#### 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): March 5, 2019

## DARÉ BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-36395 (Commission File Number)

20-4139823 (I.R.S. Employer Identification No.)

3655 Nobel Drive, Suite 260 San Diego, CA 92122 (Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: (858) 926-7655

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 Bioscience, Inc. ("Daré") and its product candidates, dated March 5, 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 March 5, 2019.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number Description 99.1 Corporate

1 <u>Corporate presentation, dated March 5, 2019</u>

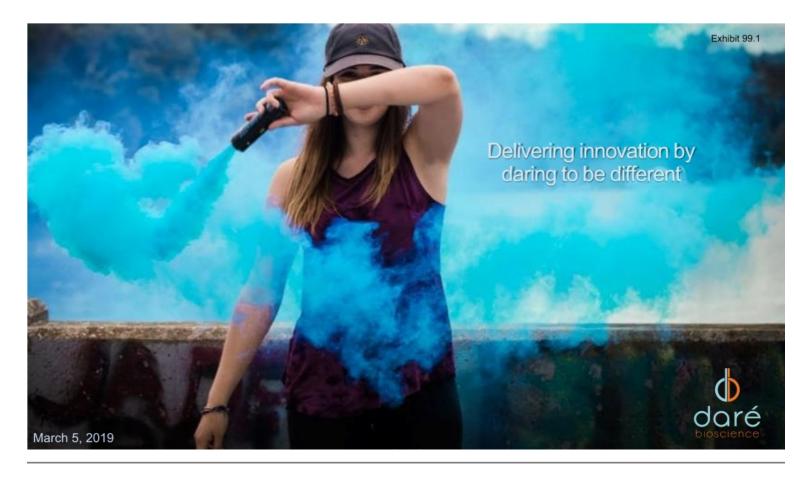
#### SIGNATURES

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: March 5, 2019

By:/s/ Sabrina Martucci JohnsonName:Sabrina Martucci JohnsonTitle:President and Chief Executive Officer



Forward Looking Statements

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Daring to be different

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 DARE'S ACTUAL RESULTS, PERFORMANCE OR ACHIEVEMENTS, INCLUDING, WITHOUT LIMITATION RISKS AND UNCERTAINTIES RELATING TO: THE OUTCOME OR SUCCESS OF CLINICAL TRIALS; DARE'S ABILITY TO RAISE ADDITIONAL CAPITAL AS NEEDED; DARE'S ABILITY TO OBTAIN AND MAINTAIN INTELLECTUAL PROPERTY PROTECTION FOR ITS PRODUCT CANDIDATES; DARE'S ABILITY TO DEVELOP PRODUCT CANDIDATES ON THE TIMELINES SET FORTH HEREIN; AND OTHER RISK FACTORS DESCRIBED IN DARE'S MOST RECENT ANNUAL 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 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.



#### Daring to be different

A pure play biopharmaceutical company focused on improving the health and well being of women. At Daré, we focus on targeted delivery of products to address persistent unmet needs in women's health. Our focus areas include:

- Pregnancy Prevention
- Sexual Health
  Vaginal Health
- Vaginal He
   Fertility

Acquisition, Licensing & Partnering Strategy:

- · Products that are commercially viable and attractive to strategic partners
- Products that have a data package including a proof-of-concept and/or the ability to leverage a 505(b)(2) regulatory pathway
- Products that address a persistent unmet needs in women's health
- The ability to deliver products in a more personalized way for women

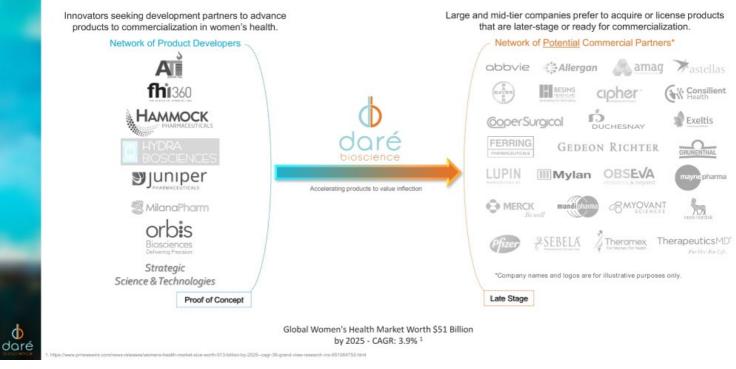
Value Creation Strategy:

- The portfolio is well positioned to drive upside value by capitalizing on market misalignments
- The majority of assets are well positioned to be first-in-category opportunities and are therefore attractive partnering candidates

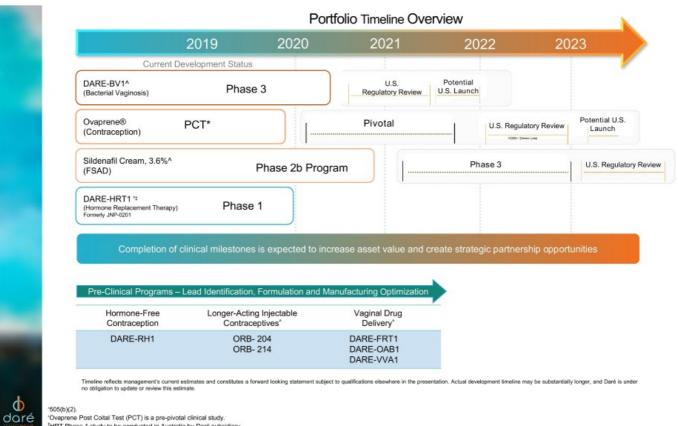
Delivering clinical milestones are key value drivers for a development stage company. We expect to deliver against multiple milestones over the next 12 - 24 months including:

- · Advancing our Bacterial Vaginosis (BV) program into a Phase 3 trial
- Topline readouts from our two pre-pivotal programs Ovaprene (2H 2019) and Sildenafil Cream, 3.6%, (4Q 2020)
- Initiating development activities on the DARE-IVR programs Hormone Replacement Therapy (HRT/VMS) program phase 1 (2019)

# Coordinating Presence in Women's Health Market Misalignment = A Value Creation Opportunity



Clindamycin	DARE-BV1 <sup>*</sup> Formerly MP-101		Phase 3 Initiation 2H 2019 Bacterial Vaginosis		
Barrier IVR Ferrous gluconate	Ovaprene® (PC	FT)*	Top line 2H 2019	CDRH / Device Lead	Non-Hormonal, Monthly Contraception
Topical Cream Sildenafil	Sildenafil Crear	m, 3.6%*	Top line 4Q 2020		Female Sexual Arousal Disorder
VR latural Estradiol + latural progesterone	DARE-HRT1*1	Fopline 2H 2019	Formerly JNP-0201		Hormone Replacement Therapy
Accelerating pre-clir IVR Natural progesterone	ical programs with collaborat	tions and non-dilutive fund	ing whenever possible		Pregnancy Maintenance (PTB & ART
IVR Natural progesterone			ing whenever possible		2
IVR Natural progesterone IVR Oxybutynin Vaginal Insert	DARE-FRT1*	Formerly JNP-0301	ing whenever possible	Vulvar i	Pregnancy Maintenance (PTB & ART Over-Active Bladder and Vaginal Atrophy (HR+ Breast Cancer Population
IVR	DARE-FRT1 <sup>*</sup>	Formerly JNP-0301	ing whenever possible	Vulvar a	Over-Active Bladder



\*Ovaprene Post Coital Test (PCT) is a pre-pivotal clinical study. \*HRT Phase 1 study to be conducted in Australia by Daré subsidiary.



