



DARÉ

IN ITALIAN, IT MEANS “**TO GIVE.**”

IN ENGLISH, IT MEANS “**TO BE BOLD.**”

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We partner so we can...

Accelerate exciting new products

Develop new solutions to **address persistent unmet needs**

Become a **pipeline resource** for large and emerging commercial companies

Drive **new innovation**

We look for...

Highly **differentiated products** with attractive market opportunities

Proof-of-concept and/or the ability to leverage a 505(b)(2) regulatory pathway

First-in-category or first-line opportunities

Personalized for women (non-systemic delivery)

We partner with...

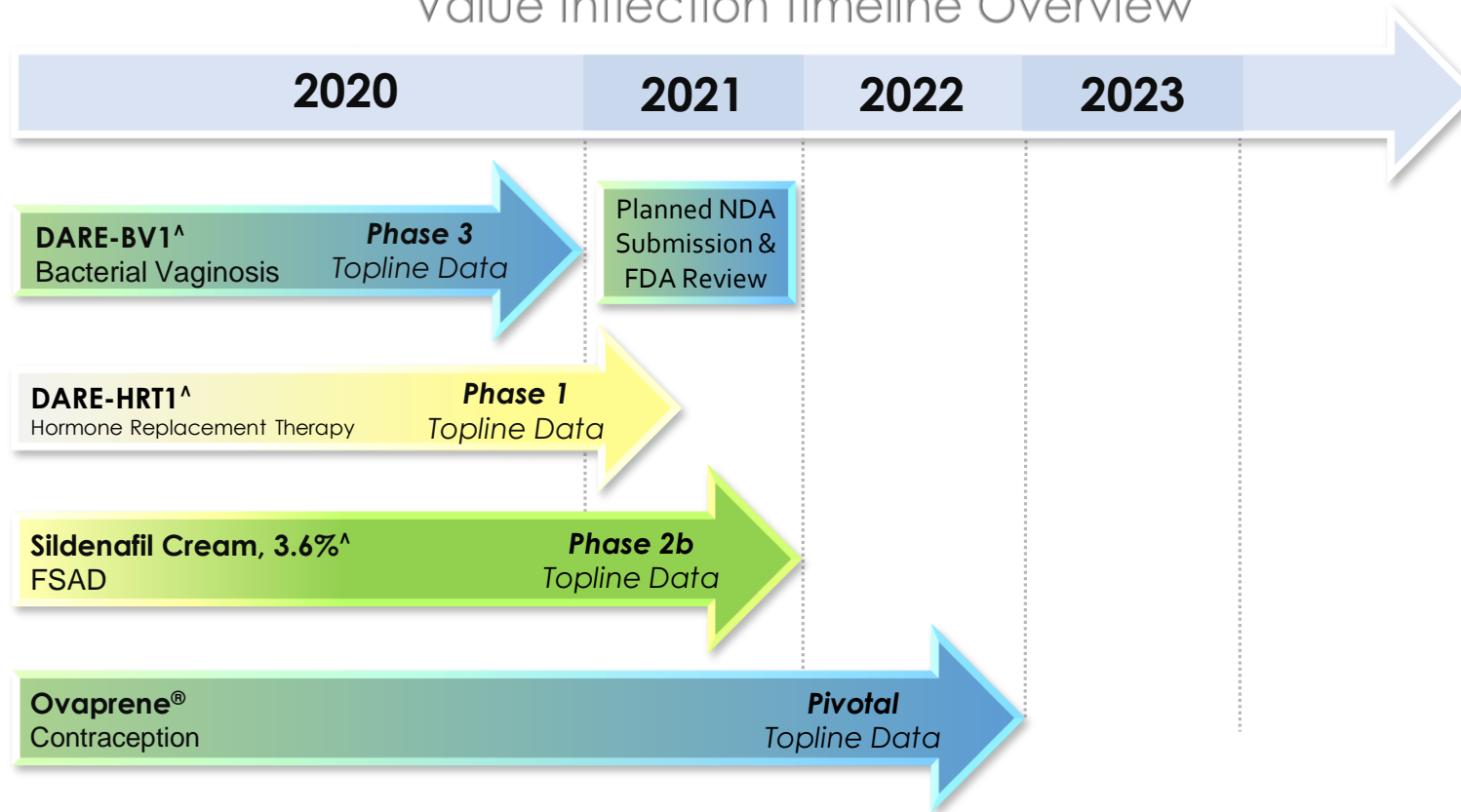


BILL & MELINDA
GATES *foundation*



WE ARE ACCELERATING INNOVATION IN WOMEN'S HEALTH

Value Inflection Timeline Overview





DARE-BV1

Clindamycin 2% gel for Bacterial Vaginosis

Bacterial Vaginosis (BV) - What is the clinical issue?

