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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 5, 2018**

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**DARÉ BIOSCIENCE, INC.**  
(Exact name of registrant as specified in its charter)

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**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.)

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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

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.

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**Item 8.01 Other Events.**

Included as Exhibit 99.1 to this report is a presentation about Daré Bioscience, Inc. ("Daré") and its product candidates, dated September 5, 2018, 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 September 5, 2018.

By filing this report, including the information contained in Exhibit 99.1 attached hereto, Daré makes no admission as to the materiality of any information in this report. The information contained in Exhibit 99.1 hereto is summary information that is intended to be considered in the context of Daré's filings with the U.S. Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K filed on March 28, 2018 (as amended by the Form 10-K/A filed on April 30, 2018), Quarterly Reports on Form 10-Q filed on May 14, 2018 and August 13, 2018, and other public announcements that Daré makes, by press release or otherwise, from time to time. Daré undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as it believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, or through other public disclosure.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| <u>Exhibit Number</u> | <u>Description</u>  |
|-----------------------|---|
| 99.1                  | <a href="#">Corporate presentation, dated September 5, 2018</a> |

**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: September 5, 2018

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



*Delivering innovation by  
daring to be different*



September 5, 2018

# 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. 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 & Mission

**Vision:** To become the **coordinating presence** in women's health.

**Mission:** We achieve this by identifying, unlocking and advancing innovation that improves health outcomes and promotes a **better quality of life for women**.

# Daré Highlights



## Daring to be different

A pure play biopharmaceutical company focused on improving the health and well being of women.

- Focused on targeted delivery of products to address persistent unmet needs in women's health:
  - Pregnancy Prevention
  - Sexual Health
  - Vaginal Health
  - Fertility

The portfolio is well positioned to drive upside value in the short and long term and each asset is positioned to be a ***first-in-category opportunity***.

- Multiple milestones and value drivers expected over the next 12 - 24 months:
  - Advancing our two Phase 2 programs, and
  - Initiating development activities on Phase 1 and preclinical programs.

Daré is building a strong and strategic network to advance **innovation in women's health**.

Women's Health  
Network of Product Developers



Strategic Science  
& Technologies



Global Women's Health Market  
Worth \$51 Billion  
by 2025 - CAGR: 3.9%<sup>1</sup>

Women's Health  
Network of Potential Commercial Partners\*



\*Company names and logos are for illustrative purposes only.

Coordinating  
Innovation in  
Women's  
Health



1. <https://www.prnewswire.com/news-releases/womens-health-market-size-worth-513-billion-by-2025-cagr-39-grand-view-research-inc-651064753.html>