# **Investment Highlights**

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## Financial Profile

#### Background

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

#### Balance sheet, September 30, 2018:

- \$9.5 million in cash
- · Non-dilutive NIH SBIR Award:
  - In Q2-2018, Daré received a Notice of Award for the first \$224,665 of an anticipated \$1.9 million in grant funding from a division of the National Institutes of Health.
- 11.4 million common shares and 3.75 million warrants outstanding
- No debt

### Management Team Daré Bioscience

Sabrina Martucci Johnson, MSc, MIM Cy President and CEO

President and 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, CONRAD, Elan Corporation
John Fair Chief Business Officer	Evofem, WCG, Gemini Healthcare, Aegis plc
Mark Walters Vice President, Operations	Pacira, SkyePharma, Alliance Pharmaceuticals, American Home Products
Mary Jarosz, RPh, RAC, FTOPRA Global Head of Regulatory Affairs	Evofem, WCG, Abbott Laboratories
Christine Mauck, MD, MPH Medical Director	CONRAD, Population Council, RW Johnson, FDA
Bridget Martell, MD, MA Medical Affairs	Juniper Pharmaceuticals, Purdue Pharma, Pfizer
Nadene Zack, MSc Sr. Director Clinical Operations	Retrophin, Aragon, Cypress Bioscience, Pfizer

## **Board of Directors**

Daré Bioscience

Roger Hawley (Chairman)	Zogenix, Alios Biopharma, Cypress Bioscience, InterMune, Elan Corporation, GSK
Jessica Grossman, MD	Medicines360, Sense4Baby, Johnson & Johnson
Susan Kelley, MD	Bayer, BMS, ArQule,Cerulean
Greg Matz	CooperSurgical - Cooper Companies, Agilent, Hewlett Packard
William Rastetter, PhD	Neurocrine Biosciences, IDEC, GRAIL, Receptos, Illumina, Cerulean
Robin Steele, JD, LLM	InterMune, Elan Corporation, Alveo, Alios Biopharma
Sabrina Martucci Johnson, MSc, MIM	Cypress Bioscience, Calibr, Advanced Tissue Sciences, WCG, Baxter Healthcare



# **Program Overview**



## 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):<sup>1</sup>
  - · 88% 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 commonly reported vaginal infection in women ages 15-44 <sup>2</sup>
- U.S. prevalence estimated to be ~21 million among women ages 14-49<sup>2</sup>
- Approved prescription drugs have less than optimal clinical cure rates (37-67%)<sup>3</sup>
- 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

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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

## Bacterial Vaginosis

Symptoms & Causes of BV

- BV is the most commonly reported vaginal infection in women ages 15-44.<sup>1</sup> BV is characterized by a shift in the vaginal flora from the dominant Lactobacillus to a polymicrobial flora.<sup>2</sup>
- BV has been associated with serious health issues, including preterm births, pelvic inflammatory disease, increased susceptibility to sexual transmitted infections (including HIV infection) and other chronic health problems.<sup>1,2</sup>
- A number of potential microbial pathogens, singly and in combinations, have been implicated in the disease process.
  - The list of possible agents includes Gardnerella, Atopobium, Prevotella, Peptostreptococcus, Mobiluncus, Sneathia, Leptotrichia, Mycoplasma, and BVassociated bacterium 1 (BVAB1) to BVAB3.<sup>1</sup>

1. Center for Disease Control and Prevention (CDC). www.cdc.gov/std/bv/stats.htm 2. Onderdonk, A. et al. "The Human Microbiome during Bacterial Vaginosis," Clinical Microbiology Reviews, April 2016 Volume 29 Number 2

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## Bacterial Vaginosis

Symptoms & Causes of BV

- BV is characterized by the presence of three of the following four criteria:
  - Vaginal pH of >4.5
  - · Clue cells on saline wet mount
  - · Release of a fish amine odor
  - · A characteristic thin, homogenous vaginal discharge
    - In 1991, Nugent et al. described a Gram stain scoring system of vaginal smears to diagnose BV. <sup>1,3</sup>
- The Nugent score is calculated by assessing for the presence of large gram-positive rods (Lactobacillus morphotypes; decrease in Lactobacillus scored as 0 to 4), small gram-variable rods (G. vaginalis morphotypes; scored as 0 to 4), and curved gram-variable rods (Mobiluncus spp. morphotypes; scored as 0 to 2) and can range from 0 to 10. A score of 7 to 10 is consistent with BV. <sup>1,3</sup>
- BV is not considered to be a sexually transmitted infection, but it is more common in women who are sexually active.



 Sha, Beverly E., et al. "Utility of Amsel Criteria, Nugent Score, and Quantitative PCR for Gardnerella vaginalis, Mycoplasma hominis, and Lactobacillus spp. for Diagnosis of Bacterial Vaginosis in Human Immunodeficiency Virus-Infected Women." JOURNAL OF CLINICAL MICROBIOLOGY, Sept. 2005, p. 4607–4612
 https://www.keepherawersome.com/Bacterial-Vaginosis
 Wilson, J. "Managing recurrent bacterial vaginosis." Sexually Transmitted Infections. 2004; 80(1): 8–11..

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### **Bacterial Vaginosis**

Market Opportunity

- In the US, an estimated 21 million women aged 14-49 years (approximately 29%) are infected with BV.<sup>1,2</sup>
  - BV leads to symptoms including abnormal vaginal discharge and odor that are unpleasant and disrupt and interfere with a woman's relationships and general quality of life.
  - BV has been associated with serious health issues, including preterm births, pelvic inflammatory disease, increased susceptibility to sexual transmitted infections (including HIV infection) and other chronic health problems.<sup>3,4</sup>
  - IMS/IQVIA
    - According to IMS/IQVIA data, the 2016 U.S. annual sales figures for BV prescriptions were in excess of \$150m for vaginal forms of Clindamycin and Metronidazole.
  - Lupin Inc., the U.S. subsidiary of India-based Lupin, acquired Symbiomix, the maker of secnidazole (a 5-nitroimidazole antibiotic granular powder) for the treatment of BV in a transaction valued at \$150m.6
    - Lupin's 1x oral Solosec<sup>®</sup> (secnidazole) launched in May of 2018.<sup>7</sup>