Frequently recurring infection that can be difficult to treat

- The most common vaginal infection in women ages 15-44¹
- Estimated to affect ~21 million women in the U.S.¹
- Current prescription drugs are less than optimal with clinical cure ranging from 37-68%²




BV increases clinical risks³

- Preterm birth – BV is linked to premature deliveries and low birth weight babies
- Sexually transmitted infections – BV makes women more susceptible to sexually transmitted infections, such as HIV, herpes simplex virus, chlamydia or gonorrhea
- BV may increase the risk of developing a post-surgical infection after gynecologic procedures
- BV can sometimes cause pelvic inflammatory disease (PID), an infection of the uterus and the fallopian tubes that can increase the risk of infertility

CURATIVE POTENTIAL FOR THE MOST COMMON VAGINAL INFECTION (WOMEN AGES 15-44)

Investigator Initiated Proof of Concept Study¹



Product	Clinical (Amsel) Cure	Bacteriologic (Nugent) Cure	Therapeutic Cure
DARE-BV1	86%	57%*	57%*
Solosec ^{®2} <small>(secnidazole 2g oral granules)</small>	53-68%	40-46%	35-40%
Clindesse ^{®3} <small>clindamycin phosphate Vaginal Cream, 2%</small>	41-64%	45-57%	30-42%
Metronidazole gel, 1.3% ⁴	37%	20%	17%

* Based on data from 7 evaluable patients

DARE-BV1 is a thermosetting vaginal gel formulated with clindamycin phosphate 2%, a well known and well characterized antibiotic, that is designed for prolonged, localized release.

Proof of Concept Study: 28 of 30 women completed the study

Primary endpoint: Test-of-Cure Visit (Day 7 – 14)

• **24 of 28 (86%) women achieved clinical cure based on Amsel criteria**

• 4 of 7 (57%) women had bacteriologic cure and 4 of 7 (57%) had therapeutic cure

Continued clinical response visit (Day 21 – 30)

• **22 of 24 (92%) women showed continued clinical cure**

• 7 of 9 women had bacteriologic cure and 6 of 9 had therapeutic cure

1. Dupre, A. et al. 2020. Proof of concept study of a novel Bioadhesive clindamycin phosphate 2% vaginal gel to treat bacterial vaginosis. Clin. Exp. Obstet. Gynecol. Vol. 47, n.4:516-18, available at <https://ceog.imrpess.com/EN/10.31083/j.ceog.2020.04.5304>; No clinical studies have been conducted to evaluate the efficacy of DARE-BV1 compared to any FDA-approved products. The cure rates presented for the FDA approved products identified in the table are based on information provided in the product's label.

2. <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.

3. <http://www.clindesse.com/pdf/PI.pdf>. Cure rate range reflects low and high cure rates across multiple studies

4. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf

DARE-BV1 (Completed Phase 3 Study)*

Phase 3 Clinical Study Design

Day 1 Baseline Visit

Tests Performed:

- Signs & symptoms
- pH
- Saline “wet mount”
- 10% KOH “whiff test”



DARE-BV1

2 to 1 Randomization



Placebo

Single administration of DARE-BV1 or placebo

Day 7 – 14

Secondary Endpoint
(Test-of-Cure Visit)

Tests Performed:

- Signs & symptoms
- pH
- Saline “wet mount”
- 10% KOH “whiff test”
- Nugent score

Day 21 – 30

Primary Endpoint
(Test-of-Cure Visit)

Tests Performed:

- Signs & symptoms
- pH
- Saline “wet mount”
- 10% KOH “whiff test”
- Nugent score

N=307 subjects enrolled (age 15 and above)
Duration ~30 days per subject
Diagnosis - Bacterial vaginosis

*Toplevel data forthcoming

Definitions:

Primary Endpoint: Clinical Cure (Day 21-30): Resolution of the abnormal vaginal discharge associated with BV; Negative 10% KOH “whiff test”; Clue cells < 20% of the total epithelial cells in the saline wet mount.

Secondary endpoints: Proportion of subjects with Clinical Cure, Bacteriological Cure and Therapeutic Cure at Day 7-14 Visit

Bacteriological Cure: a Nugent score < 4.

Therapeutic Cure: both a Clinical Cure and Bacteriological Cure.



Ovaprene[®]

Investigational Hormone-Free, Monthly Contraceptive

*The U.S. contraceptive market size is projected to reach USD 9.6 billion by 2027 expanding at a CAGR of ~4.2%*¹

*~37 million U.S. women of reproductive age are estimated to currently use a contraceptive method*²

Contraception: what kinds of products are successful?



Mirena® Hormone IUD

(levonorgestrel-releasing intrauterine system) 52mg

Physician inserted, long-acting.
low/locally delivered hormone IUS

2019 worldwide sales: **€1.2 billion** (Bayer)¹



Lo Loestrin®

(norethindrone acetate and ethinyl estradiol, ethinyl estradiol tablets)

Lowest amount of daily estrogen
(10 micrograms) available in pill form

2019 US sales: **\$588 million** (Allergan)²



NuvaRing®

(etonogestrel/ethinyl estradiol vaginal ring)

Monthly vaginal ring

2019 worldwide sales: **\$879 million** (Merck)³

Lower hormone levels and more convenient delivery platforms

1. <https://www.bayer.com/en/bayer-ag-annual-report-2019.pdf>. Includes sales for Mirena®, Kyleena® and Jaydess® / Skyla®
2. <https://www.prnewswire.com/news-releases/allergan-reports-fourth-quarter-and-full-year-2019-financial-results-301001646.html>
3. https://s21.q4cdn.com/488056881/files/doc_financials/2019/q4/2019-Form-10-K-Final.pdf.

