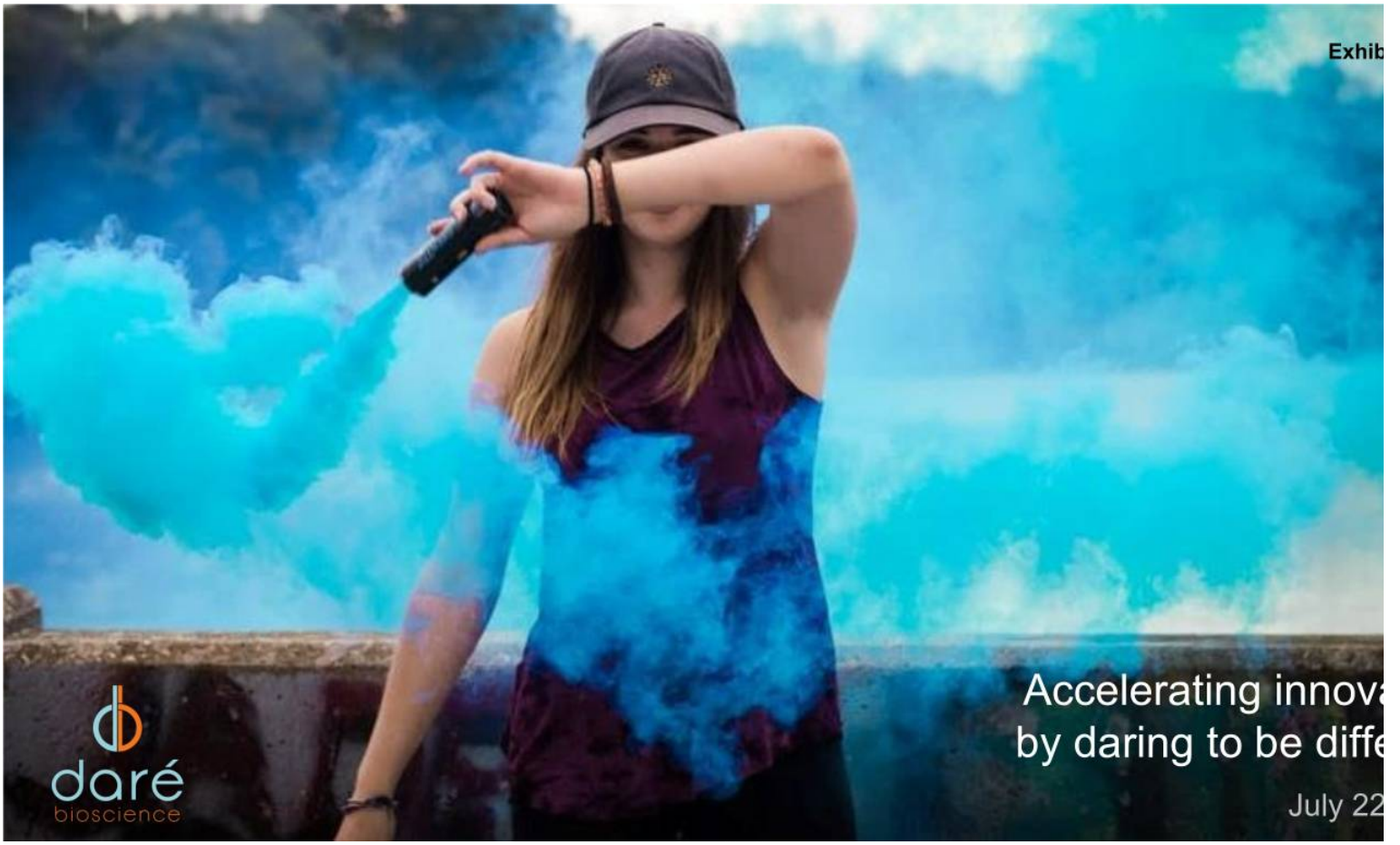
SIGNATURES

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: July 22, 2019

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


Exhib
daré
bioscience
Accelerating innova
by daring to be diffe
July 22

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.