- I. https://www.cdc.gov/std/bv/stats.htm
   Sucher, Allana et al., "Bacterial Vaginosis: A Review," US Pharmacist 2018: 43(9):32-33
   Center for Disease Control and Prevention (CDC), www.cdc.gov/std/bv/stats.htm
   4. Onderdonk, A. et al. "The Human Microbione during Bacterial Vaginosis," Clinical Microbiology Reviews, April 2016 Volume 29 Number 2
   S.MS/IQVIA data (2016). Data on file
   6. http://www.lupingharmacecuticals.com/lupin-launches-solosec-secnidazole-2g-oral-granules-in-the-us.htm

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#### Study Objective: Study the Efficacy and Safety of DARE-BV1 in the Treatment of Bacterial Vaginosis

#### Proof of Principle Study Design (n = 30)

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

Secondary Endpoints: Proportion of patients with therapeutic and bacteriologic cures,<sup>1,2</sup> 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 (Formerly MP-101) 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 (clindemycin)	88%	57%*	57%*	
Solesec®1 (secredazore 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

- · 26 of 30 women completed the study
- Test-of-Cure Visit (Day 7 14)

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- · 23 of 26 (88%) 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)

- · 23 of 24 (96%) women showed continued clinical cure
- · 8 of 9 women had bacteriologic cure and 7 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/Pl.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



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



#### Ovaprene® Overview

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### 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 ٠
- 40 million women of reproductive age currently use a contraceptive method.<sup>3</sup>

#### 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 •

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

### Ovaprene® Overview

#### 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<sup>®</sup>
  - · Monthly, convenient vaginal ring product form.
  - 2017 worldwide sales: \$761 million (Merck)<sup>5</sup>
- Mirena<sup>®</sup> Product Family
  - · Physician inserted, long-acting.
  - · Low/locally delivered hormone IUS.
  - 2017 worldwide sales: \$1.12 billion (Bayer)<sup>7</sup>

Lo Lostrin Fe contains a low-dose combination of two female hormones. https://www.loloestrin.com/loloestrin/about-lo-loestrin@ and its design are registered trademarks of Allergan
Pharmaceuticals International Limited.
 Mitastrin https://www.nuvaring.com/how-nuvaring.works/
 Hinastrin@ and its design are registered trademarks of Allergan
Pharmaceuticals International Limited.
 Hints://www.inirena-us.com/about-mirena/
 Hormorena/
 Hints://www.inirena-us.com/about-mirena/
 Annual Report on Form 10-K for fiscal year ended December 31, 2017
 Bayer Annual Report 2017. Includes sales for Mirena®, Kyleena® and Jaydess® / Skyla®

Ovaprene® Overview

#### 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 <u>not in the moment (noncoital)</u>
  - 77% 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
PIII	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 Vasectomy	4,452,344	7.2	10.6	11.8
(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

women who are sexually active; not pregnant, seeking to become pregnant or postpartum; and not noncontraceptive most applicable.

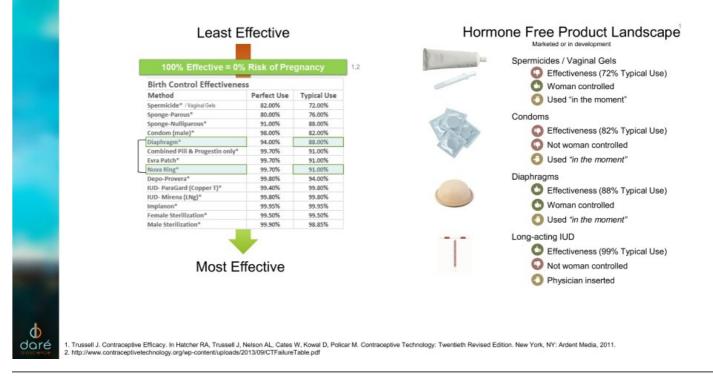
www.guttmacher.org

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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

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#### What's Missing in Contraception? Hormone free alternatives that are <u>effective and easy to use</u>



### New Contraceptive Option Ovaprene® Overview

## 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.



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Ovaprene® Overview

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= 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 Effectivenes	is	
Method	Perfect Use	Typical Use
Spermicide* / vaginal gols	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%

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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® Overview

U.S. Regulatory Strategy

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- · 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.
  - <u>25 women complete a total of 21 visits</u>
- · 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.
  - 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.

- 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.

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

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# New Contraceptive Option Ovaprene® Overview

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		🕚 Horm
		C) Effica
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		C Easily
daré	<ol> <li>Lessard, L,P.</li> <li>Hooper, DJ, (</li> <li>Ersek, J, Mat</li> <li>Journal of Re</li> </ol>	rban.org/urban-wire erspectives on Sexu Clin Drug Investig. 2 ern Child Health J (2 productive Medicine ontraceptive Efficacy

Features Desired Most in Birth Control: <sup>1.4</sup>	Design Features of Ovaprene: <sup>5,6</sup>	C
Convenience (Easy to Use & Easy to Remember)	Monthly Ring Product Form Women chose rings for the convenience of a non-daily option.	
1 Hormone Free	No Hormones in the API Unique dual action MOA (spermiostatic & barrier).	
1 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.	

re/women-want-effective-birth-control wal and Reproductive Health, Volume 44, Number 3,9-2012 2010;30(11):74963 (2011) 15:479-506 ne 2009; 54: 685-690 cy. 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):<sup>1</sup>
  - Efficacy signal observed in both pre and postmenopausal patients ٠
  - 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<sup>2</sup>

- 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

Φ

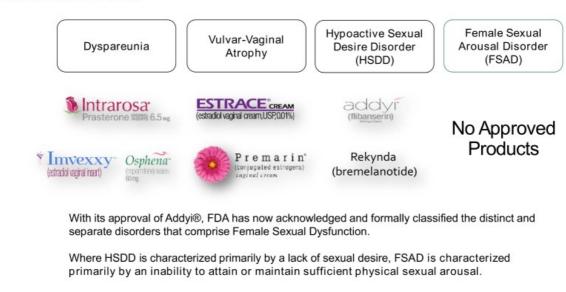
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- Patents covering the licensed technology have been granted with terms through 2031 (through June 2029 in the U.S.)
- No ANDA route: ANDA is not currently an option for topicals that result in low systemic uptake

1. Data on file 2. Ad Hoc Market Rese earch: 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%



INTRAROSA is a registered trademark of Endoceutics, Inc.
 Invexory 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 Prizer Inc.
 Addyi is a registered trademark of Prizer Inc.
 Bremelanotide is a registered trademark of Palatin Technologies, Inc.

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#### 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.<sup>\*</sup>

- 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 ctivity, 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 nother 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.

