

## Forward Looking Statements

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

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



## Accelerating Innovation in Women's Health Market Misalignment is a Value Creation Opportunity

Innovators seeking development partners to advance

products to commercialization in women's health.

Network of Product Developers ... Strategic Science & Technologies



Large and mid-tier companies prefer to acquire or license products that are later-stage or ready for commercialization.





# Daring to be different

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

Our focus areas include:

- Contraception / Pregnancy Prevention
- Sexual Health
- Vaginal Health
- Fertility

Licensing, Partnering & Value Creation Strategy:

- · The portfolio is well positioned to drive upside
- Product candidates 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
  - Candidates with the potential to be first-in-category that address persistent unmet needs in women's health
  - The ability to deliver products in a more personalized way for women

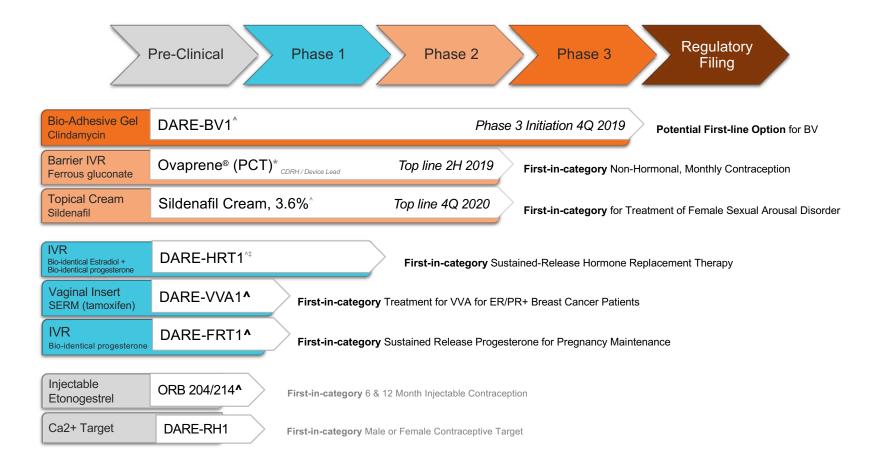


## Daring to be different

We expect to deliver against multiple milestones over the next 12 - 24 months including:

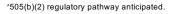
- Advancing our DARE-BV1 Bacterial Vaginosis (BV) program into a Phase 3 trial
- **Topline readouts** from our two pre-pivotal programs:
  - Ovaprene (2H 2019) and
  - Sildenafil Cream, 3.6%, (4Q 2020)
- Moving preclinical programs into Phase 1 development
  - DAER-HRT1 Hormone Replacement Therapy (HRT/VMS) Phase 1 (2019)
  - DARE-FRT1 Fertility and Pregnancy Maintenance (PTB/ART) Phase 1 (2020)
  - DARE-VVA1 –VVA in ER/PR+ Breast Cancer patients Phase 1 (2020)





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

Timeline reflects management's current estimates and constitutes a forward looking statement subject to qualifications elsewhere in the presentation. Actual development timeline may be substantially longer, and Daré is under no obligation to update or review this estimate. "First-in-category" designations are forward looking statements based on currently available, FDA approved therapies.

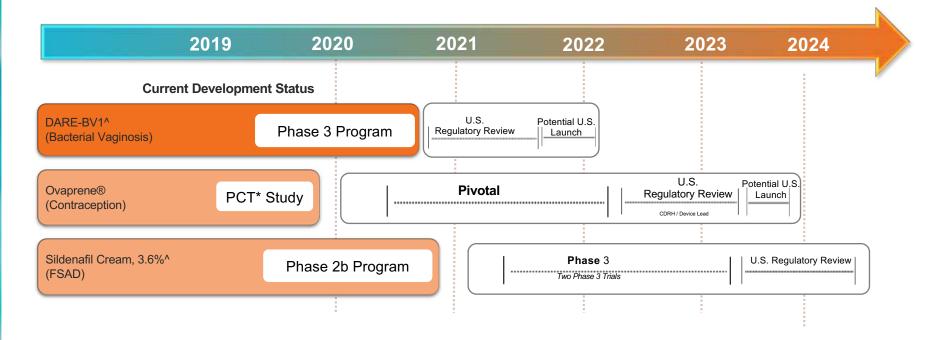


\*Ovaprene Post Coital Test (PCT) is a pre-pivotal clinical study.\*

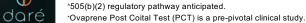
<sup>‡</sup>HRT Phase 1 study to be conducted in Australia by Daré subsidiary.



#### Portfolio Timeline Overview



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



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# Program Overview



## DARE-BV1 Overview

DARE-BV1

Phase 3 Initiation 2H 2019

Bacterial Vaginosis (BV)

## Successful Proof of Concept

- Vaginal application of DARE-BV1 (clindamycin phosphate 2%) demonstrated effectiveness against BV in a proof-of-concept investigator initiated study in women (n=30):1
  - 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%) 3
- Opportunity for significant upside and market expansion

## Patent Coverage

- Patents covering the licensed technology have been granted with terms through 2028
- Additional patents pending would have terms through 2035
- 1. Data on file



# Gel Delivery Technology

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



# Bacterial Vaginosis DARE-BV1 Proof of Principle Study Design

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

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

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

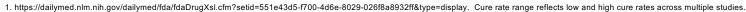


# Bacterial Vaginosis DARE-BV1 Proof of Principle Study Design

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
d daré	DARE-BV1 novel gel (clindamycin)	88%	57%*	57%*
	Solesec®1 (secnidazole 2g oral granules)	53-68%	40-46%	35-40%
Perrigo	Clindesse®2 clindamycin phosphate Vaginal Cream, 2%	41-64%	45-57%	30-42%
(}Allergan	Metrogel, 1.3% <sup>3</sup>	37%	20%	17%

