



NASDAQ: DARE
www.darebioscience.com

Daré Bioscience

DARÉ

IN ITALIAN, IT MEANS “**TO GIVE.**”

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

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Daré Bioscience - A Compelling Opportunity



Daré Bioscience is a clinical-stage biopharmaceutical company committed to advancing innovative products for women's health. The company's mission is to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Company Highlights

- ✓ June 2019 – Positive findings of Sildenafil Cream, 3.6% thermography clinical study
- ✓ Nov. 2019 – Positive topline data for Ovaprene® postcoital test clinical study
- ✓ Jan. 2020 – Exclusive licensing agreement with Bayer for Ovaprene
- ✓ May/Sept 2020 – Strategic partnerships with Health Decisions / Avomeen
- ✓ Sept. 2020 – Bill & Melinda Gates Foundation grant funding for DARE-LARC1 reaches \$20.5 million
- ✓ Dec. 2020 – Positive topline data for DARE-BV1 Phase 3 study

Anticipated Clinical & Regulatory Milestones*

- 2021** ☐ NDA submission to FDA for DARE-BV1
 - ☐ Topline data for DARE-HRT1 Phase 1 study
 - ☐ PDUFA date for DARE-BV1[^]
 - ☐ Topline data for Sildenafil Cream, 3.6% for FSAD Phase 2b study
- 2022** ☐ U.S. commercial launch of DARE-BV1
 - ☐ Data from Ovaprene pivotal Phase 3 study

* Timeline reflects management's current estimates and constitutes a forward-looking statement subject to qualifications noted elsewhere in this presentation.

[^] Would require a priority review designation from the FDA. DARE-BV1 has Fast Track and Qualified Infectious Disease Product designations from the FDA for treatment of bacterial vaginosis.

Working to accelerate innovative product options in women's health by...

- Identifying and advancing new therapies that provide additional choices
- Enhancing outcomes
- Improving ease of use

We look for...

- **Differentiated investigational products** with attractive market opportunities + unmet medical needs
- **Proof-of-concept** and/or ability to leverage a 505(b)(2) regulatory pathway
- **First-in-category** or first-line opportunities
- **Personalized** for women with novel, convenient routes of administration.

Partnering to Accelerate Innovation

We partner to...

Accelerate exciting new products

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

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

Drive **innovation**

We partner with...



BILL & MELINDA
GATES *foundation*



Advancing Products **Women Want**

PARTNERS	Product Candidate	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	REGULATORY FILING
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DARE-BV1[^] Bacterial Vaginosis- **Phase 3 Topline Data Announced December 2020**

Potential First-line Option for Bacterial Vaginosis
Bioadhesive gel, clindamycin 2%