Contraception: what features are women seeking?

Effectiveness (pregnancy prevention)

Less Hormones

- A majority of women prefer a monthly option with a lower hormone dose than the standard birth control pill.¹

Convenient dosing forms

- Independent surveys revealed that the vaginal ring has many of the features women deemed extremely important.²

Defined coverage periods

- ~70% of women who practice contraception use non-coital (*not in the moment*) methods.³

CONTRACEPTIVE METHOD CHOICE

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

METHOD	No. of women	% of women aged 15-44	% of women at risk of unintended pregnancy	% of contraceptive users
Pill	9,572,477	15.6	22.7	25.3
Tubal (female) sterilization	8,225,149	13.4	19.5	21.8
Male condom	5,496,905	8.9	13.0	14.6
IUD	4,452,344	7.2	10.6	11.8
Vasectomy (male sterilization)	2,441,043	4.0	5.8	6.5
Withdrawal	3,042,724	5.0	7.2	8.1
Injectable	1,481,902	2.4	3.5	3.9
Vaginal ring	905,896	1.5	2.1	2.4
Fertility awareness-based methods	832,216	1.3	2.0	2.2
Implant	965,539	1.6	2.3	2.6
Patch	69,106	0.1	0.2	0.2
Emergency contraception	69,967	0.1	0.2	0.2
Other methods*	234,959	0.4	0.6	0.6
No method, at risk of unintended pregnancy	4,408,474	7.2	10.5	na
No method, not at risk	19,302,067	31.4	na	na
Total	61,491,766	100.0	100.0	100.0






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

www.guttmacher.org

www.guttmacher.org

Contraception: what products are hormone-free?



Hormone-free Options	Number of pregnancies expected (per 100 women) ^{1*}	Least Effective
 Spermicides & Vaginal Gels ²	>27 (greater than 27 pregnancies)	
 Condoms (male)	18	
 Diaphragms (with a spermicide)	12	
 Copper IUD	<1 (less than 1 pregnancy)	
		Most Effective







1. U.S. Food and Drug Administration Birth Control Guide: <https://www.fda.gov/consumers/free-publications-women/birth-control-chart>

2. U.S. Food and Drug Administration Drug Data Prescribing information for a recently approved vaginal gel, Phexxi™ provides that in a multicenter, open-label, single-arm clinical trial in the U.S. (AMP002; NCT03243305), the 7-cycle cumulative pregnancy rate was 13.7% (95% CI: 10.0%, 17.5%), excluding cycles with back-up contraception, cycles <21 or > 35 days in length and cycles in which no intercourse was reported. The estimated Pearl Index, calculated based on data from the 7-cycle study, was 27.5 (95% CI: 22.4%, 33.5%). https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208352s000lbl.pdf

* The pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). For more information on the chance of getting pregnant while using a method or on the risks of a specific product, please check the product label or Trussell, J. (2011). "Contraceptive failure in the United States." Contraception 83(5):397-404.

Contraception: what's missing from hormone-free options?



Hormone-free Options	Number of pregnancies expected (per 100 women) ¹ *	Least Effective
 Spermicides & Vaginal Gels ²	>27 (greater than 27 pregnancies)	
 Condoms (male)	18	
 Diaphragms (with a spermicide)	12	
 Easy-to-use monthly option	Effectiveness approaching hormonal methods	
 Copper IUD	<1 (less than 1 pregnancy)	
		Most Effective

1. U.S. Food and Drug Administration Birth Control Guide: <https://www.fda.gov/consumers/free-publications-women/birth-control-chart>

2. U.S. Food and Drug Administration Drug Data Prescribing information for a recently approved vaginal gel, Phexxi™ provides that in a multicenter, open-label, single-arm clinical trial in the U.S. (AMP002; NCT03243305), the 7-cycle cumulative pregnancy rate was 13.7% (95% CI: 10.0%, 17.5%), excluding cycles with back-up contraception, cycles <21 or > 35 days in length and cycles in which no intercourse was reported. The estimated Pearl Index, calculated based on data from the 7-cycle study, was 27.5 (95% CI: 22.4%, 33.5%). https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208352s000lbl.pdf

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Ovaprene® Investigational Hormone-Free, Monthly Contraceptive

Desired Features of Birth Control Products: ¹⁻⁴	Design Features of Ovaprene: ⁵⁻⁷
+ Efficacy	86% - 91% Expected Typical Use Effectiveness Approaching Hormone Contraception
+ Hormone Free	No Hormones in the API Unique dual action MOA (spermistatic & barrier)
+ Convenience	Monthly Ring Form Women choose monthly rings for the convenience of a non-daily option
+ Favorable Side Effect Profile	Safety Profile Similar to a Diaphragm No significant changes in vaginal flora and no serious adverse effects observed in studies to date
+ Easily Manage Fertility	No Systemic/Long-term Activity Inserted and removed without a provider allowing for immediate return to fertility