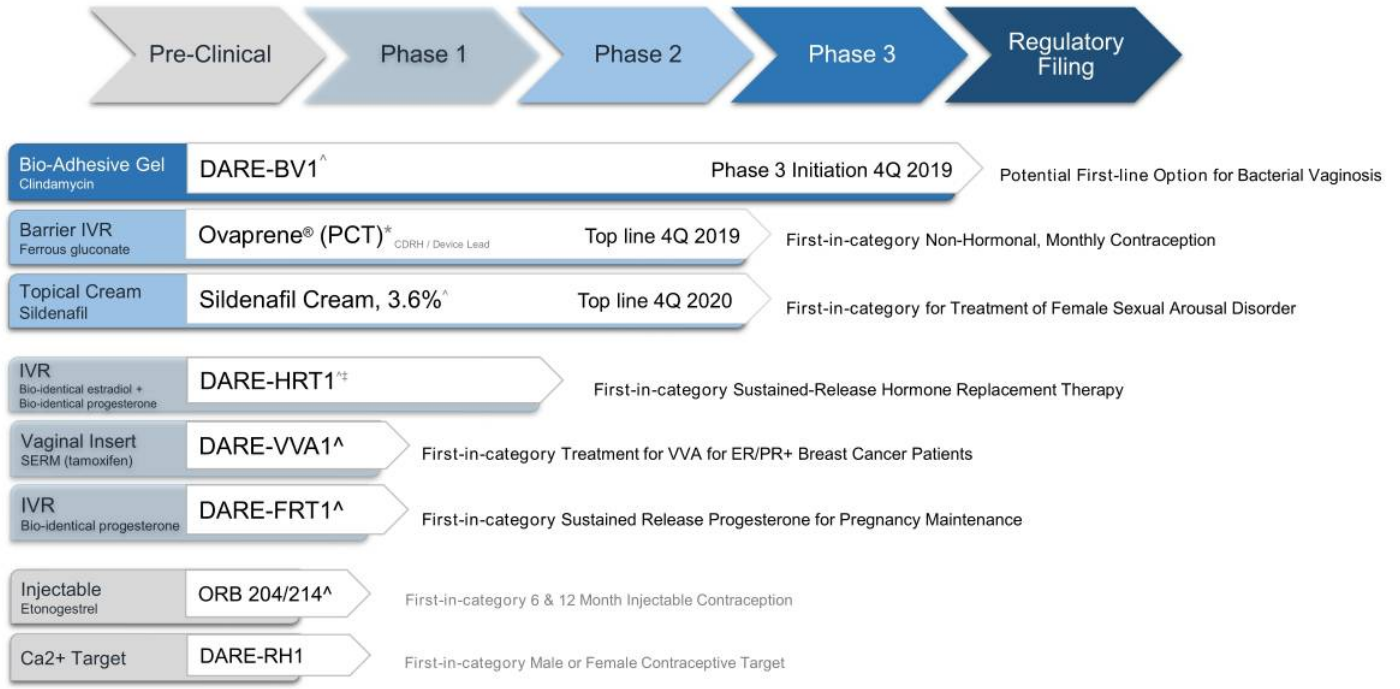
ALL FORWARD-LOOKING STATEMENTS IN THIS PRESENTATION ARE CURRENT ONLY AS OF THE DATE HEREOF AND DARÉ DOES NOT UNDERTAKE ANY OBLIGATION TO UPDATE ANY FORWARD-LOOKING STATEMENT TO REFLECT NEW INFORMATION, FUTURE DEVELOPMENTS OR OTHERWISE, EXCEPT AS REQUIRED BY LAW.