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

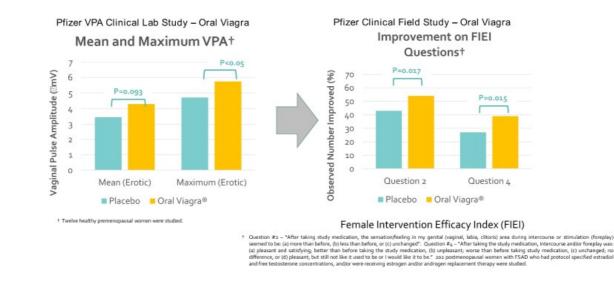
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### Sildenafil Cream 3.6%

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

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



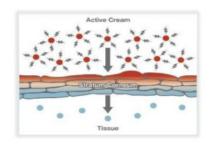
**∮** daré

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

Sildenafil Cream 3.6%

Formulation Innovation

- Sildenafil Cream, 3.6% designed to directly increase local blood flow to the genital tissue.
- The formulation delivers 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, Sildenafil Cream, 3.6% may offer a safe, effective and 'on demand' solution to difficulties with sexual arousal.

1. Data on file

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Sildenafil Cream, 3.6%

Phase 1 Study of SST-6007 (Sildenafil Cream, 3.6%)<sup>1</sup>

- Normal healthy postmenopausal women were dosed with escalating doses of Sildenafil Cream, 3.6%, using a crossover study design.
- Topical sildenafil had significantly lower systemic exposure compared to a 50 mg oral sildenafil dose
  - AUC 3-6%
  - C<sub>max</sub> 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

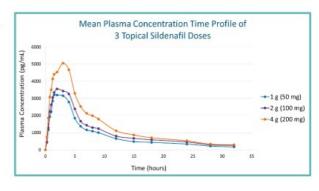
Phase 2a Study of SST-6007 (Sildenafil Cream, 3.6%)1

 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.

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Treatment	N	Sildenafil Single Dose	C <sub>max</sub> (ng/ml)	T <sub>max</sub> (hr)	AUC <sub>last</sub> (h*ng/ml)
Topical Sildenafil 1 g of cream	20	35 mg	3.4	2.37	25.6
Topical Sildenafil 2 g of cream	20	71 mg	3.8	2.27	30.8
Topical Sildenafil 4 g of cream	19	142 mg	5.3	2.22	42.5

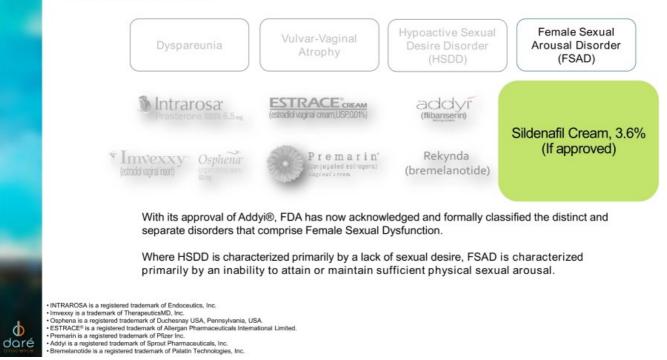


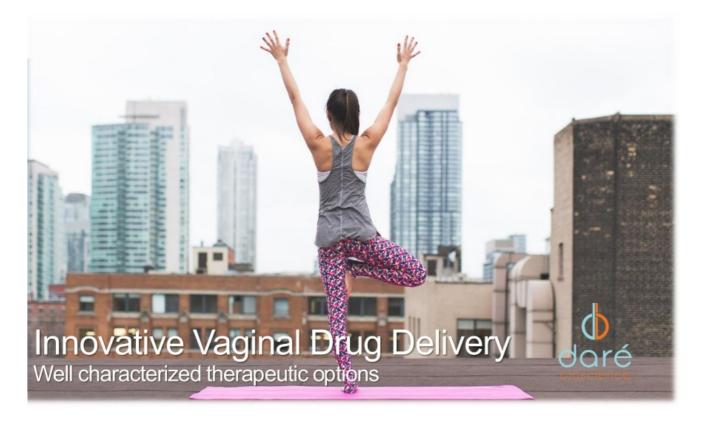
Sildenafil Cream 3.6%

**∲** daré 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)	Planned Type C Meeting     2019     At Home Study     At Home Study     Data – 4Q 2020
<ul> <li>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.</li> <li>This is a non-interventional study – participants will not be asked to use or evaluate any products.</li> </ul>	<ul> <li>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.</li> <li>The Phase 2b at-home study will allow patients to use the investigational product and placebo in their home setting.</li> <li>The FDA is agreeable to a 12-week Phase 2b for Sildenafil Cream, 3.6% to assess reasonable safety and preliminary efficacy.</li> <li>The 2016 Draft Guidance reflects expectations regarding phase 3 study length and patient population.</li> </ul>
	<ul> <li>Key Takeaways;</li> <li>The phase 2b program will consist of a content validation component followed by at-home of the investigational product and a placebo control.</li> <li>The plan is to use the selected PRO instrument and FDA agreed upon endpoints for the ph and phase 3 clinical triats.</li> </ul>

Sildenafil Cream 3.6%





## 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<sup>1</sup> and Dr. William Crowley<sup>2</sup> from Massachusetts General Hospital and Harvard Medical School. 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 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 bio-identical estradiol + progesterone ring for hormone replacement therapy.
  - DARE-FRT1

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 Formerly JNP-0301, a natural progesterone ring for the prevention of preterm birth and for fertility support as part of an IVF treatment plan.

1. http://www.iblimes.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



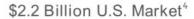
HRT remains the most effective treatment for vasomotor symptoms (VMS) and the genitourinary syndrome of menopause (GSM) and has been shown to prevent bone loss and fracture.<sup>1</sup>

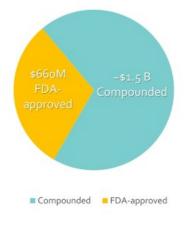
- 45M women in U.S. approaching or in menopause.<sup>2</sup>
- 2012 NAMS consensus statement supports HRT in peri- and postmenopausal women – estrogen to reduce symptoms and progesterone to prevent thickening of uterine wall.<sup>3</sup>
- NAMS recommends non-oral route over oral.<sup>3</sup>

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 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





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
 U.S. Census Bureau, Population Division. Table 2. 2015 to 2060 (NP2012-T2). Released Dec. 2012.
 Menopause, Vol. 19, No. 3, 2012.
 U.S. 2014. Source: Symphony Health Solutions Report

### Hormone Replacement Therapy (HRT) DARE-HRT1

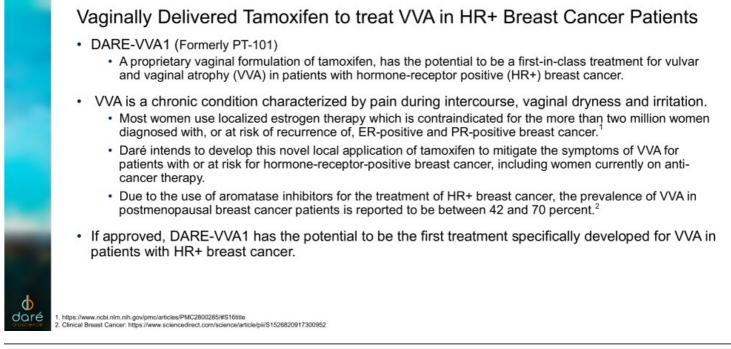
### Phase 1 - Hormone Replacement Therapy (HRT)