Physical Barrier⁶

Three-dimensional, knitted polymer barrier



Spermistatic Environment⁶

Contraceptive-loaded silicone ring releasing non-hormonal active Ferrous gluconate

1. <https://www.urban.org/urban-wire/women-want-effective-birth-control>
2. Lessard, L, Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012
3. Hooper, DJ, Clin Drug Investig. 2010;30(11):749-63
4. Ersek, J, Matern Child Health J (2011) 15:497-506
5. In PCT studies of similar size, products (diaphragms) that demonstrated no motile sperm in the cervical mucus during PCT assessments later demonstrated "typical use" contraceptive effectiveness of 86-91% in pivotal contraceptive studies evaluating pregnancy rates over six-month periods. Mauck C, Vincent K, Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437-444
6. Journal of Reproductive Medicine 2009; 54: 685-690
7. 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.

U.S. Regulatory Strategy¹

Premarket approval (**PMA**) with the Center for Devices and Radiological Health (**CDRH**) as lead review division

Step 1 (Completed)

- Postcoital Test (PCT) Study - Completed 4Q 2019

Step 2 (Ongoing)

- File investigational device exemption (**IDE**) to support 2022 pivotal study readout
- Conduct pivotal study
 - Topline data expected by year-end 2022
 - ~250 completers up to 12 months of use
 - Primary endpoints: safety and efficacy (pregnancy probability)
 - Secondary endpoints: acceptability, product fit/ease of use and assessments of vaginal health

The PCT Clinical Study Met its Primary Endpoint²

Ovaprene prevented the requisite number of sperm from reaching the cervix across all women and all cycles evaluated.

- **Specifically, in 100% of women and cycles, an average of less than five (< 5) progressively motile sperm (PMS) per high-powered field (HPF) were present in the midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place.**
- Women enrolled in the study who completed at least one Ovaprene PCT (N=26) had a **mean of 27.21 PMS/HPF in their baseline cycle (without any contraceptive device)**, a mean of 0.22 PMS/HPF in their diaphragm cycle (in the presence of an FDA-cleared diaphragm with spermicide), **and a mean of 0.48 PMS/HPF in their Ovaprene PCT cycles (in the presence of the Ovaprene device), with a median of zero PMS.**

	Mean <small>Progressively Motile Sperm</small>	Median <small>Progressively Motile Sperm</small>	Standard Deviation	Interquartile Range
Baseline PCT's	27.21	23.20	17.88	24.80
Ovaprene PCT's	0.48	0.00	1.18	0.10

¹. Anticipated regulatory pathway and timelines.
². In PCT studies of similar size, products (diaphragms) that demonstrated no motile sperm in the cervical mucus during PCT assessments later demonstrated "typical use" contraceptive effectiveness of 86-91% in pivotal contraceptive studies evaluating pregnancy rates over six-month periods.
Mauck C, Vincent K. Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437-444

Ovaprene Commercial License Agreement with Bayer¹



January 2020 - Bayer, marketer of the \$1 billion Mirena contraceptive franchise, and Daré announced that the companies signed a license agreement under which Bayer may commercialize Ovaprene in the United States once approved by the FDA.

Mirena® is the **#1 prescribed IUD** in the U.S.*

- Bayer received the right to obtain exclusive rights to commercialize the product in the U.S. following completion of the pivotal clinical trial if Bayer, in its sole discretion, makes payment to Daré of \$20 million.
- Daré may receive up to \$310 million in commercial milestone payments plus tiered royalties on net sales in the double-digits.
- Bayer supports the development and regulatory process by providing up to two full-time equivalents (internal experts), or FTEs, in an advisory capacity, which gives us access to their global manufacturing, regulatory, medical and commercial internal expertise.

We believe the licensing agreement with Bayer is validation of our broader corporate strategy and confirmation of Ovaprene's market potential as the first monthly non-hormonal contraceptive product in the US market.

* <https://www.mirena-us.com/>; supported by 2014-2016 SHS data.

1. <https://fir.darebioscience.com/news-releases/news-release-details/bayer-and-dare-bioscience-announce-exclusive-licensing-agreement>

Sildenafil Cream, 3.6%

Female Sexual Arousal Disorder (FSAD)

The global female sexual dysfunction treatment market is expected to grow at ~37% CAGR from 2019 - 2023

FSAD - what is the clinical issue?

- Female Sexual Arousal Disorder (FSAD) is characterized primarily by an inability to attain or maintain sufficient genital arousal during sexual activity and, of the female sexual function disorders, is most analogous to erectile dysfunction (ED) in men.*
- The condition should be distinguished from a general loss of interest in sexual activity and from other sexual dysfunctions, such as the orgasmic disorder (anorgasmia) and hypoactive sexual desire disorder (HSDD), which is characterized as a lack or absence of sexual fantasies and desire for sexual activity for some period of time.^{1,2}

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

1. <https://drgeo.com/womens-sexual-health-overview/>

2. <https://health.usnews.com/conditions/sexual-disorder-dysfunction>

FSAD - what is the incidence?