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

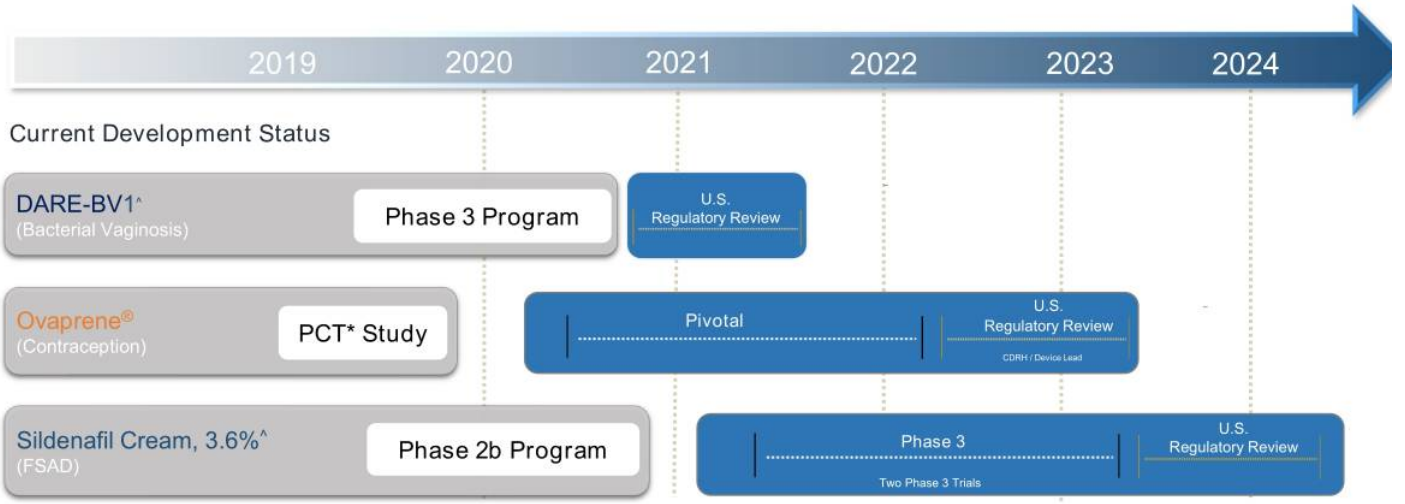


Accelerating early-stage clinical programs with collaborations and non-dilutive funding whenever possible

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 u 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.

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.
~Potential Launch Timeline


DARE-BV1 (Formerly MP-101)
Clindamycin 2% gel for Bacterial Vaginosis
daré
bioscience

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

Gel Delivery Technology

Features	Description	Innovative Product Profile
In-Situ Gelation	Undergoes solution to gel (sol-to-gel) transition using body temperature as the trigger	• Allows product to be easily and directly placed at the site of infection • Increased viscosity following application keeping the product at the site of application
Sustained-Erosion	Platform can be optimized to erode over a period of hours to multiple days	• Designed for a dual-release pattern providing maximal exposure time and amount of drug at the site of action • Allows optimization of dosing duration for clindamycin – a time dependent antibiotic
Bio-Resorption and Adhesion	Hydrophilic ingredients are compatible with a variety of APIs	• Reinforces ability of product to bio-adhere at the site of application • Eliminates need to remove product following completion of treatment regimen

Bacterial Vaginosis

DARE-BV1 Investigator Initiated Proof of Principle Study 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.

1. Therapeutic cure was a composite endpoint, which required both clinical cure (defined as clinical cure: 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

Bacterial Vaginosis

DARE-BV1 Investigator Initiated Proof of Principle Study Design

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

DARE-BV1

Bacterial Vaginosis Opportunity Overview

DARE-BV1 offers an attractive value proposition based on our belief that it has a low clinical risk profile, low development and regulatory costs, and an attractive commercial opportunity

Proof of principal study complete ○ 86% clinical cure rate in evaluable subjects ○ favorable efficacy profile compared to currently approved treatments Same API (clindamycin phosphate 2%) as in currently approved treatment	Low Clinical Risk
Single Phase 3 clinical trial for FDA approval [1] Exploiting the 505(b)2 regulatory pathway	Low Development Cost Anticipate less than $10 million (Includes manufacturing, clinical trial, regulatory filing & action)
Prevalence estimated to be ~21M among women ages 14-49 in the US Approved prescription drugs have low patient share due to limited efficacy Opportunity for upside and market expansion	Significant Market Opportunity

1. Based on prior sponsor communications with the FDA, one successful Phase 3 study with sufficient power and size may be sufficient for marketing approval in the U.S.

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

New Contraceptive Option

Ovaprene® Overview

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

New Contraceptive Option

Ovaprene® Overview

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)[5]
- NuvaRing®
  - Monthly, convenient vaginal ring product form.
  - 2018 worldwide sales: $902 million (Merck)[6]
- Mirena® Product Family
  - Physician inserted, long-acting.
  - Low/locally delivered hormone IUS.
  - 2018 worldwide sales: $1.14 billion (Bayer)[7]