- \* Based on data from 9 evaluable patients
- 26 of 30 women completed the study
- Test-of-Cure Visit (Day 7 14)
  - · 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



<sup>2.</sup> 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



## DARE-BV1

#### **Bacterial Vaginosis Opportunity Overview**

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

Proof of principal study complete

- o 88% clinical cure rate in evaluable subjects
- o favorable efficacy profile compared to currently approved treatments

Same API (clindamycin phosphate 2%) as in currently approved treatment

**Low Clinical Risk** 

Single Phase 3 clinical trial for FDA approval <sup>1</sup> Exploiting the 505(b)2 regulatory pathway

Low Development Cost
Anticipate less than \$10 million
(Includes manufacturing, clinical trial, regulatory filing & action)

Approximately 21 M cases of BV reported annually in the US

Approved prescription drugs have low patient share due to limited efficacy

Opportunity for upside and market expansion

Significant Market Opportunity





# New Contraceptive Option Ovaprene® Overview

## Successful Proof of Concept Study

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

## CDRH (Device) Regulatory Pathway

Single pivotal clinical trial expected for FDA approval

## **Attractive Market Opportunity**

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



<sup>1.</sup> Journal of Reproductive Medicine 2009; 54: 685-690

<sup>2.</sup> IMS NSP through Dec 2016

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®
  - Monthly, convenient vaginal ring product form.
  - 2017 worldwide sales: \$761 million (Merck)<sup>5</sup>
- Mirena® Product Family
  - · Physician inserted, long-acting.
  - · Low/locally delivered hormone IUS.
  - 2017 worldwide sales: \$1.12 billion (Bayer)<sup>7</sup>
- 1. Lo Loestrin Fe contains a low-dose combination of two female hormones. https://www.loloestrin.com/loloestrin.com/loloestrin.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. Annual Report on Form 10-K for fiscal year ended December 31, 2017
- 6. Bayer Annual Report 2017. Includes sales for Mirena®, Kyleena® and Jaydess® / Skyla®



## Ovaprene® Overview

### Women's Preferences

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

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# 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 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	21	2.4	
Fertility awareness-		10000			
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, lefty/kream and other methods, NOTE; "At risk" refers to women who are sexually active; not pregnant, seeking to become pregnant or postportum, and not noncontraceptivel sterile na-not applicable.

www.guttmacher.org



<sup>1.</sup> Lessard, L,Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012

<sup>2.</sup> https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states

<sup>3.</sup> Hooper, DJ, Clin Drug Investig. 2010;30(11):74963

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

#### Hormone Free Product Landscape **Least Effective** Spermicides / Vaginal Gels 100% Effective = 0% Risk of Pregnancy Effectiveness (72% Typical Use) Woman controlled Birth Control Effectiveness Method Perfect Use Typical Use Used "in the moment" Spermicide\* / Vaginal Gels 82.00% 72.00% Condoms Sponge-Parous\* 76.00% 88.00% Sponge-Nulliparous\* 91.00% Effectiveness (82% Typical Use) Condom (male)\* 98.00% 82.00% Not woman controlled Diaphragm\* 88.00% 94.00% Combined Pill & Progestin only\* 99.70% 91.00% Used "in the moment" Evra Patch® 91.00% 99.70% Nuva Ring\* 99.70% 91.00% Diaphragms Depo-Provera\* 99.80% 94.00% Effectiveness (88% Typical Use) IUD- ParaGard (Copper T)\* 99,40% 99.80% IUD- Mirena (LNg)\* 99.80% 99.80% Woman controlled Implanon\* 99.95% 99.95% Female Sterilization\* 99.50% 99.50% Used "in the moment" Male Sterilization\* 99.90% 98.85% Long-acting IUD Effectiveness (99% Typical Use) Not woman controlled Most Effective Physician inserted



Ovaprene® Overview

Ovaprene® Non-hormonal, Monthly Vaginal Ring

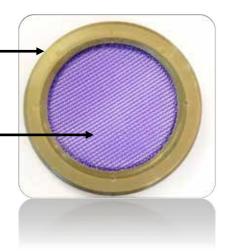
Spermiostatic Environment<sup>1</sup>

- · 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.





Ovaprene® Overview

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

- 2009 Postcoital Assessment:
  - 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.

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%
Diaphragms*	94.00%	88.00%
Combined Pill & Progestin only*	99.70%	91.00%
Evra Patch*	99.70%	91.00%
Nova Ring*	99.70%	91,00%
Depo-Provera*	99.80%	94.00%
IUD- ParaGard (Copper T)*	99.40%	99.80%
IUD- Mirena (LNg)*	99.80%	99.80%
Implanon*	99.95%	99.95%
Female Sterilization*	99.50%	99.50%
Male Sterilization*	99.90%	98.85%

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



<sup>2.</sup> 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.

<sup>3.</sup> http://www.contraceptivetechnology.org/wp-content/uploads/2013/09/CTFailureTable.pdf

### Ovaprene® Overview

#### U.S. Regulatory Strategy

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

#### Step 1 – Postcoital test (PCT) 2018 / 2019\*

- 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.
  - 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.

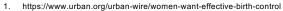
#### Step 2 – Pivotal Study 2020 / 2021\*

- 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.



# New Contraceptive Option Ovaprene® Overview

Features Desired Most in Birth Control:1-4	Design Features of Ovaprene: <sup>5,6</sup>
Convenience (Easy to Use & Easy to Remember)	Monthly Ring Product Form  Women chose rings for the convenience of a non-daily option.
Hormone Free	No Hormones in the API Unique dual action MOA (spermiostatic & barrier).
	Expected Typical Use Effectiveness Comparable to Hormone Contraception (88% vs 91%).
	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.