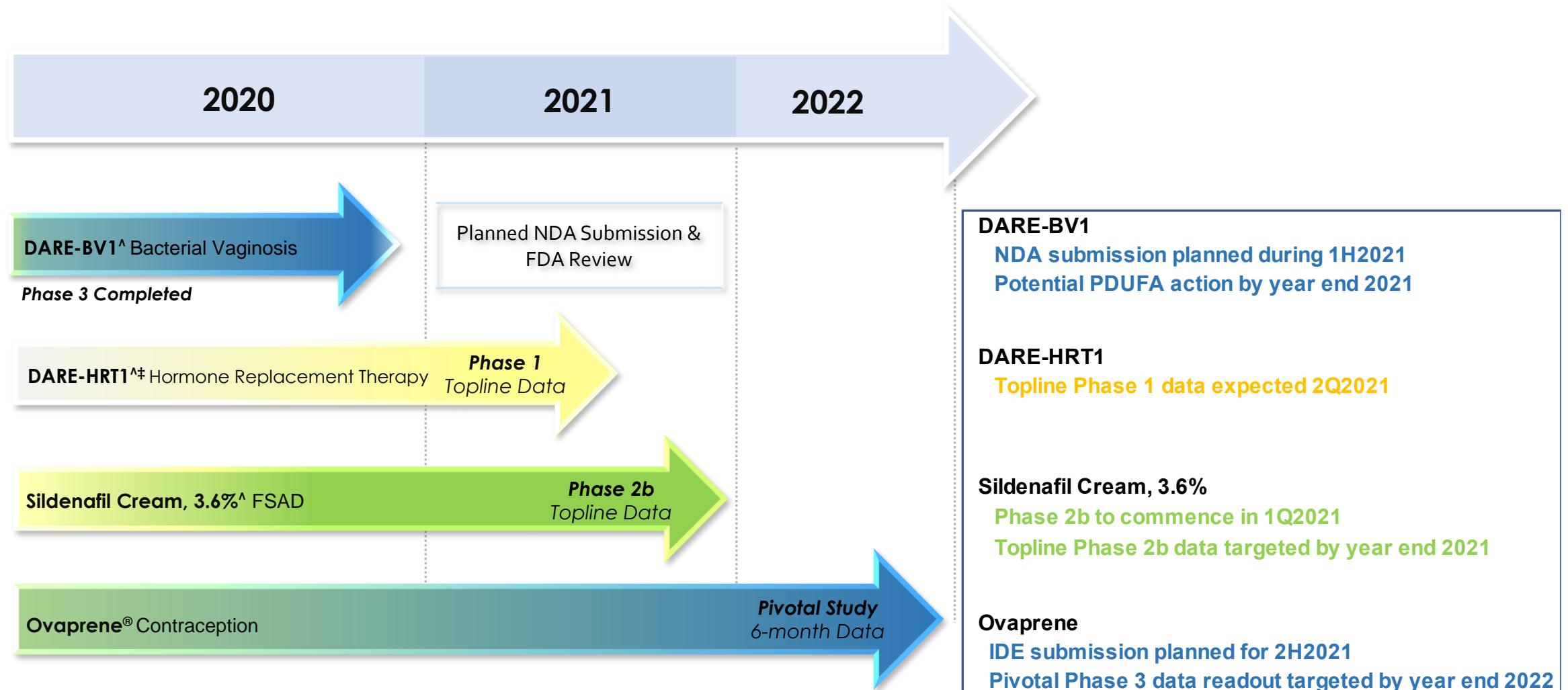
Ovaprene[®] Hormone-Free, Monthly Contraception- **Pivotal Phase 3 Study 6-Month Data 2022***

First-in-category Hormone-Free Monthly Contraception
Monthly, self-administered drug/device barrier IVR,

Sildenafil Cream, 3.6% [^] Female Sexual Arousal Disorder-**Phase 2b Topline Data 2021***































































First-in-category treatment for Female Sexual Arousal Disorder (FSAD)
Topical Cream, same active ingredient as Viagra[®]

Near Term Catalysts to Drive Value



DARE-BV1 NDA filing and **two** top-line data readouts expected during **2021**

Experienced Management & Board of Directors

Management Team		Board of Directors	
	Sabrina Martucci Johnson MSc, MIM President & CEO		William Rastetter, PhD Chairman
	   		    
	John Fair Chief Strategy Officer		Cheryl Blanchard, PhD
	  		  
	Lisa Walters-Hoffert Chief Financial Officer		Jessica Grossman, MD
	   		  
	David Friend, PhD Chief Scientific Officer		Susan Kelley, MD
	   		  
	Mary Jarosz, RPh, RAC, FTOPRA Global Head of Regulatory Affairs		Greg Matz, CPA
	  		  
	Mark Walters Vice President of Operations		Robin Steele, JD, LLM
	   		 
	Christine Mauck, MD, MPH Medical Director		Sabrina Martucci Johnson MSc, MIM President & CEO
	  		   

We are delivering **innovation** by **daring to be different®**

DARE-BV1

Clindamycin 2% gel for
Bacterial Vaginosis

Best-in-class curative potential for the **most common**¹ vaginal infection in women of reproductive age, designed for convenient, one-time administration

Expect pre-NDA meeting with FDA early 2021, planned **NDA submission 1H 2021**

1. <https://www.cdc.gov/std/bv/stats.htm>

Bacterial Vaginosis - What Is the clinical issue?

Recurring infection, difficult to treat effectively

- Most common vaginal infection in women ages 15-44, affecting **~21 million women** in the US¹
- Current Rx suboptimal: clinical cure rates of 37-68%²



Bacterial Vaginosis increases health risk³




- Preterm birth – bacterial vaginosis is linked to premature deliveries, low birth weight babies
- Sexually transmitted infections – bacterial vaginosis increases susceptibility to HIV, herpes simplex virus, chlamydia, gonorrhea
- Post-surgical infection – bacterial vaginosis may increase risk of infection after gynecologic procedures
- Pelvic inflammatory disease – bacterial vaginosis may cause PID, an infection that affects women's reproductive organs and can increase the risk of infertility