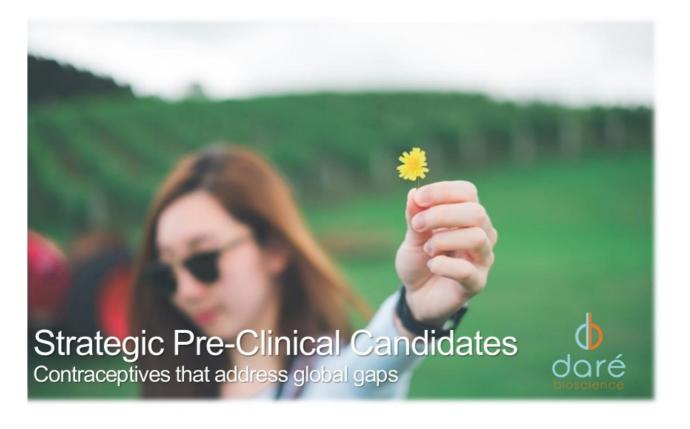
DARE-HRT1 for the treatment of VMS due to menopause – combination bio-identical estradiol and progesterone in a convenient 28 day IVR

- 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

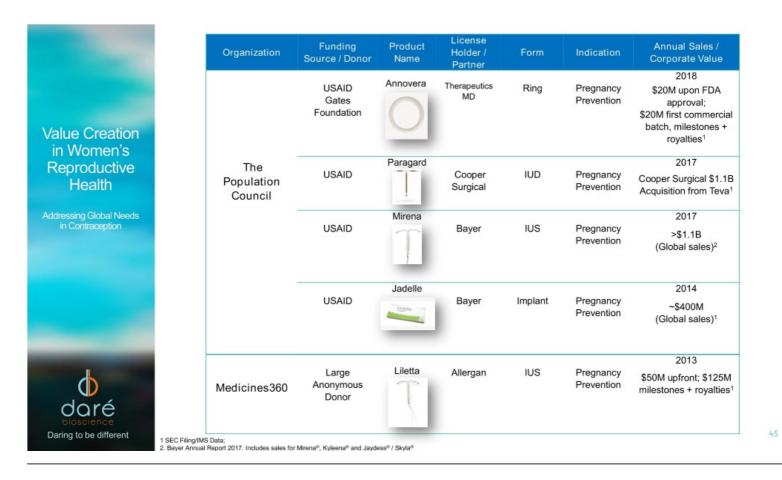


### Vaginally Delivered Tamoxifen for VVA DARE-VVA1





"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 Dare's NIH) BILL&MELINDA USAID Major foundations contribute hundreds of GATES foundation Innovation millions of dollars to fund new innovation in women's reproductive health. Engine Reproductive Health Public & Private Sector Funding CONRAD 360 @PATH fhi360 Development organizations screen and advance promising new innovation. POPULATION Daré has emerged as the coordinating presence among d these organizations and is well positioned to partner on the product candidates with significant market potential. dar Daring to be different



### 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.<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

## A New Long Acting Contraceptive Option

Microparticle 6 & 12 Month 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.

daré 1. Data on file

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# Corporate & Investor Communications

NASDAQ: DARE Trading as DARE since July 20, 2017



### www.darebioscience.com



**∲** daré





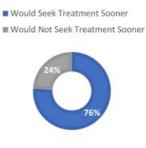
# Bacterial Vaginosis Market Insights

American Sexual Health Association (ASHA), in conjunction with Harris Poll, conducted a national survey of 304 women ages 18 to 49 who have had bacterial vaginosis (BV). The survey was conducted online by Harris Poll on behalf of Symbiomix Therapeutics, LLC, a Lupin company, and the ASHA within the United States between September 14 and 29, 2017 among 304 US women aged 18-49 who have been diagnosed by a healthcare professional with BV within the past 2 years ("women with bacterial vaginosis").

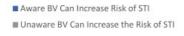
### Bacterial Vaginosis Market Insights American Sexual Health Association (ASHA) National Bacterial Vaginosis Survey

 <u>76%</u> of women with BV stated they would have gone to see a healthcare professional sooner if they were aware of the risks associated with BV if left untreated

 Only 43% of women with BV are aware that if left untreated, BV can cause an increased risk of sexually IF BV RISK FACTORS WERE KNOWN



#### AWARE OF LINK TO STI





http://www.ashasexualhealth.org/understanding-womens-experiences-with-bacterial-vaginosis/

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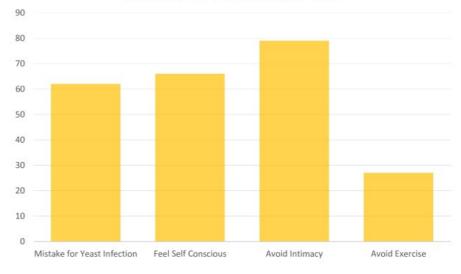
transmitted infections (STIs)

## **Bacterial Vaginosis Market Insights**

ces-with-bacterial-vaginosis/

American Sexual Health Association (ASHA) National Bacterial Vaginosis Survey

- According to the ASHA survey, 62% of women mistake BV for a yeast infection prior to diagnosis
- Most women with BV feel self-conscious (68%) and/or embarrassed (66%) due to their condition
- Women with BV avoid everyday activities including being intimate with their spouse/partner (79%), working out (27%), or going on a first date (17%)