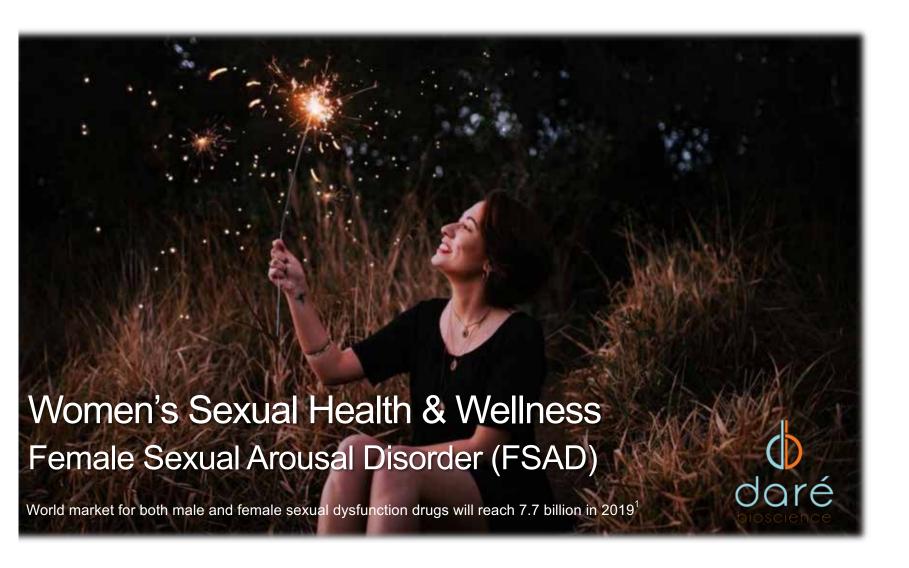


Lessard, L,Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012

<sup>3.</sup> Hooper, DJ, Clin Drug Investig. 2010;30(11):74963 Ersek, J, Matern Child Health J (2011) 15:497-506

Journal of Reproductive Medicine 2009; 54: 685-690

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.



### Female Sexual Arousal Disorder (FSAD) Sildenafil Cream, 3.6%

Topical Cream Sildenafil Cream, 3.6% Top line 4Q 2020

## Successful Proof of Concept

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

## 505(b)(2) Regulatory Pathway

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

## Attractive Market Opportunity<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

- 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



Sildenafil Cream 3.6%

**Dyspareunia** 

Vulvar-Vaginal Atrophy

Hypoactive Sexual Desire Disorder (HSDD) Female Sexual Arousal Disorder (FSAD)











No Approved Products

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

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

- INTRAROSA is a registered trademark of Endoceutics, Inc.
- Imvexxv 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.

# Female Sexual Arousal Disorder (FSAD) Sildenafil Cream 3.6%

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

- Estimated 23-33% of women suffer from arousal disorder:
  - Meta-analysis of 95 studies from 2000-2014 indicated the prevalence of Female Sexual Dysfunction in premenopausal women worldwide is 40.9%, and difficulty with arousal alone is 23%.
  - 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 <u>distressed</u> and actively seeking treatment.<sup>2</sup>

<sup>\*</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.



<sup>2.</sup> Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.

3. Based on US Census projections for 2016.



## Female Sexual Arousal Disorder (FSAD) Sildenafil Cream 3.6%

Key Takeaways of Viagra® studies:

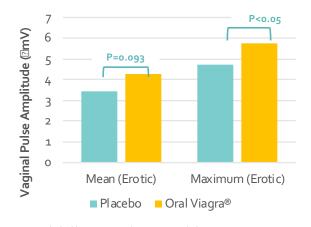
- · Oral sildenafil (Viagra) demonstrated statistically significant activity
- Side effects of the oral formulation led to the investigation of a new topical route of administration

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>

#### Pfizer VPA Clinical Lab Study - Oral Viagra

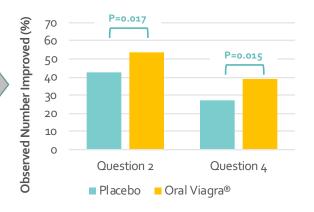
#### Mean and Maximum VPA†





#### Pfizer Clinical Field Study - Oral Viagra

# Improvement on FIEI Questions†



#### 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.

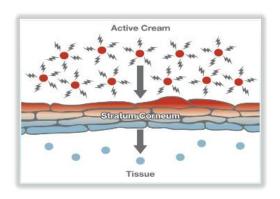


<sup>2.</sup> Safety and Efficacy of Sildenafil Citrate for the Treatment of FSAD: A Double-Blind, Placebo Controlled Study. The Journal of Urology. Vol 170, 2333-2338, December 2003.

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.



Sildenafil Cream, 3.6%

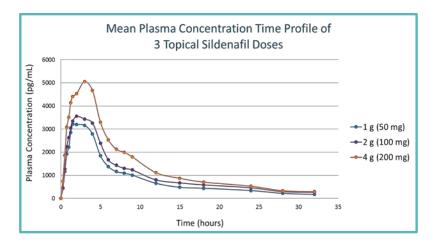
Phase 1 Study of SST-6007 (Sildenafil Cream, 3.6%)<sup>1</sup>

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

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

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%

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

→

#### **Content Validity**

Initiated (4Q 2018)

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

#### Planned Type C Meeting

 We will request at Type C meeting to get feedback on whether the agency agrees that the patient reported outcomes (PRO) instruments are content valid for the target population.