New Contraceptive Option

Ovaprene® Overview

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
Pill	9,572,477	15.6	22.7
Tubal (female) sterilization	8,225,149	13.4	19.5
Male condom	5,496,905	8.9	13.0
IUD	4,452,344	7.2	10.6
Vasectomy (male sterilization)	2,441,043	4.0	5.8
Withdrawal	3,042,724	5.0	7.2
Injectable	1,481,902	2.4	3.5
Vaginal ring	905,896	1.5	2.1
Fertility awareness-based methods	832,216	1.3	2.0
Implant	965,539	1.6	2.3
Patch	69,106	0.1	0.2
Emergency contraception	69,967	0.1	0.2
Other methods*	234,959	0.4	0.6
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

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

www.guttm

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

Current Contraceptive Landscape – **what's missing?**

- Hormone-free alternatives that are <u>effective and easy to use</u>

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

New Contraceptive Option

Ovaprene® Overview

Ovaprene® Non-hormonal, Monthly Vaginal Ring

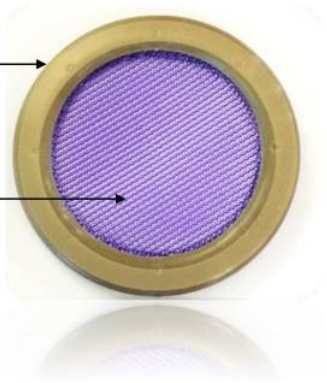
Spermiostatic Environment[1]

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

Physical Barrier[1]

- 3-D, non-braided, fluid-permeable mesh barrier.

Rx distribution (OB/GYN) – anticipated upon approval.



1. Data on file

New Contraceptive Option

Ovaprene® Overview

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	Typic
Spermicide* / vaginal gels	82.00%	72.
Sponge-Parous*	80.00%	76.
Sponge-Nulliparous*	91.00%	88.
Condom (male)*	98.00%	82.
Diaphragm*	94.00%	88.
Combined Pill & Progestin only*	99.70%	91.
Evra Patch*	99.70%	91.
Nuva Ring*	99.70%	91.
Depo-Provera*	99.80%	94.
IUD- ParaGard (Copper T)*	99.40%	99.
IUD- Mirena (LNg)*	99.80%	99.
Implanon*	99.95%	99.
Female Sterilization*	99.50%	99.
Male Sterilization*	99.90%	98.

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

New Contraceptive Option

Ovaprene® Overview

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) 2018 / 2019*

- 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 2020 / 2021*

- 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
    - 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.

New Contraceptive Option

Ovaprene® Overview

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 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.

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 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.

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream, 3.6%

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.

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream, 3.6%

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.

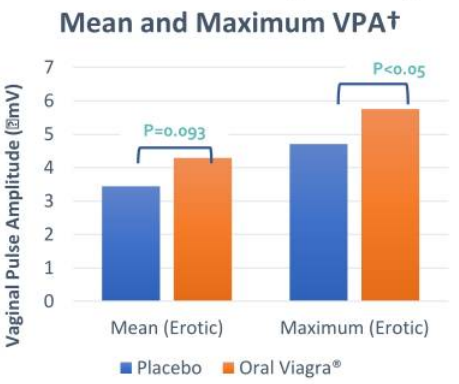
Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream, 3.6%

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

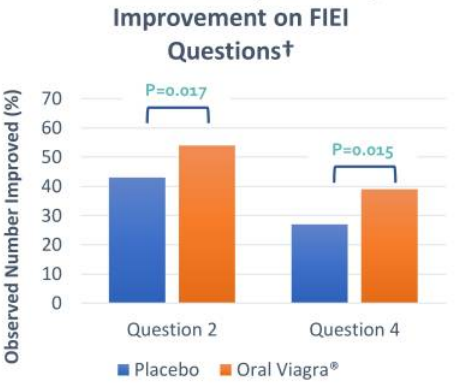
- Statistically significant increases in Vaginal Pulse Amplitude (VPA)[1]
- Statistically significant improvement in genital stimulation (FIEI)[2]

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 ac Viagra) demonstrated statistically significant a
- Side effects of the oral formulation led to the investigation of a new t route of administratio

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.