1. <https://www.cdc.gov/std/bv/stats.htm>

2. Bacterial vaginosis product data: <http://www.clindesse.com/pdf/PI.pdf>; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf

3. <https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-20352279>

DARE-BV1: Potential for Improved Clinical Cure Rates vs. Current Branded Rx

Product	Frequency, Dose, and Route of Administration	Study Descriptions		Clinical Cure Rates
 DARE-BV1 (Investigational) (clindamycin phosphate vaginal gel, 2%)	1 time, 5g applicator, applied vaginally	Randomized Placebo-Controlled Phase 3 Trial ¹		
		Topline data		
		DARE-BVFREE (Day 21-30) <i>Modified-Intent-to-Treat Population at 21-30 Days</i>	DARE-BV1 (N=121) Placebo (N=59)	70.2% 35.6%
		DARE-BVFREE (Day 7-14) <i>Modified- Intent-to-Treat Population at 7-14 Days</i>	DARE-BV1 (N=121) Placebo (N=59)	76.0% 23.7%
	1 time, 2g dose, taken orally	DARE-BVFREE (Day 21-30) <i>Per Protocol Population at 21-30 Days</i>	DARE-BV1 (N=101) Placebo (N=47)	77.2% 42.6%
		DARE-BVFREE (Day 7-14) <i>Per Protocol Population at 7-14 Days</i>	DARE-BV1 (N=101) Placebo (N=47)	81.2% 29.8%
		Two Randomized, Placebo-Controlled Phase 3 Studies ²		
	1 time, 5g applicator, applied vaginally	Study 1 (Day 21-30) <i>Modified-Intent-to-Treat Population at 21-30 Days</i>	SOLOSEC (N=62) Placebo (N=62)	67.7% 17.7%
		Study 2 (Day 21-30) <i>Modified-Intent-to-Treat Population at 21-30 Days</i>	SOLOSEC (N=107) Placebo (N=57)	53.3% 19.3%
		Study 2 (Day 7-14) <i>Modified- Intent-to-Treat Population at 7-14 Days</i>	SOLOSEC (N=107) Placebo (N=57)	57.9% 24.6%
	1 time, 5g applicator, applied vaginally	Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study ³		
		Study 1 (Day 21-30) <i>Modified-Intent-to-Treat Population at 21-30 Days</i>	Clindesse (N=78) Placebo (N=66)	41.0% 19.7%
		Randomized, Investigator-Blind, Active-Controlled Comparative Study		
Nuversa™ (metronidazole vaginal gel 1.3%)	1 time, 5g applicator, applied vaginally	Study 2 (Day 21-30) <i>Modified-Intent-to-Treat Population at 21-30 Days</i>	Clindesse Single Dose (N=221) Clindamycin Vaginal Cream, 7 doses (N=211)	53.4% 54.0%
		Study 2 (Day 21-30) <i>Per Protocol Population at 21-30 Days</i>	Clindesse Single Dose (N=126) Clindamycin Vaginal Cream, 7 doses (N=125)	64.3% 63.2%
		Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study ⁴		
		Study 1 (Day 21-30)	NUVESSA (N=292) Vehicle Gel (N=285)	37.0% 26.7%
		Study 1 (Day 7)	NUVESSA (N=292) Vehicle Gel (N=285)	41.1% 20.0%

1. Data on file
2. SOLOSEC PRESCRIBING INFORMATION <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=551e43d5-f700-4d6e-8029-026f8a8932ff&type=display>
3. Clindesse PRESCRIBING INFORMATION <https://www.clindesse.com/pdf/PI.pdf>
4. Nuversa PRESCRIBING INFORMATION https://www.nuversa.com/nuversa_files/Nuversa%20PI%202018-08.pdf

DARE-BV1 delivered **better clinical cure rate values than currently marketed FDA-approved products** for treatment of bacterial vaginosis.¹ DARE-BVFREE Study:

- 70% at Day 21-30 (primary endpoint) and 76% at Day 7-14 in the mITT population, and rates of 77% at Day 21-30 and 81% at Day 7-14 in the per protocol population.²
- Demonstrated that DARE-BV1 is significantly effective in what we believe was a representative patient population, including a large proportion of patients who reported one or more episodes of bacterial vaginosis diagnosed in the 12 months before they were randomized into the study (75% of the ITT population).³
- We expect **pre-NDA meeting with FDA early 2021** and NDA submission 1H 2021
- NDA may qualify for priority review and, if granted, receive a **2021 PDUFA date**, permitting potential 2022 commercial launch in the U.S.