#### At Home Study

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

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

#### Key Takeaways:

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



# Female Sexual Arousal Disorder (FSAD) Sildenafil Cream 3.6%

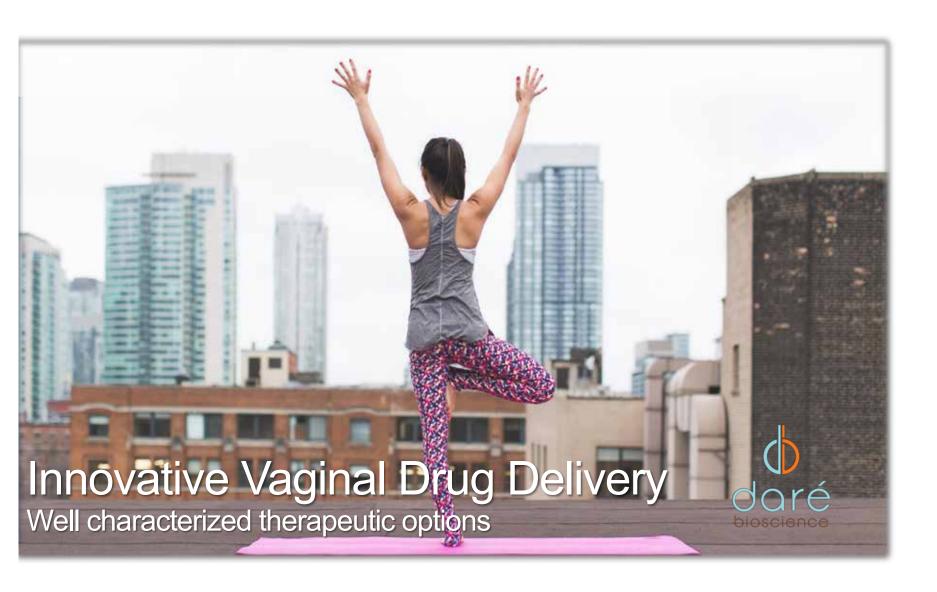


With its approval of Addyi®, FDA has now acknowledged and formally classified the distinct and separate disorders that comprise Female Sexual Dysfunction.

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.





# Intravaginal Ring (IVR) Technology Platform

Daré has an exclusive, global license to Juniper's novel IVR technology originally developed by Dr. Robert Langer from MIT¹ and Dr. William Crowley² 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-HRT1

 Formerly JNP-0201, a combination bio-identical estradiol + bio-identical progesterone ring for hormone replacement therapy

#### DARE-FRT1

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



# Hormone Replacement Therapy (HRT)

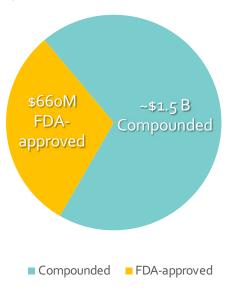
DARE-HRT1 (bio-identical estradiol + progesterone)



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

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





<sup>1.</sup> 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

<sup>2.</sup> U.S. Census Bureau, Population Division. Table 2. 2015 to 2060 (NP2012-T2). Released Dec. 2012.

<sup>3.</sup> Menopause, Vol. 19, No. 3, 2012.

### Hormone Replacement Therapy (HRT)

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

#### Phase 1 - HRT

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

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



## **Pregnancy Maintenance**

DARE-FRT1 (bio-identical progesterone)

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



https://www.grandviewresearch.com/press-release/global-assisted-reproductive-technology-market



## Vaginally Delivered Tamoxifen for VVA DARE-VVA1



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

- DARE-VVA1 (Formerly PT-101)
  - A proprietary formulation of tamoxifen for vaginal administration.
  - Potential to be the first treatment specifically approved for the treatment of vulvar and vaginal atrophy (VVA) in patients with hormone-receptor positive (HR+) breast cancer.
- VVA is a chronic condition characterized by pain during intercourse, vaginal dryness and irritation.
  - Most women use localized estrogen therapy which is contraindicated for the more than two million women diagnosed with, or at risk of recurrence of, ER-positive and PR-positive breast cancer.<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 anticancer 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>

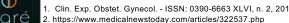


## Vaginal Tamoxifen – Proof of Concept Study<sup>1</sup>

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

Vaginal Tamoxifen	Enrollment (Baseline)	On Treatment (Month 3)	Paired Difference (Baseline vs. Month 3)
Median Vaginal pH  Lower pH value is a measure of symptom relief  Normal vaginal pH is usually less than 4.5.2	<b>7.1</b> range 6.5 to 7.5	<b>5.0</b> range 5.0 to 5.2	<b>-2.0 median</b> range -2.5 to -1.5
Vaginal Dryness  Rated using a visual analogue scale (VAS) that ranged from:  0 = Not bothered by dryness  10 = Extremely bothered by dryness  Decreased vaginal dryness is a measure of symptom relief	<b>8.0</b> range of 7.5 to 9.0	<b>3.0</b> range 2.0 to 3.0	<b>-5.5 median</b> range -6.0 to -4.5

- In addition, systemic absorption of tamoxifen was not significant.
  - After 8 weeks of study treatment with vaginal tamoxifen, the median plasma concentration of tamoxifen was 5.8 ng/ml, with a range of 1.0 to 10.0 ng/ml
  - In comparison, after 3 months of administration of 20mg, once-daily oral tamoxifen citrate (Nolvadex),<sup>2</sup> the average steady state plasma concentration of tamoxifen is **122 ng/ml** with a range of 71 to 183 ng/ml



<sup>3.</sup> US Food and Drug Administration: "Drug Approval Package: Nolvadex (Tamoxifen Citrate) NDA# 21-109.2002". Available at: https://www.accessdata.fda.gov/drugsatfda docs/nda/2002/21109 Nolvadex.cfm





## A New Long Acting Contraceptive Option Microparticle 6 & 12 Month Injectable Contraception

Injectable ORB 204 & 214^

## 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.



# A New Contraceptive Target DARE-RH1 CatSper

Ca2+ Target DARE-RH1

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.