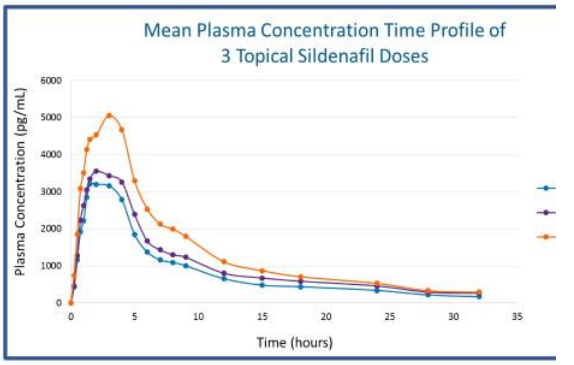
Female Sexual Arousal Disorder (FSAD)

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

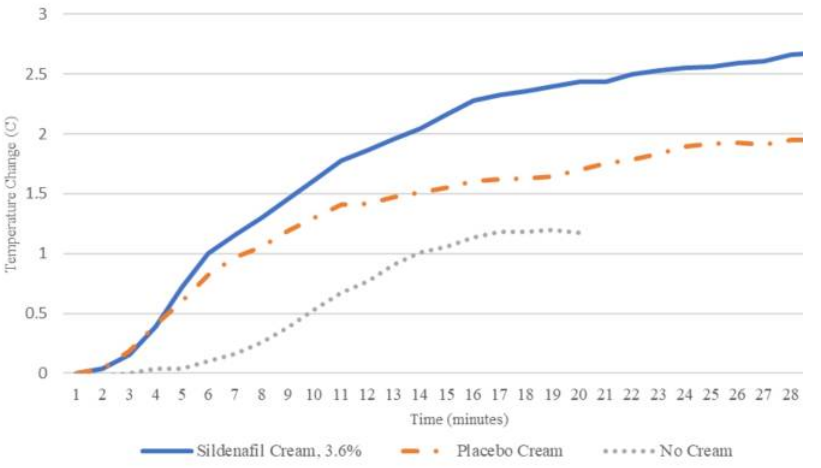
"The results from the first six subjects to complete all assessments indicate the utility of thermography technology to detect statistically meaningful differences in genital temperature changes, a surrogate for genital blood flow, and support the ongoing evaluation of Sildenafil Cream as a treatment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

1. Data on file.

Figure 1. Clitoral temperature change during the sexually explicit film



Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream, 3.6%

Phase 2b Program: Continue to explore additional clinical and non-clinical work that might be valuable or required to support the overall program and the anticipated design of the Phase 2b.

Content Validity
Initiated (4Q 2018)

- 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 will not be asked to use or evaluate any products.

Planned Type C Meeting
2019

- We will request at 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.

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:

- The Phase 2b program will consist of a content validation component (ongoing), followed by at-home dosing of the investigational product and a placebo control. The plan is to use the selected PRO instrument and FDA agreed upon endpoints for the Phase 2b and Phase 3 clinical trials.

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 6.5 mg)

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

addyi® (flibanserin)

Imvexxy® (estradiol vaginal insert)

Osphena® (ospemifene 60 mg)

Premarin® (conjugated estrogens) vaginal cream

vyleesi®

Upon Approval

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.**


Innovative Vaginal Drug Delivery
Well characterized therapeutic options
daré
bioscience

Intravaginal Ring (IVR) Technology Platform

Daré has an exclusive, global license to novel IVR technology originally developed by Dr. Robert Langer from MIT and Dr. William Crowley from Massachusetts General Hospital and Harvard Medical School that has been further developed by Juniper Pharmaceuticals. Daré's exclusive license covers all rings in development as well as additional applications of the IVR technology platform in other therapeutic areas.

- Features of the intravaginal ring technology include:
  - Sustained drug delivery
  - Variable dosing and duration
  - Single or multiple drug delivery via a solid ethylene vinyl acetate polymer matrix (without the need for a membrane or reservoir to contain the active drug or control the release)
- Current 505(b)(2) candidates licensed from Juniper include:
  - **DARE-HRT1**
    - A combination bio-identical estradiol + bio-identical progesterone ring for hormone replacement therapy
  - **DARE-FRT1**
    - A bio-identical progesterone ring for the prevention of preterm birth and for fertility support as part of an IVF treatment plan

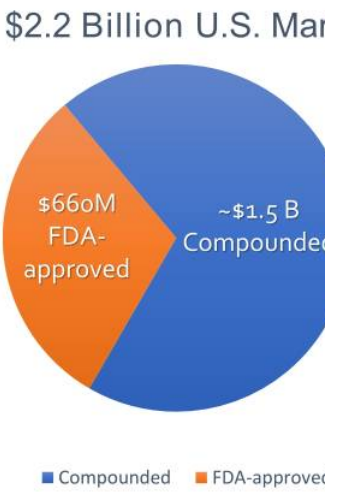
1. http://www.ibtimes.com/robert-langer-top-mit-biomedical-engineer-father-30-companies-how-launch-successful-2141263
2. https://reproendo.mgh.harvard.edu/programs/research-investigators/dr-william-crowley/