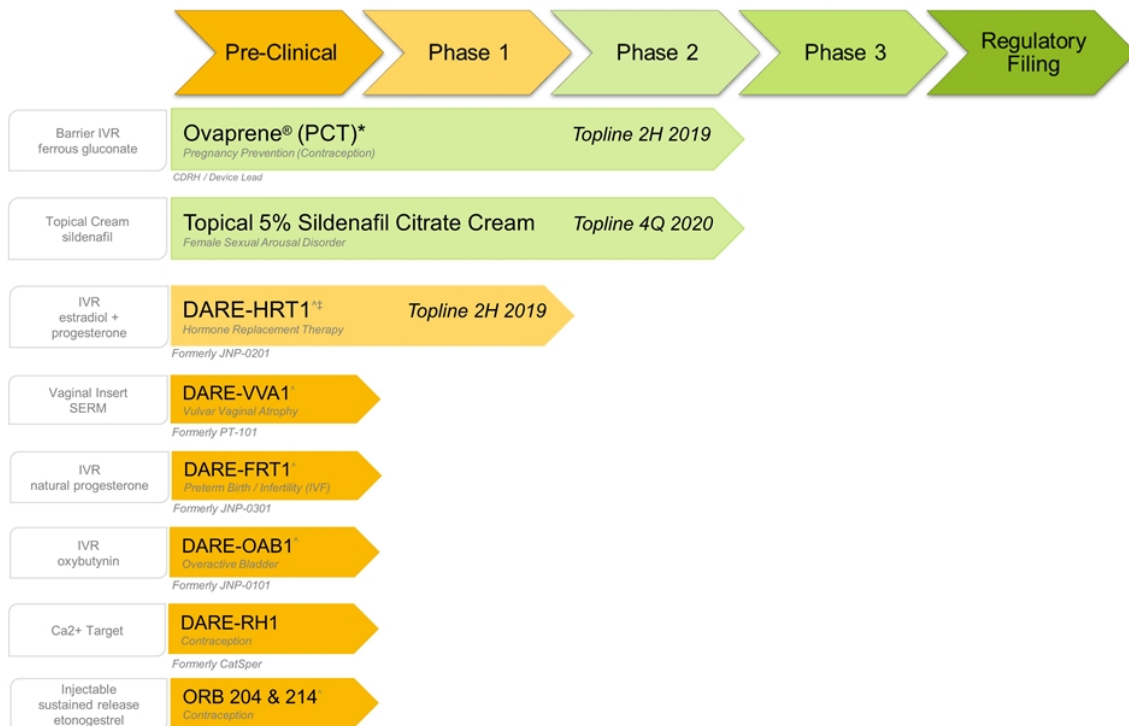


# Portfolio Overview



Daring to be different

## Innovative Women's Health Pipeline

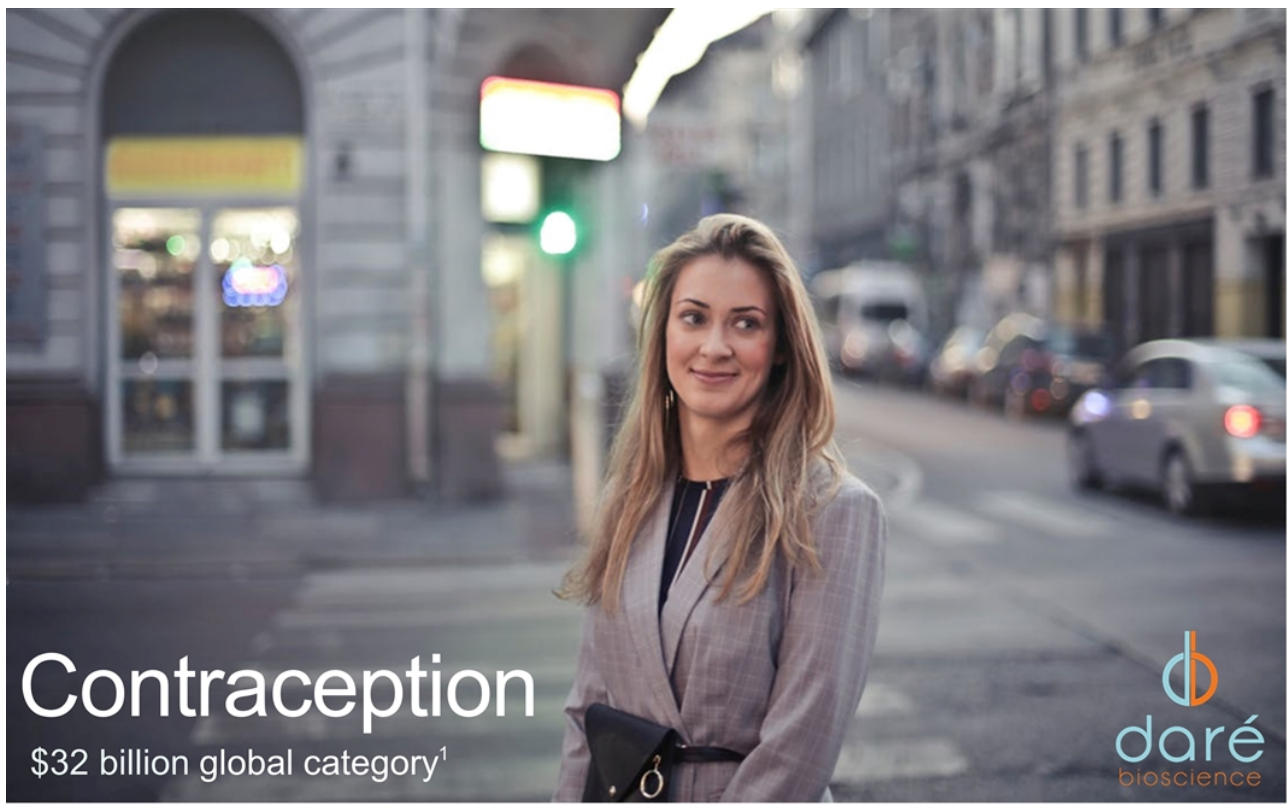


<sup>A</sup> 505(b)(2).

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

<sup>†</sup>HRT Phase 1 study to be conducted in Australia by Daré subsidiary.

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.



# Contraception

\$32 billion global category<sup>1</sup>



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>

## What's Driving Innovation in Contraception

### Innovation in Contraception

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



Convenience is driving new innovation

- NuvaRing®
  - Monthly, convenient vaginal ring product form.
  - 2017 revenue: \$761 million (Merck).<sup>5</sup>
- Mirena®
  - Physician inserted, long-acting.
  - Low/locally delivered hormone IUS.
  - 2017 revenue: \$1.12 billion (Bayer).<sup>5</sup>

1. Lo Loestrin Fe contains a low-dose combination of two female hormones. <https://www.loloestrin.com/loloestrin/about-lo-estrin>. Lo Loestrin® and its design are registered trademarks of Allergan Pharmaceuticals International Limited.