Meta-analysis of 95 studies from 2000-2014 indicated the prevalence of Female Sexual Dysfunction in premenopausal women worldwide is 40.9%, and difficulty with arousal alone is 23%.¹

Market research estimates:

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



1. McCool et al. Sex Med Rev 2016;4:197-212.

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

3. Based on US Census projections for 2016.

Topically administered Sildenafil Cream¹ is...

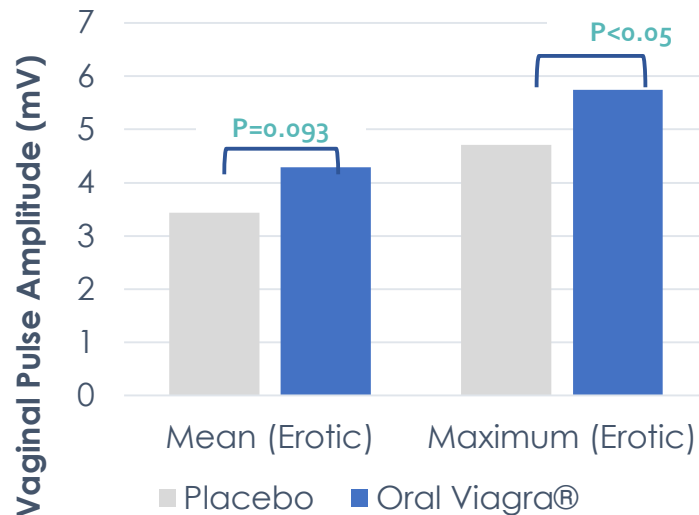
- A PDE5 inhibitor utilized in ED medications for men (Viagra®)
- Designed to increase local blood flow to provide an improvement in genital arousal response
- Applied topically, avoiding hepatic first-pass metabolism response resulting in lower systemic exposure resulting in reduced side effects compared to oral sildenafil, including Viagra®
- Given the similarities between ED and FSAD, the active ingredient in Viagra® - sildenafil - may improve genital arousal response and overall sexual experience for women as it does in men

There are no FDA-approved treatments for FSAD

1. Sildenafil Cream, 3.6%, (formerly SST-6007)

Statistically significant increases in Vaginal Pulse Amplitude (VPA)¹

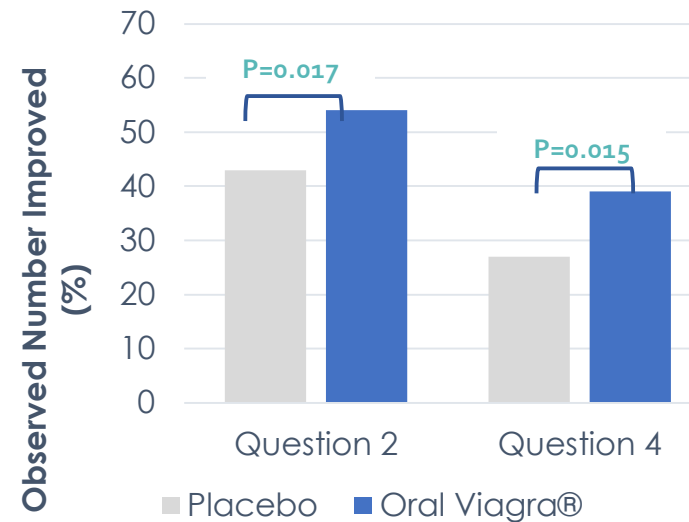
Pfizer VPA Clinical Lab Study – Oral Viagra
Mean and Maximum VPA[†]



[†] Twelve healthy premenopausal women were studied.

Statistically significant improvement in genital stimulation (FIEI)²

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.

Key Takeaways of Viagra® studies:

- **Increased blood flow** and clinical efficacy observed with oral sildenafil (Viagra®) in women.
- The side effect profile of the **oral formulation was not optimal for women** - leading to the exploration of alternative delivery options including a **topical route of administration**.

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

Normal healthy postmenopausal women were dosed with escalating doses of Sildenafil Cream, 3.6%, using a cross-over study design.