### IMPACT OF BV ON DAILY LIFE

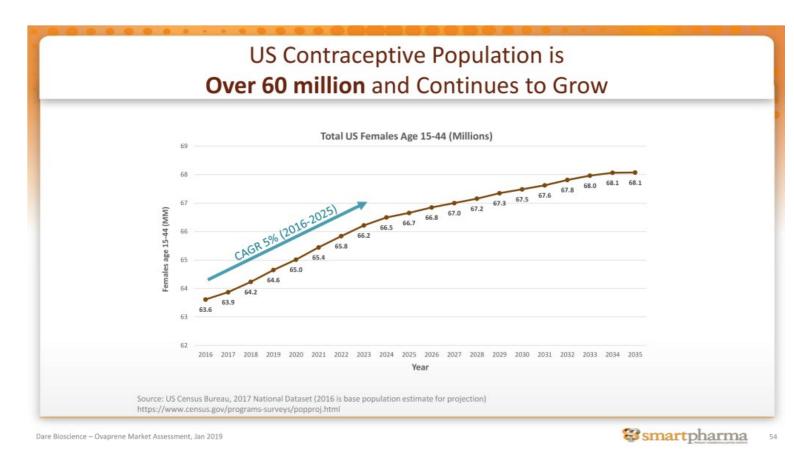
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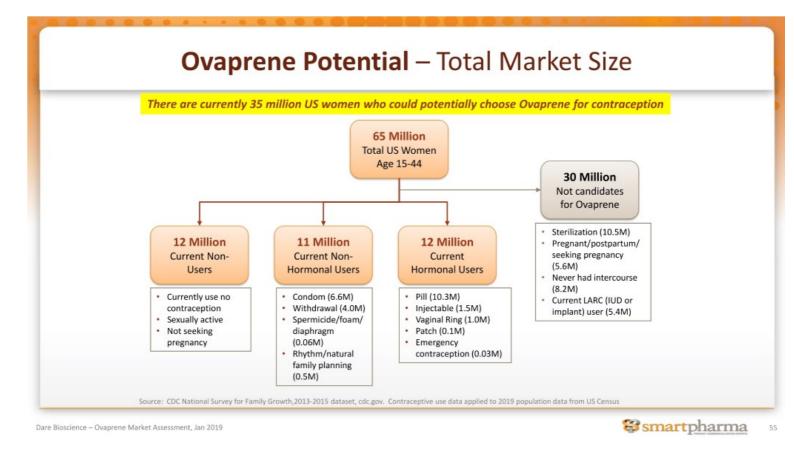
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# Ovaprene Market Insights

Secondary Market Research & Market Sizing Data Prepared by SmartPharma, February 2019. Data on File.





# **Negative Information** About Hormones is Persistent in the Public Domain

As a non-hormonal option, Ovaprene does not have to overcome myths or negative "press"

#### 5 Reasons Women Avoid Birth Control

- Reason #1: "I don't want to get fat"
- Reason #2: "It might make me depressed"
- Reason #3: "Birth control causes cancer"
- Reason #4: "I don't want to put chemicals in my body"
- Reason #5: "I'm not at risk for getting pregnant"

6 Reasons Why You Shouldn't Take The Pill Long Term

April 4, 2017 by Fertility Friday / 21 Comments

- The pill lowers your sex drive
- The pill shrinks your clitoris and causes painful sex
- The pill causes depression and anxiety
- Long term pill use puts you at an increased risk of cervical cancer
- Long term pill use is associated with a delay in your return to fertility



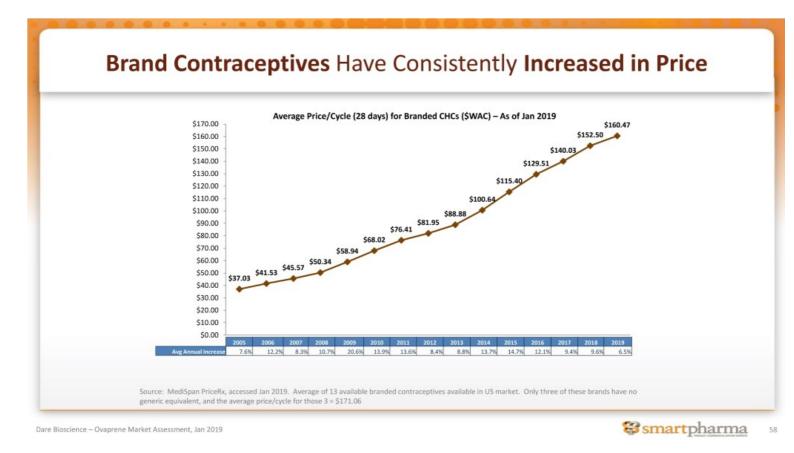
Dare Bioscience - Ovaprene Market Assessment, Jan 2019

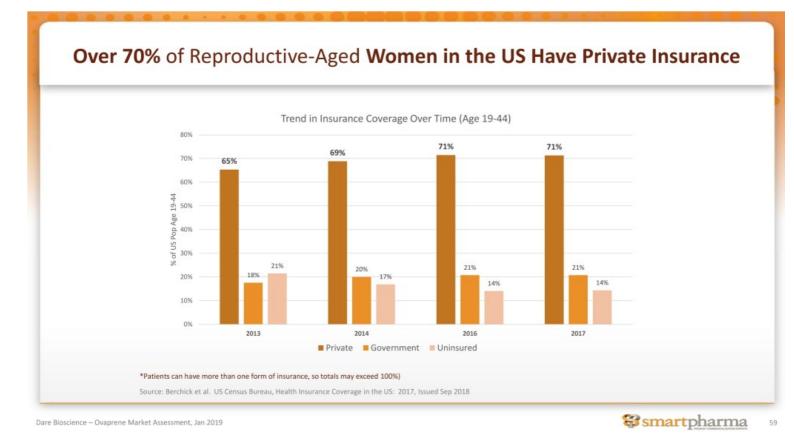
Smartpharma



Dare Bioscience - Ovaprene Market Assessment, Jan 2019

Smartpharma







ACA Contracept				
Current Status of Co	ntracept	ive Polic	CV .	
	Minimum Contraceptive Coverage Requirements Clarified by HHS Guidance			
<ul> <li>Insurance plans must cover all FDA-</li> </ul>	Contraceptive Method	Products/Options	Must Cover	
approved methods with no copay or cost	Surgical sterilization	Also called tubal ligation	4	
	Implant sterilization	Only Essure available	4	
sharing to patients <sup>1</sup>	Implantable Rod	Multiple	√at least 1	
<ul> <li>They must cover at least one type of each method</li> </ul>	IUD ~ Copper	Only ParaGard available	4	
in each category	IUD - Progestin	Multiple	√at least 1	
<ul> <li>62.8 million women (age 18-64) now have</li> </ul>	Injection	Multiple	√ at least 1 (may be generic)	
birth control coverage with no cost sharing <sup>2</sup>	Oral contraceptives - combined	Multiple	√ at least 1 (may be generic)	
<ul> <li>Exemptions and accommodations for religious</li> </ul>	Oral Contraceptives - progestin only	Multiple	√at least 1 (may be generic)	
and moral objections are in place, but they affect only 6.400 to 127,000 women <sup>3</sup>	Oral Contraceptives - extended/continuous use	Multiple	√at least 1 (may be generic)	
<ul> <li>The latest attempts by the current administration</li> </ul>	Patch	Multiple**	√ at least 1 (may be generic)	
to broaden the exemption has been blocked by	Vaginal Ring	Only NuvaRing available	1	
two federal courts⁴	Diaphragm with Spermicide	Only Milex Omnifiex available	1	
<ul> <li>If Ovaprene is approved, it has the potential</li> </ul>	Sponge with Spermicide	Only Today Sponge available	v/*	
	Cervical Cap with Spermicide	Only FemCap available	1	
to be the only product in the category, as it	Female Condom	Multiple	v <sup>lu</sup>	
is a vaginal ring with a spermiostatic active.	Spermicide alone	Multiple	√at least 1 (may be generic)*	
	Emergency Contraception- Progestin	Multiple	v <sup>1</sup> at least 1 (may be generic)*	
	Emergency Contraception- Ulipristal Acetate	Only ella available	v	
<sup>1</sup> www.HealthCare.gov/coverage/birth-control-benefits/ <sup>2</sup> National Women's Law Center Fact Sheet, Nov 2018 <sup>3</sup> HHS Fact Sheet, Nov 7 2018 <sup>Q</sup> National Women's Law Center Fact Sheet, Oct 2018 and Washington Post, Jan 14, 2019	*Approved for sale over-the-counter but only covered at no cost with a prescription. **The manufacturer of the brand name (OrthoEvral patch has discontinued production and the generic alternative will be the only patch available. SQURCES: FMA, Binh Control Guide and Depts of Labor. Health and Human Services. and Treasury. FAGs about			