DARE-BV1
Qualified Infectious
Disease Product
(QIDP) and Fast
Track Designations

QIDP and Fast
Track designations
support request for
Priority Review

1. Based on topline data from the Phase 3 DARE-BVFREE study and the prescribing information for currently marketed products.

2. For more detail regarding topline study results see our December 7, 2020 announcement available at: <https://ir.darebioscience.com/news-releases/news-release-details/dare-bioscience-announces-positive-topline-results-dare-bvfree>; the per protocol population (N=148) includes subjects from the mITT population who have no major protocol violations that impact the primary or secondary endpoints or who received any other bacterial vaginosis therapy for any reason.

3. Prior episodes were self reported

Sildenafil Cream, 3.6%

Potential **First-In-Category treatment** for Female Sexual Arousal Disorder (FSAD), which has no FDA-approved therapies

Novel cream formulation of sildenafil to treat FSAD, utilizing active ingredient in Viagra®

Female Sexual Arousal Disorder (FSAD) is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity and, of female sexual function disorders, is most analogous to **erectile dysfunction (ED)** in men.*

FSAD  HSDD

The condition should be distinguished from a general loss of interest in sexual activity and from other sexual dysfunctions, such as orgasmic disorder (anorgasmia) and **hypoactive sexual desire disorder (HSDD)**, which is characterized as 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.

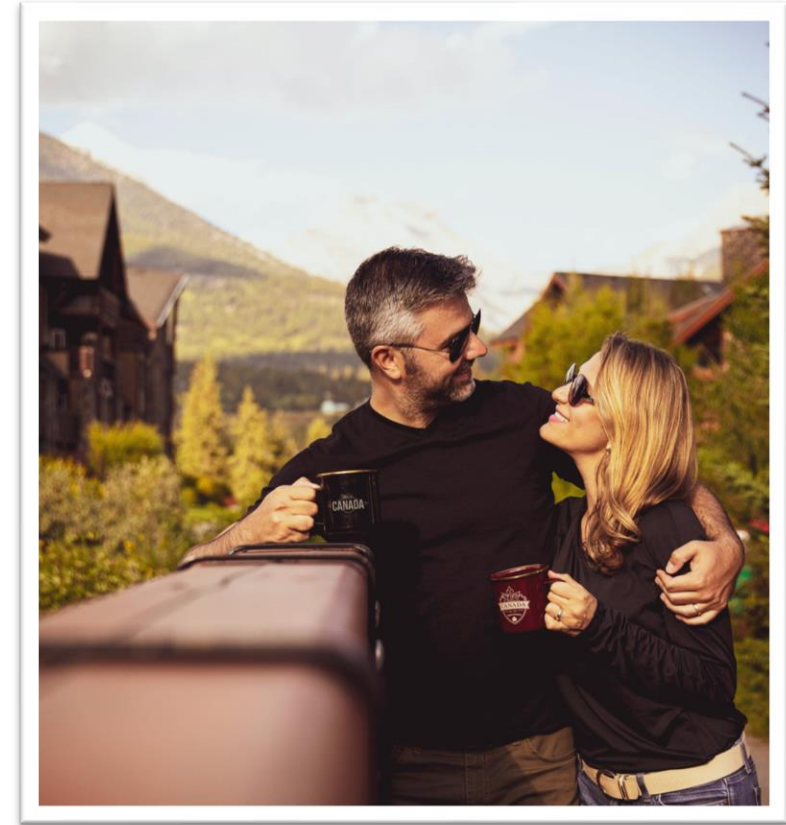
1. <https://drgeo.com/womens-sexual-health-overview/>;
2. <https://health.usnews.com/conditions/sexual-disorder-dysfunction>

FSAD – What Is the Incidence?

Meta-analysis of 95 studies from 2000-2014 indicated prevalence of **Female Sexual Dysfunction in premenopausal women worldwide is 41%, and difficulty with arousal alone is 23%.¹**

Market research estimates:

- 33% of US women aged 21 to 60 (~ **20 million women**), experience symptoms of low or no sexual arousal.^{2,3}
- **10 million women** are considered distressed and actively seeking treatment.²



Topically administered investigational Sildenafil Cream¹ is...