- Sildenafil Cream had significantly lower systemic exposure compared to a 50 mg oral sildenafil dose
 - AUC – 3-6%
 - C_{max} – 1-2%
- Sildenafil Cream was safe and well tolerated at clinically relevant doses (1-2g)
- Favorable product characteristics as self-reported by subjects
 - Easy to use
 - Readily absorbed

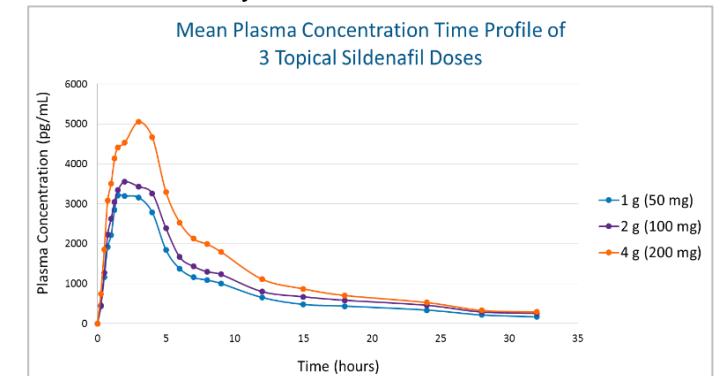
Phase 2a Study of SST-6007 (Sildenafil Cream, 3.6%)¹

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.

Phase 1 Study

Treatment	N=59	Sildenafil Single Dose	C _{max} (ng/ml)	T _{max} (hr)	AUC _{last} (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

Phase 1 Study



Positive Data – Thermography Study*

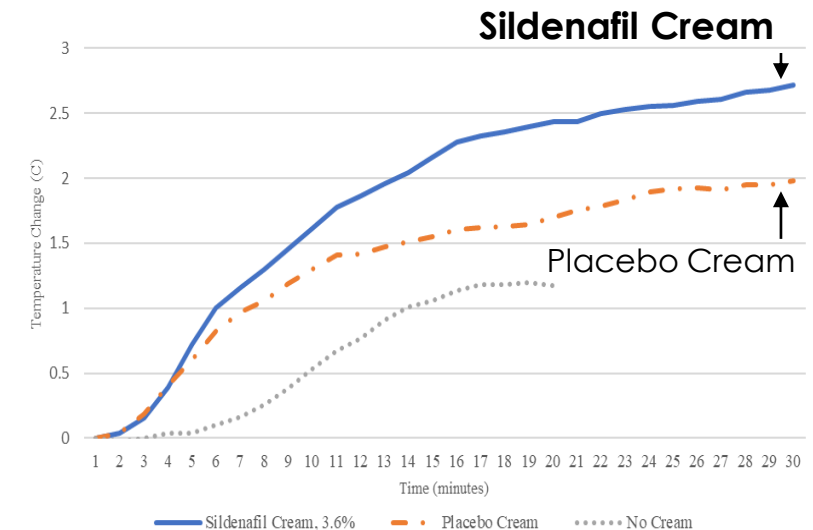
Positive findings for Sildenafil Cream, 3.6% (as shown in Figure 1.)

- Positive cognitive arousal responses were noted.
- Significantly greater **increases in genital temperature** after application of Sildenafil Cream compared to placebo cream and no cream.
- Significantly **greater self-reported arousal responses** reported during Sildenafil Cream visits compared to placebo cream visits.

Thermography Study Design & Methodology (N=6)¹

Phase 1, single-dose, double-blind, placebo-controlled, 2-way crossover study evaluating the feasibility of using thermography to assess the pharmacodynamics of Sildenafil Cream, 3.6% in normal healthy women. The study required 3 visits and a follow up contact: Visit 1 (screening), Visits 2-3 (double-blind dosing) and a phone call (safety follow-up).

Figure 1. Clitoral temperature change during the sexually explicit film



Statistically significant greater linear slope during minutes 11-15 of the sexually explicit stimuli as compared to the placebo cream for the vestibule.

1. Data on file.

* Thermography utilizes sensitive cameras capable of detecting and recording temperature variations over time. Genital temperature changes are a surrogate for genital blood flow.

Phase 2b – At Home Study

The Phase 2b study is designed to evaluate Sildenafil Cream versus placebo over twelve weeks of dosing following both a non-drug and placebo run-in period.

- In the Phase 2b study women will use Sildenafil Cream and placebo in their home setting.
- Primary endpoint patient reported outcome (PRO) instruments to measure **improvement in localized genital sensations of arousal** and **reduction in the distress** that women with FSAD experience.
- Several exploratory efficacy endpoints will be measured and could potentially prove to be additional measurements of efficacy in a future Phase 3 program.



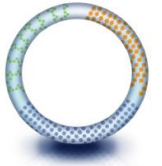


Vaginal Drug Delivery

New prescription drug delivery options for women

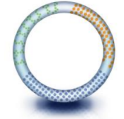
The Vaginal Route of Drug Administration¹

- Vaginal drug delivery offers many potential advantages due to the large surface area, a dense network of blood vessels and high elasticity due to presence of smooth muscle fibers
- Recognized advantages include: comparable ease of administration and ability to bypass hepatic first-pass metabolism



Our Intravaginal Ring (IVR) Technology – Design Features:

- Sustained drug delivery
- Variable dosing and duration
- Solid ethylene vinyl acetate (EVA) polymer matrix that can contain and release a single or multiple active drugs
- No need for a membrane or reservoir to contain the active drug(s) or control the release



DARE-HRT1

A combination bio-identical estradiol + bio-identical progesterone IVR for hormone replacement therapy

Hormone Replacement Therapy (HRT)

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.²

- The 2017 Hormone Therapy Position Statement of The **North American Menopause Society** (NAMS), supports HRT in peri-and post-menopausal women.²

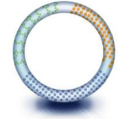
NAMS observes that **non-oral routes may offer advantages** over oral routes of administration.²

Ongoing Phase 1 VMS/HRT 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.