2. Minastrin <https://www.minastrin24.com>. Minastrin® is a registered trademark of Allergan Pharmaceuticals International Limited.

3. <https://www.nuvaring.com/how-nuvaring-works/>

4. <https://www.mirena-us.com/about-mirena/>

5. 2017 SEC Financial Filings

U.S.  
Contraceptive  
Market

\$6 Billion



*Daring to be different*

## The US Contraceptive Market is Large

- >\$6 billion in US Rx sales of contraceptive products (2016).<sup>1</sup>
- 40 million women of reproductive age currently use a contraceptive method.<sup>2</sup>

## Ready for Innovation

- 4 in 10 women not satisfied with their current method.<sup>2</sup>
- ~50% of women opting for a shorter-acting reversible method.<sup>3</sup>

## Limited product mix in the OTC non-hormonal contraceptive category

- Most non-hormonal options are over the counter (OTC) and are not optimal in terms of effectiveness or convenience.
  - Largest SKUs in the OTC channel are condoms and Plan-B.<sup>4</sup>

1. IMS NSP through Dec 2016  
2. [www.guttmacher.org](http://www.guttmacher.org), contraceptive fact sheet  
3. Ersek, J, *Matern Child Health J* (2011) 15:497-506  
4. IRI Data

# What Women Want from Birth Control

## Women's Preferences

- Effective Pregnancy Prevention
- Convenient Product Forms
  - Independent surveys revealed that the vaginal ring has many of the features women deemed extremely important.<sup>1</sup>
- Less Hormones
  - A majority of women prefer a monthly option with a lower hormone dose than the pill.<sup>2</sup>
- Methods *not in the moment* (noncoital)
  - 75% of women who practice contraception currently use non-coital (*not in the moment*) methods.<sup>3</sup>

### 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 | % of contraceptive users |
|--|--------------|-----------------------|--|--------------------------|
| Pill                                       | 9,572,477    | 15.6                  | 22.7                                       | 25.3                     |
| Tubal (female) sterilization               | 8,225,149    | 13.4                  | 19.5                                       | 21.8                     |
| Male condom                                | 5,496,905    | 8.9                   | 13.0                                       | 14.6                     |
| IUD  | 4,452,344    | 7.2                   | 10.6                                       | 11.8                     |
| Vasectomy (male sterilization)             | 2,441,043    | 4.0                   | 5.8  | 6.5                      |
| Withdrawal                                 | 3,042,724    | 5.0                   | 7.2  | 8.1                      |
| Injectable                                 | 1,481,902    | 2.4                   | 3.5  | 3.9                      |
| Vaginal ring                               | 905,896      | 1.5                   | 2.1  | 2.4                      |
| Fertility awareness-based methods          | 832,216      | 1.3                   | 2.0  | 2.2                      |
| Implant                                    | 965,539      | 1.6                   | 2.3  | 2.6                      |
| Patch                                      | 69,106       | 0.1                   | 0.2  | 0.2                      |
| Emergency contraception                    | 69,967       | 0.1                   | 0.2  | 0.2                      |
| Other methods*                             | 234,959      | 0.4                   | 0.6  | 0.6                      |
| No method, at risk of unintended pregnancy | 4,408,474    | 7.2                   | 10.5                                       | na                       |
| No method, not at risk                     | 19,302,067   | 31.4                  | na   | na                       |
| Total                                      | 61,491,766   | 100.0                 | 100.0                                      | 100.0                    |

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

[www.guttmacher.org](http://www.guttmacher.org)



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

# What's Driving Innovation in Contraception

## Innovation in Contraception - What's Missing?

Non-hormonal, non-coital alternatives that are effective and easy to use.

### Non-hormonal Products (marketed or in development)<sup>1</sup>

- Spermicides / vaginal gels
  - Least effective woman controlled.
  - On-demand / pre-coital application.
- Condoms
  - Effective, not woman controlled.
  - On-demand / pre-coital application.
- Diaphragms
  - Most effective woman controlled.
  - On-demand / pre-coital insertion.
- Long-acting IUD
  - Most effective.
  - Requires physician insertion/removal.

### 100% Effective = 0% Risk of Pregnancy

| Birth Control Effectiveness     |             |             |
|---------------------------------|-------------|-------------|
| 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%      |

A non-hormonal, non-daily, woman controlled option with efficacy approaching traditional hormonal methods aligns well with consumer need states.