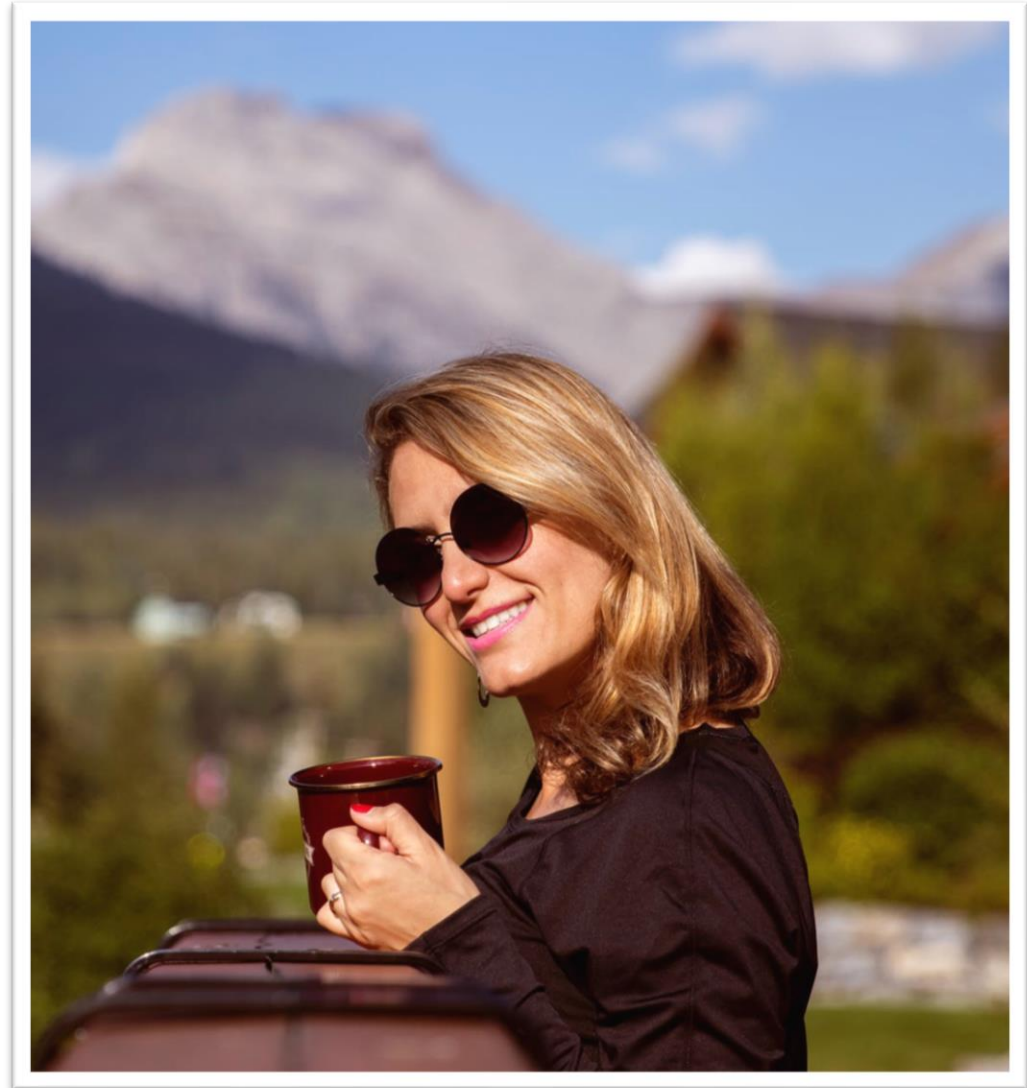
- A PDE5 inhibitor utilized in ED medications for men – ED product Viagra[®] peaked at \$2.05 billion in sales in 2012.²
- Designed to increase local blood flow to provide improvement in genital arousal response.
- **Applied topically**, avoiding hepatic first-pass metabolism response, resulting in lower systemic exposure potentially resulting in reduced side effects vs. oral sildenafil, including Viagra[®]
- Given **similarities between ED and FSAD**, sildenafil - the active ingredient in Viagra[®] - may improve genital arousal response and overall sexual experience for women as it does in men.

There are no FDA-approved treatments for FSAD

Sildenafil Cream, 3.6% - Phase 2b

The planned Phase 2b clinical study aims to evaluate Sildenafil Cream vs. placebo over 12 weeks of dosing following both a non-drug and placebo run-in period.