N=30

45M women in U.S. approaching or in menopause³



DARE-FRT1

A bio-identical progesterone IVR for the prevention of preterm birth and IVF/fertility support

Prevention of Preterm Birth (PTB)

After steadily declining from 2007 to 2014,² the premature birth rate in the United States rose for the fourth straight year in 2018 with ~10% of babies born preterm (less than 37 weeks).³



NIH Grant Funding for DARE-FRT1 (PTB)

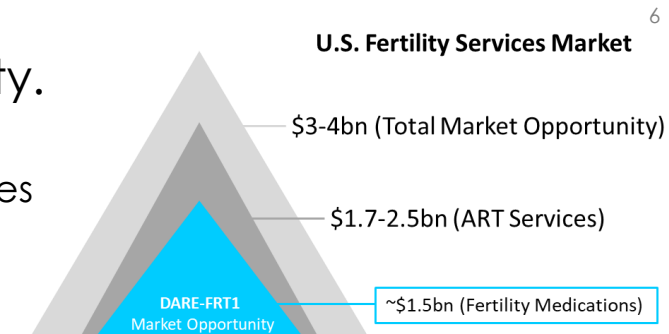
Potential for up to \$2.3 million in grant funding from the NIH to support the DARE-FRT1 program.

- Notice of award for initial \$300,000 in grant funding announced Aug 2020.
Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health Award Number R44 HD101169.

Assisted Reproductive Technologies (ART)/IVF

As women wait longer to have children, they increase their risk of infertility.

- An estimated 12-15% of couples are unable to conceive after 1-year of unprotected sex.⁴
- Approximately 20% of U.S. women have their first child after age 35 and about 1/3 of couples in which the woman is older than 35 years have fertility problems.⁵



505(b)(2) candidate¹

1. Anticipated regulatory pathway. Daré has not had any communications with the FDA regarding the specific marketing approval requirements for DARE-HRT1 or DARE-FRT1
2. 2019 March of Dimes Report Card, <https://www.marchofdimes.org/mission/reportcard.aspx>
3. CDC's National Center for Health Statistics, National Vital Statistics Reports, Births: Final Data for 2018, Nov 27, 2019, https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13-508.pdf
4. Retrieved May 26, 2020 from <https://www.nichd.nih.gov/health/topics/infertility/conditioninfo/common>
5. Retrieved May 26, 2020 from <https://www.cdc.gov/reproductivehealth/infertility/index.htm>
6. Harris Williams & Co. Fertility market overview. May 2015.

DARE-VVA1

A proprietary formulation of tamoxifen for vaginal administration

Vulvar and vaginal atrophy (VVA)

A chronic condition characterized by pain during intercourse, vaginal dryness and irritation

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.

- Approximately 3.8 million women in the U.S. have a history of breast cancer and HR+ is the most common type.²
- Localized estrogen therapy for VVA may be contraindicated for women diagnosed with, or at risk of recurrence of, ER-positive and PR-positive breast cancer.

VVA prevalence in postmenopausal breast-cancer survivors is estimated to be between **42 and 70%**.³



Daré is developing this novel local application of tamoxifen to mitigate the symptoms of VVA for patients HR+ breast cancer, including women currently on anti-cancer therapy.

This exploratory study in four postmenopausal women diagnosed with VVA demonstrated that a self-administered 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 Normal vaginal pH is usually less than 4.5. ²	7.1 range 6.5 to 7.5	5.0 range 5.0 to 5.2	-2.0 median range -2.5 to -1.5 Lower pH value is a measure of symptom relief
Vaginal Dryness Rated using a visual analogue scale (VAS) that ranged from: 0 = Not bothered by dryness 10 = Extremely bothered by dryness	8.0 range of 7.5 to 9.0	3.0 range 2.0 to 3.0	-5.5 median range -6.0 to -4.5 Decreased vaginal dryness is a measure of symptom relief

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),³ the average steady state plasma concentration of tamoxifen is 122 ng/ml with a range of 71 to 183 ng/ml