Hormone Replacement Therapy (HRT)

DARE-HRT1 (bio-identical estradiol + bio-identical progesterone)

HRT remains the most effective treatment for vasomotor symptoms (VMS) and the genitourinary syndrome of menopause (GSM) and has been shown to prevent bone loss and fracture.[1]

- 45M women in U.S. approaching or in menopause.[2]
- 2012 NAMS consensus statement supports HRT in peri- and post-menopausal women – estrogen to reduce symptoms and progesterone to prevent thickening of uterine wall.[3]
- NAMS recommends non-oral route over oral.[3]
- 2002 Women's Health Initiative (WHI) study showed that the long-term use of certain synthetic hormones (a combination of medroxyprogesterone and conjugated equine estrogens) increased the risk of breast cancer, stroke, heart attack and blood clots



1. The 2017 hormone therapy position statement of The North American Menopause Society; Menopause: The Journal of The North American Menopause Society Vol. 24, No. 7, pp. 728-753
2. U.S. Census Bureau, Population Division. Table 2. 2015 to 2060 (NP2012-T2). Released Dec. 2012.
3. Menopause, Vol. 19, No. 3, 2012.
4. U.S. 2014. Source: Symphony Health Solutions Report

Hormone Replacement Therapy (HRT)

DARE-HRT1 (bio-identical estradiol + bio-identical progesterone)

Phase 1 - HRT

DARE-HRT1 for the treatment of VMS due to menopause – combination bio-identical estradiol and progesterone in a convenient 28 day IVR

- Proposed Study:
  - A Phase 1, Open-Label, 3-arm Parallel Group Study to Evaluate the Pharmacokinetics and Safety of DARE-HRT1 (80 µg and 160 µg Estradiol/ 4 mg and 8 mg Progesterone Intravaginal Rings) in Healthy Post-Menopausal Women.
- Primary Objectives:
  - To describe the PK parameters over 28 days using two different dose combinations of DARE-HRT1 Intravaginal ring (IVR):
    - Estradiol 80 µg/Progesterone 4 mg IVR
    - Estradiol 160 µg/Progesterone 8 mg IVR
  - Identify the steady-state PK after 28 days of each DARE-HRT1
- N=30

Pregnancy Maintenance

DARE-FRT1 (bio-identical progesterone)

- Prevention of Pre-term Birth (PTB)
  - In the US, approximately 12% of pregnancies are preterm (less than 37 weeks)[1]
  - Standard interventions include steroids, hormones and tocolytic agents to stop/slow the frequency and duration of contractions[2]
- Assisted Reproductive Technologies (ART)
  - The global ART market is expected to reach **USD 45 billion by 2025**, according to a new report by Grand View Research, Inc.[3]
    - Childbearing postponement is a high impact driver of the infertility treatment market.
    - Increasing marital age, rising tobacco and alcohol consumption, and increasing obesity rates are some of the other factors contributing to the market growth.
    - Furthermore, increasing incidence rate of conditions such as poly-cystic ovarian syndrome (PCOS), tubal factors and endometriosis are other drivers of the market.
  - Record number of women using IVF to get pregnant [4]
    - More American women have had medical help to have their babies than ever, according to the latest annual report from the Society for Assisted Reproductive Technology.

1. https://www.stanfordchildrens.org/en/topic/default?id=prematurity-90-P02401
2. https://www.uptodate.com/contents/preterm-labor-beyond-the-basics
3. https://www.grandviewresearch.com/press-release/global-assisted-reproductive-technology-market
4. https://www.cnn.com/2014/02/17/health/record-ivf-use/index.html