# Sildenafil Cream, 3.6% FSAD Demographic Insights & Concept Test

Market Research Report Conducted by Ad Hoc Research on behalf of Strategic Science & Technologies, LLC. 222 Third Street, Suite 2242, Cambridge, MA 02142 – December 2015

# FSAD - Psychological & Physiological Impact



**∲** daré

#### The Current Experience of FSAD Sufferers

(Physical and Psychological)

# Experience of FSAD Sufferers

- The concept definitely has potential. FSAD sufferers are likely to purchase it and are willing to give it a try.
- A few questions remain:

They often feel	They do not often feel
The inability to attain an adequate level of sexual excitement	Genital tenseness or tightness
The lack of desire for intimacy	Genital pulsing or throbbing
Lack of genital or clitoral fullness, pressure or engorgement	The feeling of muscle contractions in their genitals
Lack of genital wetness or lubrication	The feeling of readiness
	Satisfaction with their level of physical arousal

## Experience of Female Sexual Arousal Disorder (FSAD) Sufferers

#### 3. What is the psychological impact of this disorder?

- The impact appears to be immense. Emotions run the gamut from dissatisfaction with to anger about their sex lives.
- The most frequent feelings include:
- · Dissatisfaction with their sex lives;
- · Bothered by their low sexual desire;
- Unhappiness about their sexual relationships; and
- Frustration due to their sexual problems.
- Thus, conveying an understanding of these feelings, either in claims, in communications or both, will promote interest in the product.



#### 4. What "remedies" have they tried to combat the disorder?

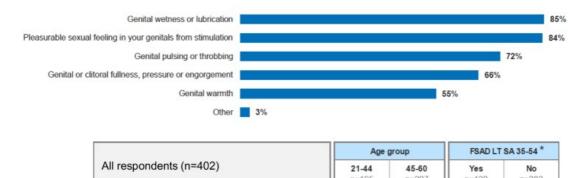
the average number of remedies tried to combat FSAD

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- Almost all FSAD sufferers surveyed have tried "something" to treat their difficulties getting or staying physically aroused.
- The most common are **topical lubricants** and **a vibrator/other accessory** for stimulation.

Source data on File: Research Report -December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 41-47.

## Female Sexual Arousal Disorder (FSAD) Respondents Indicators of Sexual Arousal



All respondents (n=402)	<b>21-44</b> n=195	<b>45-60</b> n=207	Yes n=120	<b>No</b> n=282
Genital wetness or lubrication	87%	81%	83%	85%
Pleasurable sexual feeling in your genitals from stimulation	84%	84%	85%	84%
Genital pulsing or throbbing	75%	69%	69%	74%
Genital or clitoral fullness, pressure or engorgement	65%	68%	66%	66%
Genital warmth	58%	50%	51%	56%
Other	3%	2%	2%	3%

SA - currently sexually active 35-54 - ages of 35 to 54

**∲** daré

Source data on File: Research Report - December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 41-47.

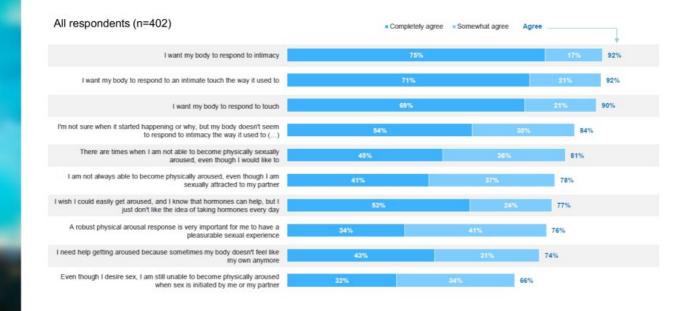
## Female Sexual Arousal Disorder (FSAD) Respondents Signs & Symptoms

Inability to attain an adequate level of sexual excitement	27%		55%	82%
Lack of desire for intimacy	22%		59%	81%
Lack of genital or clitoral fullness, pressure or engorgement	20%		62%	81%
Lack of genital wetness or lubrication	31%		47%	78%
Any genital feeling	34%		43%	78%
Pleasurable genital or clitoral sensitivity to the touch	15%	55%		70%
Feeling of sexual turn off	14%	53%	67	%
Pleasurable sensation in your genitals	11%	54%	65%	
Desire to have a sexual experience	14%	46%	60%	
Discomfort or pain when having intercourse with a partner	20%	39%	59%	
Feeling receptive to a partner's sexual initiation	11%	47%	58%	
Feeling of mental excitement	11%	47%	58%	
Feeling of warmth or tingling in genitals	9%	47%	57%	
Thinking or fantasizing about having sex	15%	42%	57%	
Genital tenseness or tightness	13%	41%	54%	
Genital pulsing or throbbing	4%	50%	54%	
Feeling of muscle contractions in genitals	11%	42%	54%	
Feeling of readiness	9%	44%	52%	

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Source data on File: Research Report - December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 41-47.

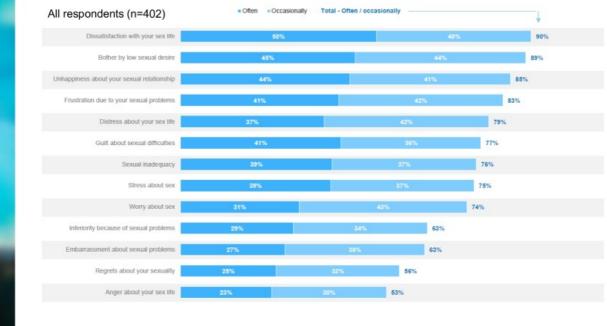
## Psychological Impact of FSAD



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Source data on File: Research Report -December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 41-47.