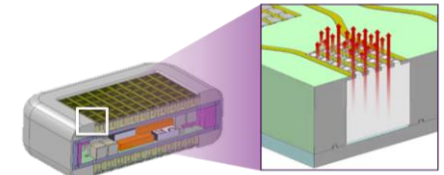


User-Controlled Long-Acting Reversible Contraception

(UC-LARC) / Microchips Technology

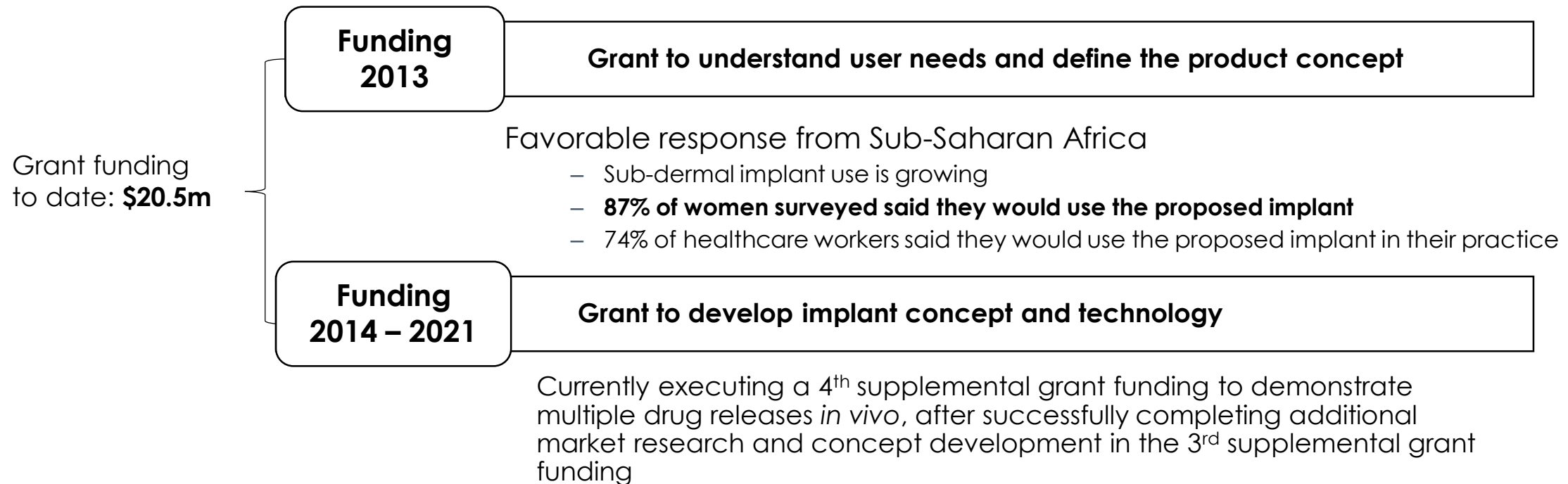
Design Features of the Technology:

- Drug Storage
 - Individual doses are stored in micro-reservoir arrays
 - Reservoirs are hermetically sealed at room temperature
 - Thin membranes over each reservoir protect drug post-sealing
- Drug Release
 - Drug doses are initiated automatically on schedule or wirelessly on-demand by a patient
 - Reservoirs are opened via electrothermal ablation of membranes
 - Upon opening, interstitial fluid diffuses in and drug diffuses out



Pre-programmed or
wireless activation

The Bill & Melinda Gates Foundation has strong interest in family planning.
An estimated 215 million women in developing countries do not have access to contraception.



Q3-2020 Financial Highlights:

- Cash provided from financing activities* through 9/30/20: \$16.7 million (net)
- Cash and equivalents (as of 9/30/20): \$5.4 million

Updates from October 1 through November 11, 2020:

- Cash provided by sales of stock: \$4.5 million (net)
- Common shares o/s: ~ 38 million
- Warrants o/s: ~1.9 million

Funding sources:

- Since our inception, we have raised cash through the sale of our equity securities, M&A transactions, warrant and option exercises, non-dilutive grants, and license fees.
- We will endeavor to be creative and opportunistic in seeking the capital required to advance our candidates and to be efficient in the use of such capital.

** Financing activities during the period included sales of stock, warrant exercises and proceeds from a PPP loan.*

Grant funding:

- \$1.9 million grant for Ovaraprene R&D expenses from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH).
 - Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health Award Number R44 HD095724-01.
- \$20.5 million grant funding from Bill & Melinda Gates Foundation (2013-2021) to support development of DARE-LARC1.
 - September 21, 2020 Daré announced receipt of the final ~ \$0.9 million in funding under the current grant from the Bill & Melinda Gates Foundation.
- Potential for up to \$2.3 million grant from the NIH to be awarded in phases to support the DARE-FRT1 program. Notice of award for initial \$300,000 in grant funding announced Aug 2020.
 - Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health Award Number R44 HD101169.

Cost optimization and value creation through partnerships and affiliates:

- Health Decisions, a CRO specializing in women's health; our agreement will provide dedicated resources and new pricing structures, which together with Health Decisions' expertise and established relationships, are expected to accelerate the development of key programs in a capital-efficient manner.
- Avomeen, an accredited, independent contract research, development, and manufacturing organization specializing in chemical analysis and product development; our agreement provides a preferred discounting price structure and should enable Daré to leverage Avomeen's scientific expertise, including advanced instrumentation and development techniques.
- Australia's R&D tax incentive currently allows for a refundable cash credit of up to 43.5% of investments made by eligible companies in eligible R&D activities. We intend to apply for the maximum amount allowable under our DARE-HRT1 program.

Management Team & Board of Directors

MANAGEMENT TEAM



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Lisa Walters-Hoffert
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