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>

Ovaprene®

A New  
Contraceptive  
Opportunity



*Daring to be different*

Monthly Non-Hormonal Opportunity



Ovaprene®

A New  
Contraceptive  
Opportunity

 daré  
bioscience

*Daring to be different*

## Ovaprene® Non-hormonal, Monthly Vaginal Ring

### Spermiostatic Environment<sup>1</sup>

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

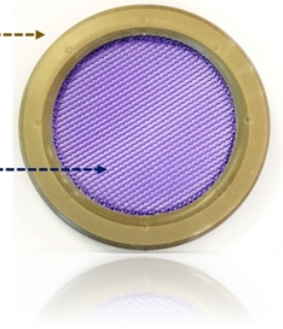
### Physical Barrier<sup>1</sup>

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

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

### Patent Protection<sup>1</sup>

- 12 issued patents worldwide (9 U.S.).
- IP coverage through August 2028.
  - Potential extension to 2033.



1. Data on file



Ovaprene®

A New  
Contraceptive  
Opportunity

  
daré  
bioscience

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## Ovaprene® Non-hormonal, Monthly Vaginal Ring

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

- 2009 - Postcoital Assessment:<sup>1</sup>
  - Open-label, single-arm, pilot safety and tolerability study.
  - Published in the Journal of Reproductive Medicine, 2009.
- Patients:
  - N= 21; 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.

| 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%      |
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| 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>

Ovaprene®

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Contraceptive  
Opportunity

  
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## Ovaprene® Non-hormonal, Monthly Vaginal Ring

### 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\*

- The study is enrolling 50 couples.
  - 25 women 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 motile sperm per high powered field (HPF) in the cervical mucus, post coitus.
- Safety assessments, PK, acceptability, fit, and ease of use.



#### 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 use.
    - Assessments of vaginal health.

- Data from the study is expected to be available in the second half of 2019.
- **If there is demonstration of feasibility in the PCT clinical trial, 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.**

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

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## Ovaprene® Non-hormonal, Monthly Vaginal Ring

| Features Desired Most in Birth Control: <sup>1-4</sup> | Design Features of Ovaprene: <sup>5</sup>  |
|--|--|
| ✓ Convenience<br>(Easy to Use & Easy to Remember)      | <b>Monthly Ring Product Form</b><br><i>Women chose rings for the convenience of a <b>non-daily option</b>.</i>   |
| ✓ Hormone Free   | <b>No Hormones in the API</b><br><i>Unique dual action MOA (spermistatic &amp; barrier).</i>   |
| ✓ Efficacy   | <b>Potential</b> for Contraceptive Effectiveness at the <b>Lower End</b> of the <b>Hormone Contraceptive Range</b> .                                     |
| ✓ Favorable Side Effect Profile                        | <b>No Colposcopic Abnormalities</b><br><i>No significant changes in vaginal flora.<br/>No serious adverse effects observed in prior published study.</i> |
| ✓ Easily Manage Fertility                              | <b>No Systemic Activity</b><br><i>Inserted and removed without a provider.<br/>Immediate return to fertility.</i>  |



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



# 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 2019<sup>1</sup>

1. [https://www.visiongain.com/Press\\_Release/911/Sexual-dysfunction-drugs-market-will-reach-7-7bn-in-2019](https://www.visiongain.com/Press_Release/911/Sexual-dysfunction-drugs-market-will-reach-7-7bn-in-2019)

# Female Sexual Dysfunction

## Market Landscape

### Female Sexual Dysfunction (FSD)



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.  
 • Imvexxy 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.  
 • Bremelanotide is a registered trademark of Palatin Technologies, Inc.

# Female Sexual Arousal Disorder

## FSAD



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## Female Sexual Arousal Disorder (FSAD)

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%.<sup>1</sup>
  - **33% of women in the U.S. age 21 to 60** (approximately 20 million women), experience symptoms of low or no sexual arousal.<sup>2,3</sup>
  - **10 million women are considered distressed and actively seeking treatment.**<sup>2</sup>

\*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.

Topical 5%  
Sildenafil  
Citrate  
Cream

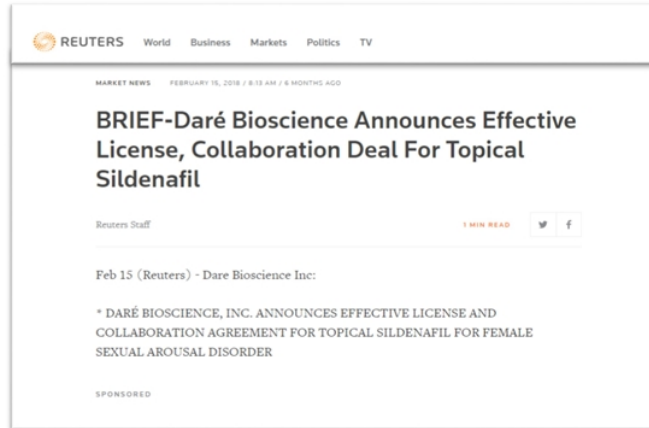
FSAD



## Female Sexual Arousal Disorder (FSAD)

Daré licensed the rights to Topical 5% Sildenafil Citrate Cream in February, 2018 for all women's health indications related to female sexual dysfunction and female reproductive health.