# **Investment Highlights**

### Financial Profile

### **Background**

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

#### Balance sheet, December 31, 2018:

- \$6.8 million in cash
- Non-dilutive NIH SBIR Award:
  - In Q1-2019 Daré received a second Notice of Award of \$982,851, part of a grant providing up to \$1.9 million in the aggregate for Ovaprene® research from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH). The first award under the grant in 2018 was \$224,665.
  - This second Notice of Award, for the additional \$982,851, followed the NIH's review of a data analysis and other results of the first phase of work.
- 11.4 million common shares and 3.75 million warrants outstanding
- No debt



## Management Team Daré Bioscience

Sabrina Martucci Johnson, MSc, MIM 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



## **Corporate & Investor Communications**

NASDAQ: DARE Trading as DARE since July 20, 2017







www.darebioscience.com







## 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").

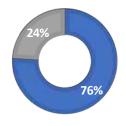
# Bacterial Vaginosis Market Insights American Sexual Health Association (ASHA) National Bacterial Vaginosis Survey

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

#### IF BV RISK FACTORS WERE KNOWN

■ Would Seek Treatment Sooner

■ Would Not Seek Treatment Sooner

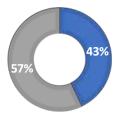


#### Only 43% of women with BV are aware that if left untreated, BV can cause an increased risk of sexually transmitted infections (STIs)

#### **AWARE OF LINK TO STI**

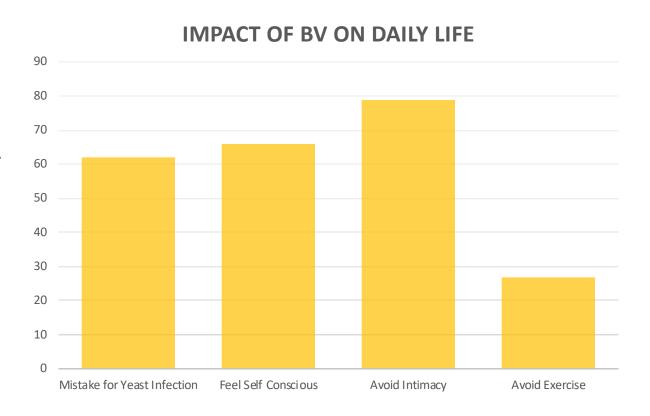
■ Aware BV Can Increase Risk of STI

■ Unaware BV Can Increase the Risk of STI



# Bacterial Vaginosis Market Insights 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%)



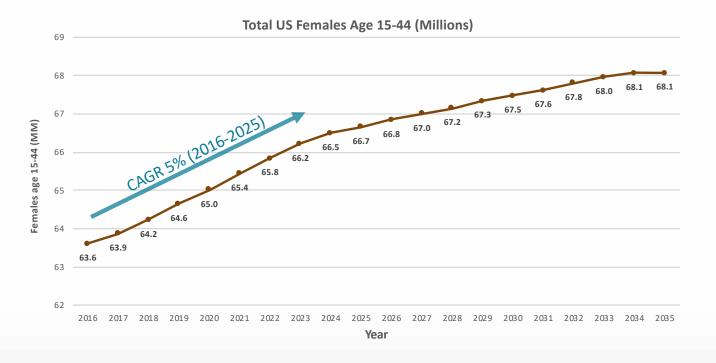




## Ovaprene Market Insights

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

# US Contraceptive Population is Over 60 million and Continues to Grow

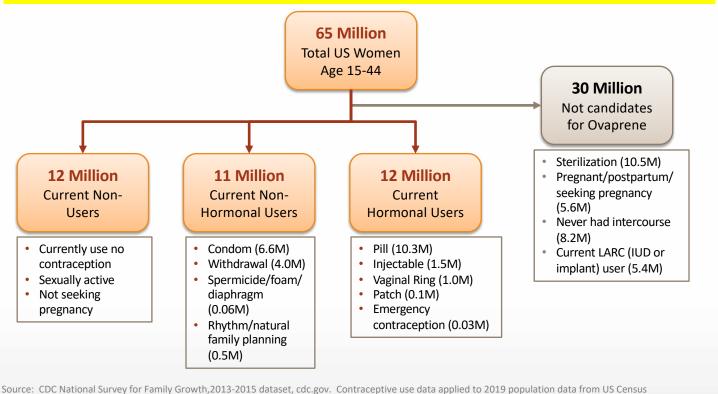


Source: US Census Bureau, 2017 National Dataset (2016 is base population estimate for projection) https://www.census.gov/programs-surveys/popproj.html



## Ovaprene Potential – Total Market Size

There are currently 35 million US women who could potentially choose Ovaprene for contraception



# **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"

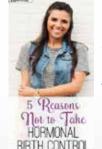
Reason #4: "I don't want to put chemicals in my body"

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



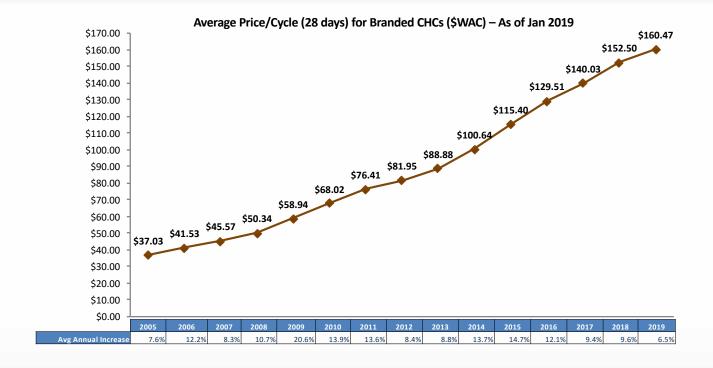
- 1. Hormonal Birth Control Comes with Side Effects
- 2. Birth Control is Full of Hormones/Chemicals
- 3. Birth Control Works Against Your Body
- 4. Birth Control \*May\* Cause Abortions
- 5. A Whole Host of Other Reasons

Sources:

HelloFlo, Mar 22, 2017, www.helloflo.com
Fertility Friday, April 4,2017, www.fertilityfriday.com
Equipping Godley Women, April 15, 2015, www.equippinggodleywomen.com