Vaginally Delivered Tamoxifen for VVA

DARE-VVA1

Vaginally Delivered Tamoxifen to treat VVA in HR+ Breast Cancer Patients

- DARE-VVA1 (Formerly PT-101)
  - A proprietary formulation of tamoxifen for vaginal administration.
  - Potential to be the first treatment specifically approved for the treatment of vulvar and vaginal atrophy (VVA) in patients with hormone-receptor positive (HR+) breast cancer.
- VVA is a chronic condition characterized by pain during intercourse, vaginal dryness and irritation.
  - Most women use localized estrogen therapy which is contraindicated for the more than two million women diagnosed with, or at risk of recurrence of, ER-positive and PR-positive breast cancer.[1]
  - Daré intends to develop this novel local application of tamoxifen to mitigate the symptoms of VVA for patients with or at risk for hormone-receptor-positive breast cancer, including women currently on anti-cancer therapy.
  - Due to the use of aromatase inhibitors for the treatment of HR+ breast cancer, the prevalence of VVA in postmenopausal breast cancer patients is reported to be between 42 and 70 percent.[2]

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2800285/#S16title
2. Clinical Breast Cancer: https://www.sciencedirect.com/science/article/pii/S1526820917300952

Vaginal Tamoxifen – Proof of Concept Study[1]

This exploratory study in four postmenopausal women diagnosed with VVA demonstrated that a self-administered va suppository containing tamoxifen (20mg) dosed daily for one week and twice weekly for three months was effective reducing vaginal pH and vaginal dryness.

Vaginal Tamoxifen	Enrollment (Baseline)	On Treatment (Month 3)	Paired Difference (Baseline vs. Month 3)
Median Vaginal pH Lower pH value is a measure of symptom relief Normal vaginal pH is usually less than 4.5.[2]	7.1 range 6.5 to 7.5	5.0 range 5.0 to 5.2	-2.0 median range -2.5 to -1.5
Vaginal Dryness Rated using a visual analogue scale (VAS) that ranged from: 0 = Not bothered by dryness 10 = Extremely bothered by dryness Decreased vaginal dryness is a measure of symptom relief	8.0 range of 7.5 to 9.0	3.0 range 2.0 to 3.0	-5.5 median range -6.0 to -4.5

In addition, systemic absorption of tamoxifen was not significant.

- After 8 weeks of study treatment with vaginal tamoxifen, the median plasma concentration of tamoxifen was 5.8 n with a range of 1.0 to 10.0 ng/ml
- In comparison, after 3 months of administration of 20mg, once-daily oral tamoxifen citrate (Nolvadex),2 the avera steady state plasma concentration of tamoxifen is 122 ng/ml with a range of 71 to 183 ng/ml

1. Clin. Exp. Obstet. Gynecol. - ISSN: 0390-6663 XLVI, n. 2, 2019
2. https://www.medicalnewstoday.com/articles/322537.php
3. US Food and Drug Administration: "Drug Approval Package: Nolvadex (Tamoxifen Citrate) NDA# 21-109.2002". Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21109_Nolvadex.cfm


Strategic Pre-Clinical Candidates
Contraceptives that address global gaps
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A New Long Acting Contraceptive Option

Microparticle 6 & 12 Month Injectable Contraception

ORB-204 and ORB-214, injectable etonogestrel

The initial development on Orbis' long-acting injectable contraceptive program was carried out under a subcontract funded by Family Health International (FHI 360) through a grant from the Bill & Melinda Gates Foundation.

ORB-204 & 214 – a potential new injectable contraceptive that is designed to provide discreet, non-invasive, longer-acting reversible protection:

- Designed to overcome the limitations of the currently marketed injectable contraceptives
- Pre-clinical studies for the 6- and 12- month formulations have been completed to date[1]
- Target product profile of longer-acting injectable etonogestrel
  - Prolonged duration (6 to 12 months)
  - Improved ease of use, with an improved side effect profile
  - More predictable return to fertility

1. Data on file

A New Contraceptive Target

DARE-RH1 CatSper

A Novel Approach To Male And Female Contraception.

- The identification of the CatSper target represents the potential to develop a novel class of non-hormonal contraceptive products for both men and women.
  - The discovery of a sperm-specific ion channel, CatSper, was validated in animal models where it was demonstrated that male mice lacking CatSper have poor sperm motility.
  - CatSper proteins are ion channels expressed solely in the membranes of sperm flagellum and are essential to sperm motility.
- Pre-clinical research has demonstrated CatSper mediates hyperactive motility of sperm.
  - Sperm hyperactivity is necessary to penetrate the physical barrier known as the zona pellucida which encloses the ovum and protects the egg.[1]
  - The contraceptive benefit of targeting CatSper is achieved by inhibiting sperm hyperactivity and preventing egg fertilization.

1. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0028359

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Investment Highlights

Financial Profile

NASDAQ: DARE

Balance Sheet, March 31, 2019*:

- Cash: $3.5 million
- Common shares: 11.42 million
- Common stock warrants: 3.75 million
- No debt

*April 2019: Underwritten public offering of 5.3 million common shares for net proceeds of approximately $5.2 mil

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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 Natic Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH). T Company previously received award payments totaling $224,665.
- Second Notice of Award, for the additional $982,851, followed the NIH's review of a data analysis and other resul the first phase of research supporting Ovaprene.

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Management Team

Management Team

Daré Bioscience

Sabrina Martucci Johnson, MSc, MIM
President & CEO

Cypress Bioscience, Calibr,
Advanced Tissue Sciences,
WCG, Baxter Healthcare

Lisa Walters-Hoffert
Chief Financial Officer

ROTH Capital Partners,
Citicorp Securities,
Bank of America, Oppenheimer & Co.

David Friend, PhD
Chief Scientific Officer

Evofem Biosciences, CONRAD,
Elan Corporation,
Stanford Research Institute (SRI)

John Fair
Chief Business Officer

Evofem LLC, WCG,
Synovate/Aegis Group plc,
MCM Group, PwC, Express Scripts

Mark Walters
Vice President of Operations

Pacira, SkyePharma,
Alliance Pharmaceuticals,
American Home Products

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

Evofem LLC, WCG, Abbott Laboratories,
University of Wisconsin Hospital

Christine Mauck, MD, MPH
Medical Director

CONRAD, Population Council,
RW Johnson, FDA

MarDee Haring-Layton
Vice President of Finance

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Greg Matz

CooperSurgical - Cooper Companies, Agilent, Hewlett Packard

Robin Steele, JD, LLM

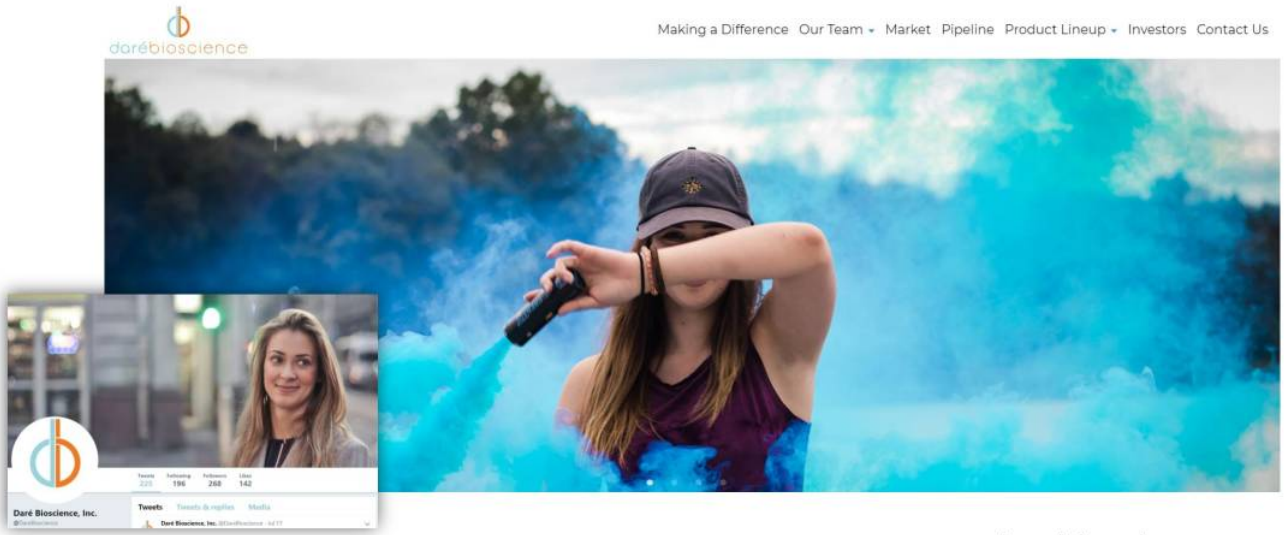
InterMune, Elan Corporation, Alveo, Alios Biopharma

Sabrina Martucci Johnson

Corporate & Investor Communications

NASDAQ: DARE

Trading as DARE since July 20, 2017



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