- In a Phase 2a study, Topical 5% Sildenafil Citrate Cream formulation demonstrated an increase in blood flow to the vaginal tissue in both pre- and postmenopausal women with FSAD.



# Pfizer Viagra® Studies

Increased Blood Flow and Clinical Efficacy with Oral Sildenafil in Women



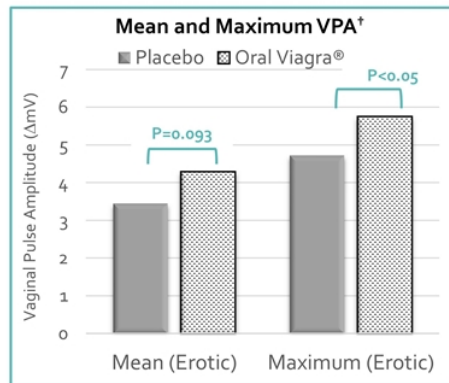
Daring to be different

## Female Sexual Arousal Disorder (FSAD)

### Sildenafil Demonstrated Statistically Significant Results

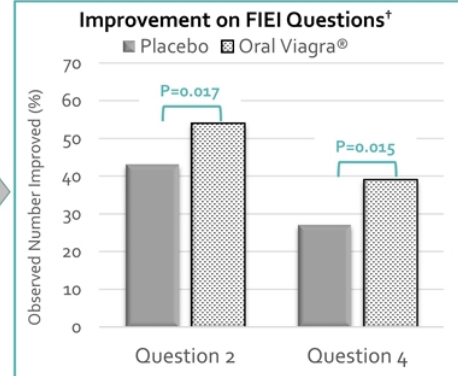
- Statistically significant increases in Vaginal Pulse Amplitude (VPA)<sup>1</sup>
- Statistically significant improvement in genital stimulation (FIEI)<sup>2</sup>

#### 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.

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.



Topical 5%  
Sildenafil  
Citrate  
Cream

FSAD

 daré  
bioscience

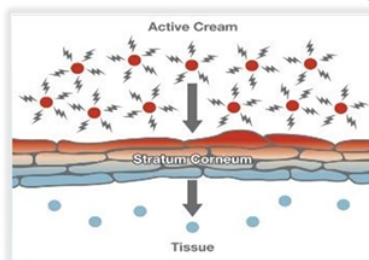
*Daring to be different*

## Female Sexual Arousal Disorder (FSAD)

### Topical 5% Sildenafil Citrate Cream – Formulation Innovation

- Topical 5% Sildenafil Citrate Cream designed to directly increase local blood flow to the genital tissue. Localized action, with minimal systemic uptake of the active drug.<sup>1</sup>

#### SST Formulation Technology



- **6 issued patents in the U.S.** on the topical delivery of Sildenafil and other PDE-5 inhibitors.
- Leveraging the known therapeutic benefit of oral sildenafil to stimulate increased blood flow to the genital tissue.
- If approved, Topical 5% Sildenafil Citrate Cream may offer a safe, effective and 'on demand' solution to difficulties with sexual arousal.

1. Data on file

Topical 5%  
Sildenafil  
Citrate  
Cream

FSAD



## Female Sexual Arousal Disorder (FSAD)

TYPE C Meeting, 3Q 2018—our meeting goals:

1. Align with the agency on key aspects of the Phase 2b and the overall clinical program to support the planned NDA, including the patient reported outcome (PRO) assessments used to accurately diagnose FSAD, and the PRO instruments to be used as **primary efficacy endpoints for pivotal clinical studies, study duration, and the target patient population** to be studied.
2. Review nonclinical and clinical information available to date and begin dialogue to determine what else may be required to support the conduct of the planned Phase 2b multiple-dose efficacy and safety clinical study and overall NDA.

Topical 5%  
Sildenafil  
Citrate  
Cream

FSAD



## Female Sexual Arousal Disorder (FSAD)

### Primary Endpoints for Phase 2b:

- While the 2016 Draft Guidance<sup>1</sup> on arousal disorder discusses the use of the Female Sexual Function Index (FSFI) arousal questions as a possible PRO instrument for evaluating arousal improvement — and suggests for FSAD co-primary endpoints of improvement in satisfactory sexual events and arousal — the agency is open to considering an alternative approach.
- A tangible result of our meeting was the agency’s receptivity to our proposal that the co-primary endpoints assess the most important and relevant symptoms of the disorder – lack of genital sensations of arousal (an adequate lubrication-swelling response of sexual excitement) and personal distress. We believe the agency is receptive to our alternative approach because of its openness to collaborate with drug development companies to establish reliable patient-reported outcome measures capable of discerning the effectiveness of the product being investigated for the indication.
- We agreed that our Phase 2b program should commence with a content validity study to demonstrate that the symptoms we plan to assess are the most important and relevant to our target population.
- Because our plan is for the endpoints used in the Phase 2b to reflect the endpoints used in the Phase 3 trials, after the qualitative study is completed and before the Phase 2b at-home trial is initiated, we will request a Type C meeting to get feedback on whether the agency agrees that the PRO instruments are content valid for the target population.