# **Contraceptive Pricing and Reimbursement**

## Brand Contraceptives Have Consistently Increased in Price

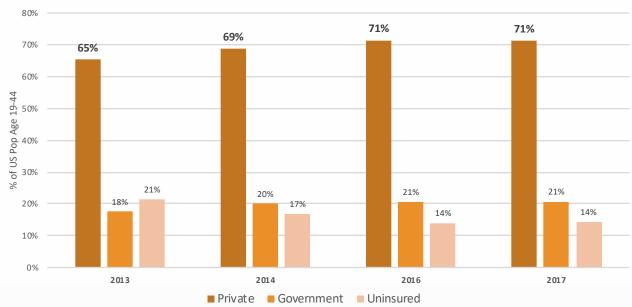


Source: MediSpan PriceRx, accessed Jan 2019. Average of 13 available branded contraceptives available in US market. Only three of these brands have no generic equivalent, and the average price/cycle for those 3 = \$171.06



## Over 70% of Reproductive-Aged Women in the US Have Private Insurance





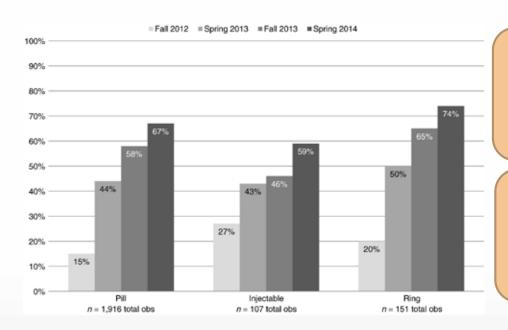
\*Patients can have more than one form of insurance, so totals may exceed 100%)

Source: Berchick et al. US Census Bureau, Health Insurance Coverage in the US: 2017, Issued Sep 2018

# Most Women Pay \$0 For Birth Control Since the ACA Was Enacted

#### Percent of Women with \$0 Copay for Birth Control Over Time

(n=892 women age 18-39 with private health insurance who used a prescription contraceptive method)



By spring 2014, mean and median out-of-pocket costs for the pill were \$6.48 and \$0 per month, respectively

HHS issued a clarification in May 2015 that required coverage of at least 1 product per method with \$0 copay – therefore the percentages have likely increased since this data

Sources:

Guttmacher Institute Continuity and Change in Contraceptive Use Study in: Sonfeld A, et al. Contraception 2015;91:44-48 US Dept of Health and Human Services (HHS) FAQs About ACA Implementation (Part XXVI), www.cms.gov



# ACA Contraceptive Mandate: Current Status of Contraceptive Policy

- Insurance plans must cover all FDAapproved methods with no copay or cost sharing to patients<sup>1</sup>
  - They must cover at least one type of each method in each category
- 62.8 million women (age 18-64) now have birth control coverage with no cost sharing<sup>2</sup>
  - Exemptions and accommodations for religious and moral objections are in place, but they affect only 6,400 to 127,000 women<sup>3</sup>
  - The latest attempts by the current administration to broaden the exemption has been blocked by two federal courts<sup>4</sup>
- If Ovaprene is approved, it has the potential to be the only product in the category, as it is a vaginal ring with a spermiostatic active.

Contraceptive Method	Products/Options	Must Cover		
Surgical sterilization	Also called tubal ligation	√		
Implant sterilization	Only Essure available	✓		
Implantable Rod	Multiple	√at least 1		
IUD - Copper	Only ParaGard available	✓		
IUD - Progestin	Multiple	Çt least 1		
Injection	Multiple	√at least 1 (may be generic)		
Oral contraceptives - combined	Multiple	√at least 1 (may be generic)		
Oral Contraceptives - progestin only	Multiple	√at least 1 (may be generic)		
Oral Contraceptives - extended/continuous use	Multiple	√at least 1 (may be generic)		
Patch	Multiple**	√at least 1 (may be generic)		
Vaginal Ring	Only NuvaRing available	√		
Diaphragm with Spermicide	Only Milex Omniflex available	4		
Sponge with Spermicide	Only Today Sponge available	y <sup>ta</sup>		
Cervical Cap with Spermicide	Only FemCap available	√		
Female Condom	Multiple	yle:		
Spermicide alone	Multiple	√at least 1 (may be generic)*		
Emergency Contraception- Progestin	Multiple	√at least 1 (may be generic)*		
Emergency Contraception- Ulipristal Acetate	Only ella available	√		

\*Approved for sale over the counter but only covered at no cost with a prescription.

\*\*The manufacturer of the brand name (OrthoEvra) patch has discontinued production and the generic alternative will be the only patch available.

SOURCES: FDA, Birth Control Guide and Depts of Labor, Health and Human Services, and Treasury, FAQs about Affordable Care Act Implementation (Part XXVI).



¹www.HealthCare.gov/coverage/birth-control-benefits/

<sup>&</sup>lt;sup>2</sup>National Women's Law Center Fact Sheet, Nov 2018

<sup>&</sup>lt;sup>3</sup>HHS Fact Sheet, Nov 7 2018

<sup>&</sup>lt;sup>4</sup>National Women's Law Center Fact Sheet, Oct 2018 and Washington Post, Jan 14, 2019



## 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



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:
  - 1. What do they currently experience during sexual activity that they are hoping the cream will rectify?

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

#### 2. What are their main physical desires when it comes intimacy?

- They are desperate for their bodies to respond, be it to...
- Intimacy;
- · An intimate touch;
- Touch.





## 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.



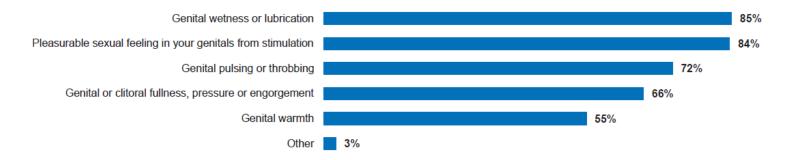
#### 4. What "remedies" have they tried to combat the disorder?

the average number of remedies tried to combat FSAD

- 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.