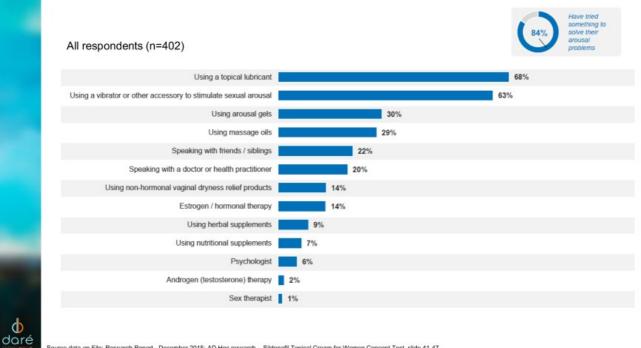
## Psychological Impact of FSAD



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Source data on File: Research Report -December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 41-47.

### Without an FDA Approved Product for FSAD, Women's Options are Suboptimal

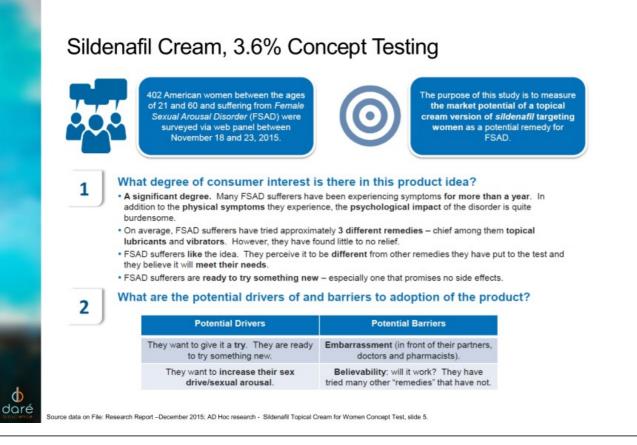


Source data on File: Research Report -December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 41-47.

## Sildenafil Cream, 3.6% Product Profile Market Research



Sildenafil Cream, 3.6% Concept Test



## Sildenafil Cream, 3.6% Concept Testing

#### What are the most motivating claims?

• In concrete terms, the elements of the concept they like the most are:

- ✓ No side effects (the #1 claim, by a very wide margin);
- Proven safe;

3

- Clinically tested;
- Odorless;
- Absorbs completely;
- Available without a prescription.

• Any support point that enhances the legitimacy of the product is naturally motivating, be it:

- Doctor recommended;
- Available by prescription only for two years before being available without a prescription;
- ✓ The same active ingredient as in Viagra (although slightly less so than the previous two).



Source data on File: Research Report -December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 6.



## Sildenafil Cream, 3.6% Concept Testing - Cream Formulation

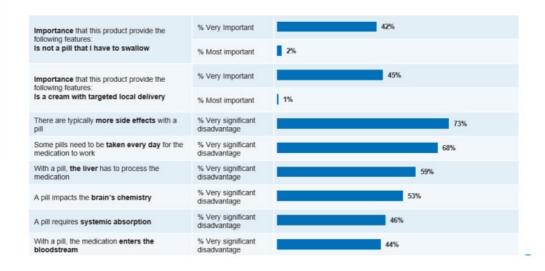
4

#### It's not a pill. How do FSAD sufferers react to that?

· Pills tend to be synonymous with side effects, need to be taken regularly to be effective and their contents are

metabolized by the liver because they enter the bloodstream. · FSAD sufferers agree that these are the primary disadvantages of pills.

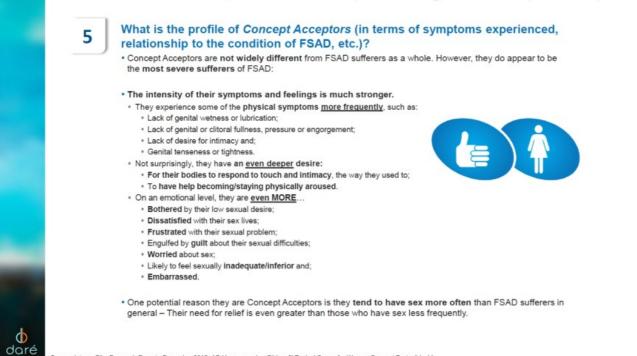






Source data on File: Research Report -December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 10.

## Sildenafil Cream, 3.6% Concept Testing - Concept Acceptors



Source data on File: Research Report -December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slide 11.

## Sildenafil Cream, 3.6% Concept Testing – Purchase Interest

- 82% of respondents indicated they would be likely to purchase the product if it were currently available.
- A subgroup of respondents aged 35-54 had a higher purchase interest (86%) vs. the aggregate (82%).

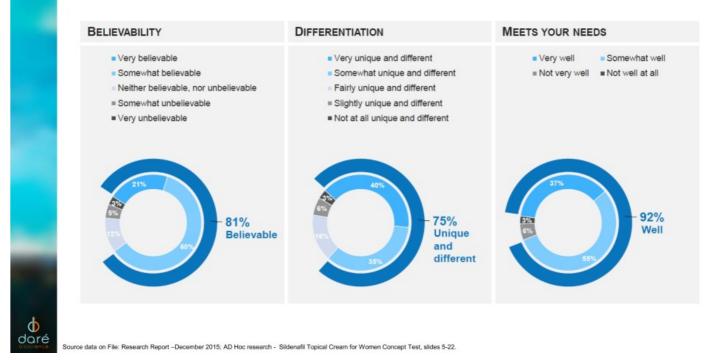
	Total n=402	Age g	roup	FSAD LT SA 35-54		
		<b>21-44</b> n=195	<b>45-60</b> n=207	Yes n=120	<b>No</b> n=282	
Likely	82%	81%	84%	86%	80%	
Very likely	35%	31%	39%	46% 🕈	29% 🔸	
Somewhatlikely	47%	50%	44%	40% +	51% 🕈	
Neither likely, nor unlikely	10%	9%	12%	10%	10%	
Unlikely	8%	11% 🕈	5% 🔸	4%	10%	
Somewhat unlikely	4%	6%	3%	2%	6%	
Very unlikely	4%	5%	2%	2%	4%	

\* LT- in a long-term relationship SA - currently sexually active 35-54 - ages of 35 to 54

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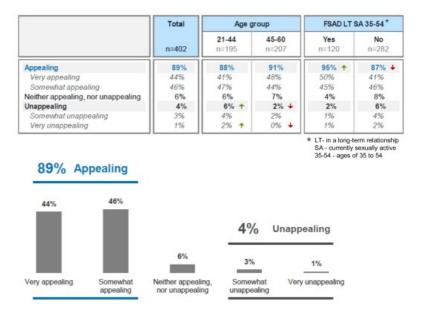
Source data on File: Research Report – December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, sildes 5-22.

## Sildenafil Cream, 3.6% Concept Testing - Believability & Viability



## Sildenafil Cream, 3.6% Concept Testing - Concept Appeal

- The majority of respondents (89%) considered the concept appealing.
- The largest proportion of respondents to consider the concept very appealing were women between the ages of 35-54.



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Source data on File: Research Report – December 2015; AD Hoc research - Sildenafil Topical Cream for Women Concept Test, slides 5-22.