1. The 2016 Draft Guidance for Industry –Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment (the 2016 Draft Guidance)

Topical 5%  
Sildenafil  
Citrate  
Cream  
  
FSAD



## Female Sexual Arousal Disorder (FSAD)

### Length of study:

- The agency is agreeable to a 12-week Phase 2b trial to assess reasonable safety and preliminary efficacy. The 2016 Draft Guidance specifies 24 weeks for each of the two Phase 3 trials.

### Patient population:

- The agency confirmed that the 2016 Draft Guidance reflects its expectations regarding patient population to be studied (menopause status and concomitant conditions).
- Inclusion and exclusion criteria should reflect the population anticipated to use the drug, if approved. Further, the FDA reiterated its position that efficacy should be established separately in pre- and post-menopausal women to enable an adequate benefit/risk determination. As noted in the 2016 Draft Guidance, sponsors can choose to study pre- and postmenopausal women in separate trials or study these populations within the same trial, however, efficacy should be demonstrated for each group.

### In summary:

- We will commence Phase 2b related activities this year, as planned, with the initiation of the content validity PRO study,
- In parallel, we will 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,
- We plan to have follow up communications with the agency, as requested, that specifically address the adequacy of the data package generated before initiating the Phase 2b at-home trial.

# Female Sexual Dysfunction

## Market Landscape

### Female Sexual Dysfunction (FSD)



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 and/or maintain sufficient physical sexual arousal.**

- INTRAROSA is a registered trademark of Endoceutics, Inc.
- Imvexxy is a trademark of TherapeuticsMD, Inc.
- Ospheña 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.
- Bremelanotide is a registered trademark of Palatin Technologies, Inc.



# Innovative Vaginal Drug Delivery

Well characterized therapeutic options



# IVR Technology



**daré**  
bioscience

*Daring to be different*

## Intravaginal Ring (IVR) Technology Platform

Daré has an exclusive, global license to Juniper's novel IVR technology originally developed by Dr. Robert Langer from MIT and Dr. William Crowley from Massachusetts General Hospital and Harvard Medical School.

- Features of the Juniper 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-OAB1**
    - Formerly JNP-0101, an oxybutynin ring for the treatment of overactive bladder;
  - **DARE-HRT1**
    - Formerly JNP-0201, a combination estradiol + progesterone ring for hormone replacement therapy.
  - **DARE-FRT1**
    - Formerly JNP-0301, a natural progesterone ring for the prevention of preterm birth and for fertility support as part of an IVF treatment plan.



Daré's exclusive license covers all rings in development as well as additional applications of the intravaginal ring technology platform in other therapeutic areas.

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

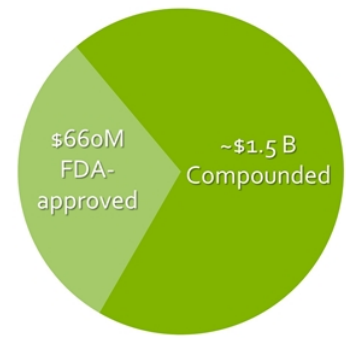
# HRT Market Overview

## Hormone Replacement Therapy (HRT)

Hormone therapy (HT) 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.<sup>1</sup>

- 45M women in U.S. approaching or in menopause.<sup>2</sup>
- 2012 NAMS consensus statement supports HRT in peri- and post-menopausal women.<sup>3</sup>
- NAMS recommends Non-oral route over oral.<sup>3</sup>

\$2.2 Billion U.S. Market<sup>4</sup>



■ Compounded ■ FDA-approved



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



# DARE-HRT1

## Phase 1 Overview



### Hormone Replacement Therapy (HRT)<sup>1</sup>

For Treatment of Vasomotor Symptoms due to Menopause

- 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/ 5 mg and 10 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 5 mg IVR
    - Estradiol 160 µg/Progesterone 10 mg IVR
  - Identify the steady-state PK after 28 days of each DARE-HRT1
- N=60

1. Data on file

## DARE-VVA1

Vaginally  
Delivered  
Tamoxifen for VVA



Daring to be different

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

- DARE-VVA1 (Formerly PT-101)
  - A proprietary vaginal formulation of tamoxifen, has the potential to be a first-in-class treatment for 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 more than two million women diagnosed with, or at risk of recurrence of, ER-positive and PR-positive breast cancer.<sup>1</sup>
  - 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.<sup>2</sup>
- **If approved, DARE-VVA1 has the potential to be the first treatment specifically developed for VVA in patients with hormone-receptor positive breast cancer.**