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

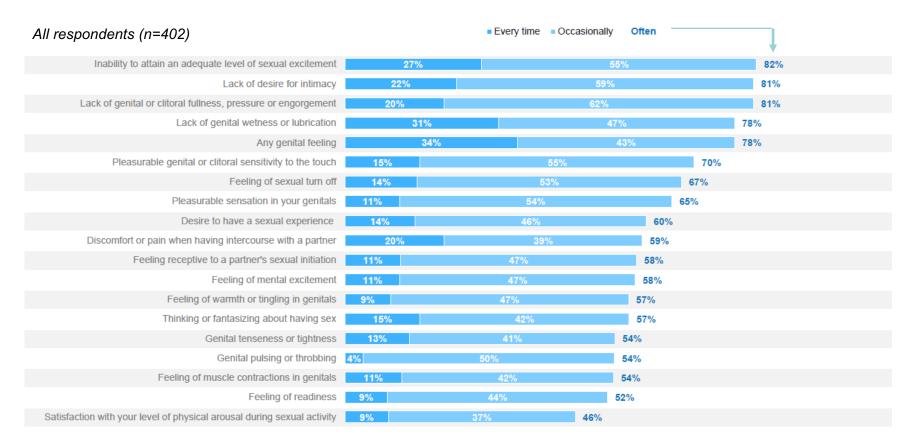


	Age	group	FSAD LT SA 35-54 *	
All respondents (n=402)	<b>21-44</b> n=195	<b>45-60</b> n=207	<b>Yes</b> n=120	<b>No</b> n=282
Genital wetness or lubrication	87%	81%	83%	85%
Pleasurable sexual feeling in your genitals from stimulation	84%	84%	85%	84%
Genital pulsing or throbbing	75%	69%	69%	74%
Genital or clitoral fullness, pressure or engorgement	65%	68%	66%	66%
Genital warmth	58%	50%	51%	56%
Other	3%	2%	2%	3%

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

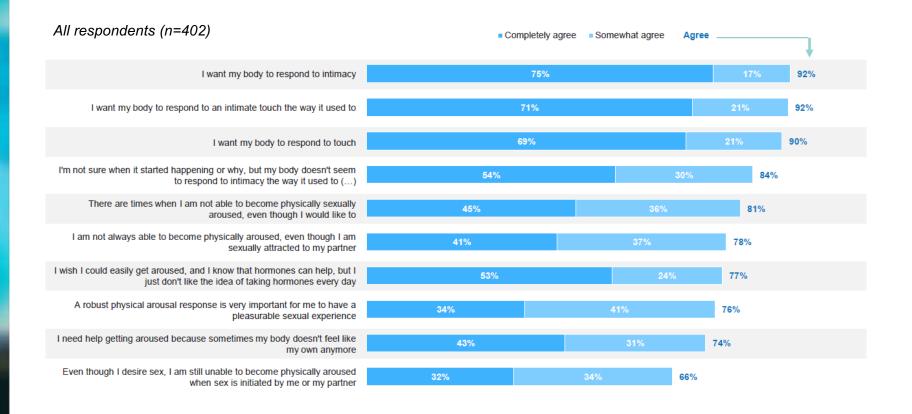


## Female Sexual Arousal Disorder (FSAD) Respondents Signs & Symptoms



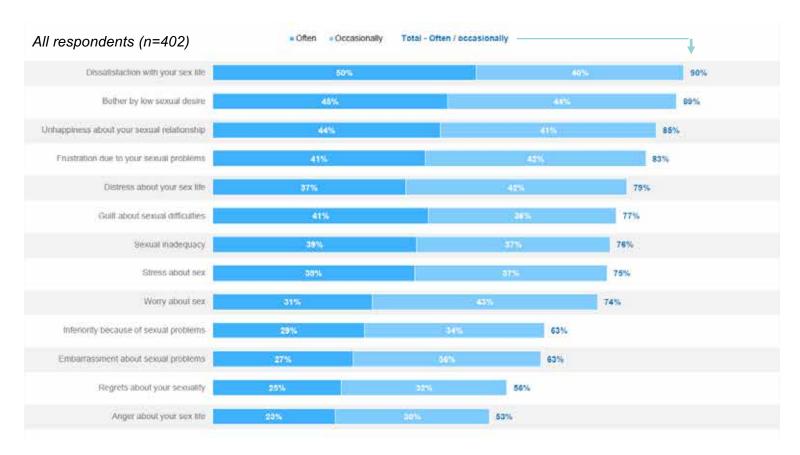


## Psychological Impact of FSAD



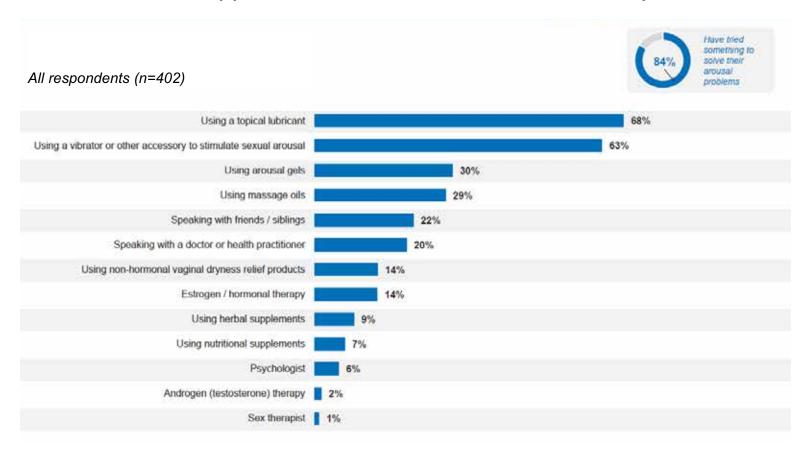


## Psychological Impact of FSAD





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





## Sildenafil Cream, 3.6% Product Profile Market Research



Sildenafil Cream, 3.6% Concept Test

## Sildenafil Cream, 3.6% Concept Testing



402 American women between the ages of 21 and 60 and suffering from Female Sexual Arousal Disorder (FSAD) were surveyed via web panel between November 18 and 23, 2015.



The purpose of this study is to measure the market potential of a topical cream version of sildenafil targeting women as a potential remedy for FSAD.



#### What degree of consumer interest is there in this product idea?

- A significant degree. Many FSAD sufferers have been experiencing symptoms for more than a year. In addition to the physical symptoms they experience, the psychological impact of the disorder is quite burdensome.
- On average, FSAD sufferers have tried approximately 3 different remedies chief among them topical lubricants and vibrators. However, they have found little to no relief.
- FSAD sufferers like the idea. They perceive it to be different from other remedies they have put to the test and
  they believe it will meet their needs.
- FSAD sufferers are ready to try something new especially one that promises no side effects.



#### What are the potential drivers of and barriers to adoption of the product?

Potential Drivers	Potential Barriers		
They want to give it a try. They are ready to try something new.	Embarrassment (in front of their partners doctors and pharmacists).		
They want to increase their sex drive/sexual arousal.	Believability: will it work? They have tried many other "remedies" that have not.		



## Sildenafil Cream, 3.6% Concept Testing

3

#### 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:
  - ✓ 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).

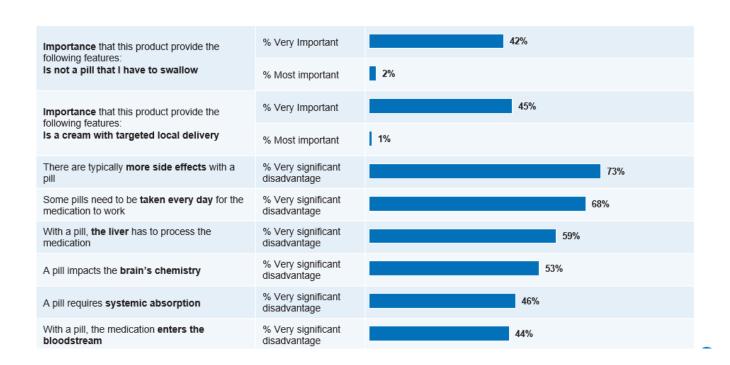


## Sildenafil Cream, 3.6% Concept Testing – Cream Formulation



#### 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.



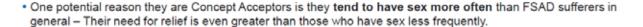


## Sildenafil Cream, 3.6% Concept Testing – Concept Acceptors



## What is the profile of *Concept Acceptors* (in terms of symptoms experienced, relationship to the condition of FSAD, etc.)?

- Concept Acceptors are not widely different from FSAD sufferers as a whole. However, they do appear to be the most severe sufferers of FSAD:
- . The intensity of their symptoms and feelings is much stronger.
- . They experience some of the physical symptoms more frequently, such as:
  - · Lack of genital wetness or lubrication;
  - · Lack of genital or clitoral fullness, pressure or engorgement;
  - · Lack of desire for intimacy and:
  - · Genital tenseness or tightness.
- · Not surprisingly, they have an even deeper desire:
  - . For their bodies to respond to touch and intimacy, the way they used to;
  - To have help becoming/staying physically aroused.
- On an emotional level, they are even MORE...
  - . Bothered by their low sexual desire;
  - Dissatisfied with their sex lives;
  - · Frustrated with their sexual problem;
  - Engulfed by guilt about their sexual difficulties;
  - Worried about sex;
  - Likely to feel sexually inadequate/inferior and;
  - Embarrassed.







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

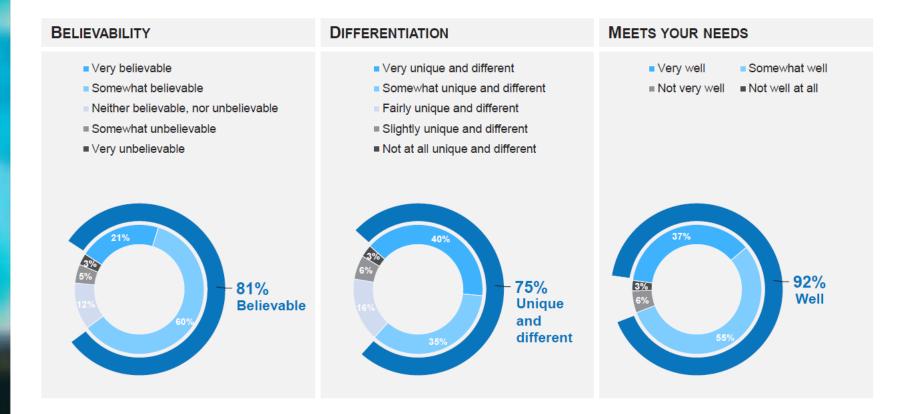
- 82% of respondents indicated they would be likely to purchase the product if it were currently available.
- A subgroup of respondents aged 35-54 had a higher purchase interest (86%) vs. the aggregate (82%).

	Total	Age group		FSAD LT SA 35-54		
	n=402	<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%	

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



## 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.

	Total n=402	Age group		FSAD LT SA 35-54	
		21-44 n=195	<b>45-60</b> n=207	Yes n=120	No n=282
Appealing	89%	88%	91%	95% +	87% +
Very appealing	44%	41%	48%	50%	41%
Somewhat appealing	46%	47%	44%	45%	46%
Neither appealing, nor unappealing	6%	6%	7%	4%	8%
Unappealing	4%	6% +	2% +	2%	6%
Somewhat unappealing	3%	4%	2%	1%	4%
Very unappealing	1%	2% +	0% +	1%	2%

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