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



# Strategic Pre-Clinical Candidates

Contraceptives that address global gaps

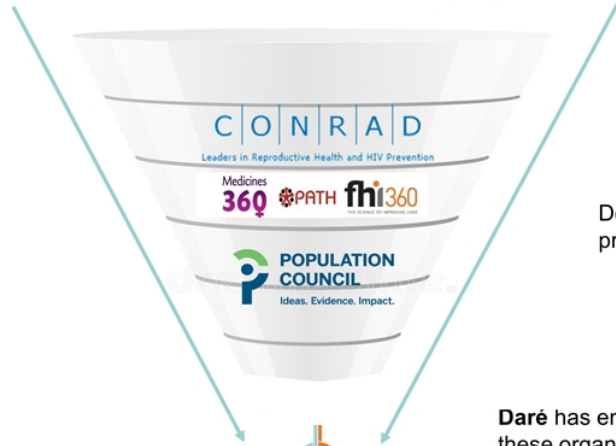


**"Innovative partnerships increase access to family planning, helping more women plan their lives and shape their futures."**

*Chris Elias, President Global Development Program, Bill & Melinda Gates Foundation*



**Major foundations contribute hundreds of millions of dollars** to fund new innovation in women's reproductive health.



Development organizations screen and advance promising new innovation.

**Daré** has emerged as the coordinating presence among these organizations and is well positioned to partner on the product candidates with significant market potential.

## Daré's Innovation Engine

Reproductive Health  
Public & Private  
Sector Funding








# Value Creation in Women's Reproductive Health

Addressing Global Gaps in  
Contraception



Daring to be different

| Organization                  | Funding Source / Donor | Product Name  | License Holder / Partner | Form    | Indication           | Annual Sales / Corporate Value <sup>1</sup>  |
|-------------------------------|------------------------|---|--------------------------|---------|----------------------|--|
| <b>The Population Council</b> | USAID Gates Foundation | Anovera<br>  | Therapeutics MD          | Ring    | Pregnancy Prevention | \$20M upon FDA approval; \$20M first commercial batch, milestones + royalties 2018 |
|                               | USAID                  | Paragard<br> | Cooper Surgical          | IUD     | Pregnancy Prevention | Cooper Surgical \$1.1B Acquisition from Teva 2017                                  |
|                               | USAID                  | Mirena<br>   | Bayer                    | IUS     | Pregnancy Prevention | >\$1.1B (Global sales) 2018  |
|                               | USAID                  | Jadelle<br>  | Bayer                    | Implant | Pregnancy Prevention | ~\$400M (Global sales)   |
| <b>Medicines360</b>           | Large Anonymous Donor  | Liletta<br>  | Allergan                 | IUS     | Pregnancy Prevention | \$50M upfront; \$125M milestones + royalties, 2013                                 |

<sup>1</sup> SEC Filing/IMS Data

# DARE-RH1 CatSper

## Contraception



### **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.<sup>1</sup>
  - 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>

Long-acting  
Injectable

Contraception



## ORB-204 and ORB-214, injectable etonogestrel<sup>1</sup>

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**.

- Pre-clinical studies for the 6- and 12- month formulations have been completed to date:
  - Establishing pharmacokinetics and pharmacodynamics profiles.

An injectable contraceptive is designed to provide discreet, non-invasive protection over several months

- Limitations of the currently marketed injectable contraceptive: provides contraceptive protection for only three months, and can delay the ability to get pregnant for up to ten months after receiving the injection.

Target product profile of long-acting injectable

- Prolonged duration (6 to 12 months), improved ease of use, with an improved side effect profile and predictable return to fertility.

1. Data on file



# Investment Highlights



# Financial Profile



## Background

- NASDAQ:DARE
- Publicly traded via reverse merger that closed July 19, 2017.

## Balance sheet, June 30, 2018:

- \$12.4 million in cash.
- Non-dilutive NIH SBIR Award (Q2-2018):
  - Daré received a Notice of Award for the first \$224,665 of an anticipated \$1.9 million in grant funding
- 11.4 million in common shares and 3.7 million warrants
- No debt.

Experienced  
Team to  
Move the  
Field  
Forward

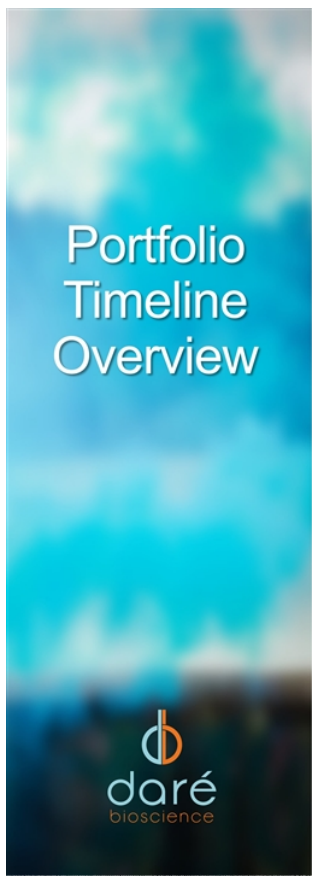


*Daring to be different*

| <b>Sabrina Martucci Johnson, MSc, MIM<br/>President and CEO</b>    | <b>Cypress Bioscience, WCG<br/>Advanced Tissue Sciences, Baxter Healthcare</b>    |
|--|---|
| Lisa Walters-Hoffert<br>Chief Financial Officer                    | ROTH Capital Partners, Citicorp Securities,<br>Bank of America, Oppenheimer & Co. |
| David Friend, PhD<br>Chief Scientific Officer                      | Evoform Biosciences, CONRAD, Elan Corporation                                     |
| John Fair, MA<br>Chief Business Officer                            | Evoform Biosciences, WCG, Gemini Healthcare, NPA                                  |
| Mark Walters<br>Vice President, Operations                         | Pacira, SkyePharma, Alliance Pharmaceuticals,<br>American Home Products           |
| Mary Jarosz, RPh, RAC, FTOPRA<br>Global Head of Regulatory Affairs | Evoform Biosciences, WCG, Abbott Laboratories                                     |
| Christine Mauck, MD, MPH<br>Medical Director                       | CONRAD, Population Council, RW Johnson, FDA                                       |
| Bridget Martell, MD, MA<br>Medical Affairs                         | Juniper Pharmaceuticals, Purdue Pharma, Pfizer                                    |
| Nadene Zack, MSc<br>Sr. Director Clinical Operations               | Retrophin, Aragon, Cypress Bioscience, Pfizer                                     |

## Experienced Board of Directors

| <b>Roger Hawley (Chairman)</b>     | <b>Zogenix, Alios Biopharma, InterMune, Elan Corporation</b>         |
|------------------------------------|--|
| Susan Kelley, MD                   | Cerulean, Bayer, BMS, ArQule   |
| William Rastetter, PhD             | Cerulean, GRAIL, Receptos, Illumina, IDEC                            |
| Robin Steele, JD, LL.M.            | InterMune, Elan Corporation, Alveo, Alios Biopharma                  |
| Jessica Grossman, M.D.             | Medicines360, Sense4Baby, Johnson & Johnson                          |
| Sabrina Martucci Johnson, MSc, MIM | Cypress Bioscience, WCG, Advanced Tissue Sciences, Baxter Healthcare |



Ovaprene (Contraception)

- 2018: PCT
- 2019: Pivotal
- 2022: Regulatory Filing (CDRH / Device Lead)
- 2023: Potential Launch

Topical 5% Sildenafil Citrate Cream<sup>^</sup> (FSAD)

- 2019: Phase 2b
- 2021: Phase 3 (Two Phase 3 Trials)
- 2023: Regulatory Filing

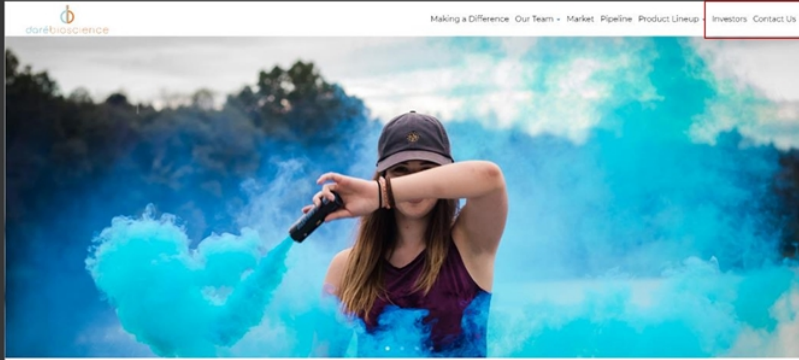
DARE-HRT1<sup>^</sup> (Hormone Replacement Therapy) Formerly JNP-0201

- 2019: Phase 1

Pre-Clinical & Strategic Development Options

- Vaginal Drug Delivery<sup>^</sup>
  - DARE-FRT1
  - DARE-OAB1
  - DARE-VVA1
- Longer-Acting Injectable<sup>^</sup>
  - ORB- 204
  - ORB- 214
- Hormone-free Contraception
  - DARE-RH1

<sup>^</sup>505(b)(2).  
 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.



**DARÉ BIOSCIENCE:**

*Delivering Innovation By Daring To Be Different*

[www.darebioscience.com](http://www.darebioscience.com)

NASDAQ: DARE

*Trading as DARE since July 19, 2017*