- Compares Sildenafil Cream vs. placebo in patients' home setting.
- Primary endpoint: patient reported outcome (PRO) instruments to measure improvement in localized genital sensations of arousal and reduction in FSAD related distress.
- Several exploratory efficacy endpoints will be measured and could become additional measurements of efficacy in a future Phase 3 program.



Ovaprene®

Investigational potential first-in-category, hormone-free, monthly birth control

Partnered with



Ovaprene® - Commercial License Agreement with Bayer¹



January 2020 - Bayer, which markets the \$1 billion Mirena contraceptive franchise, and Daré announced the execution of a license agreement under which Bayer may commercialize Ovaprene investigational contraceptive in the US once approved by FDA.

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

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

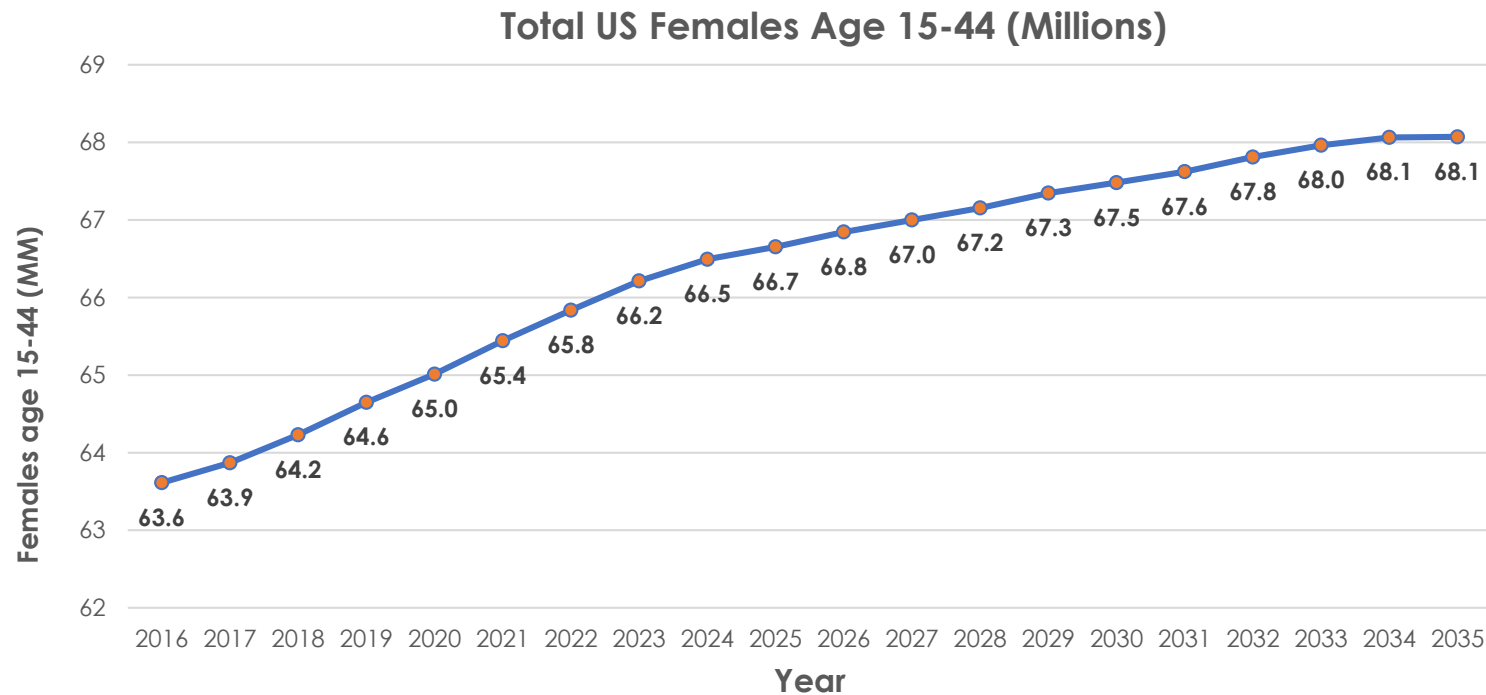
We believe the licensing agreement with Bayer is validation of our broader corporate strategy and confirmation of Ovaprene's market potential, if approved, as the first monthly non-hormonal contraceptive product in the US market.

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

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

Contraception: Large Market Opportunity

Women in the Reproductive Health & Contraception Market Segment (over 60 million women)



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

Successful Contraceptive Brands



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

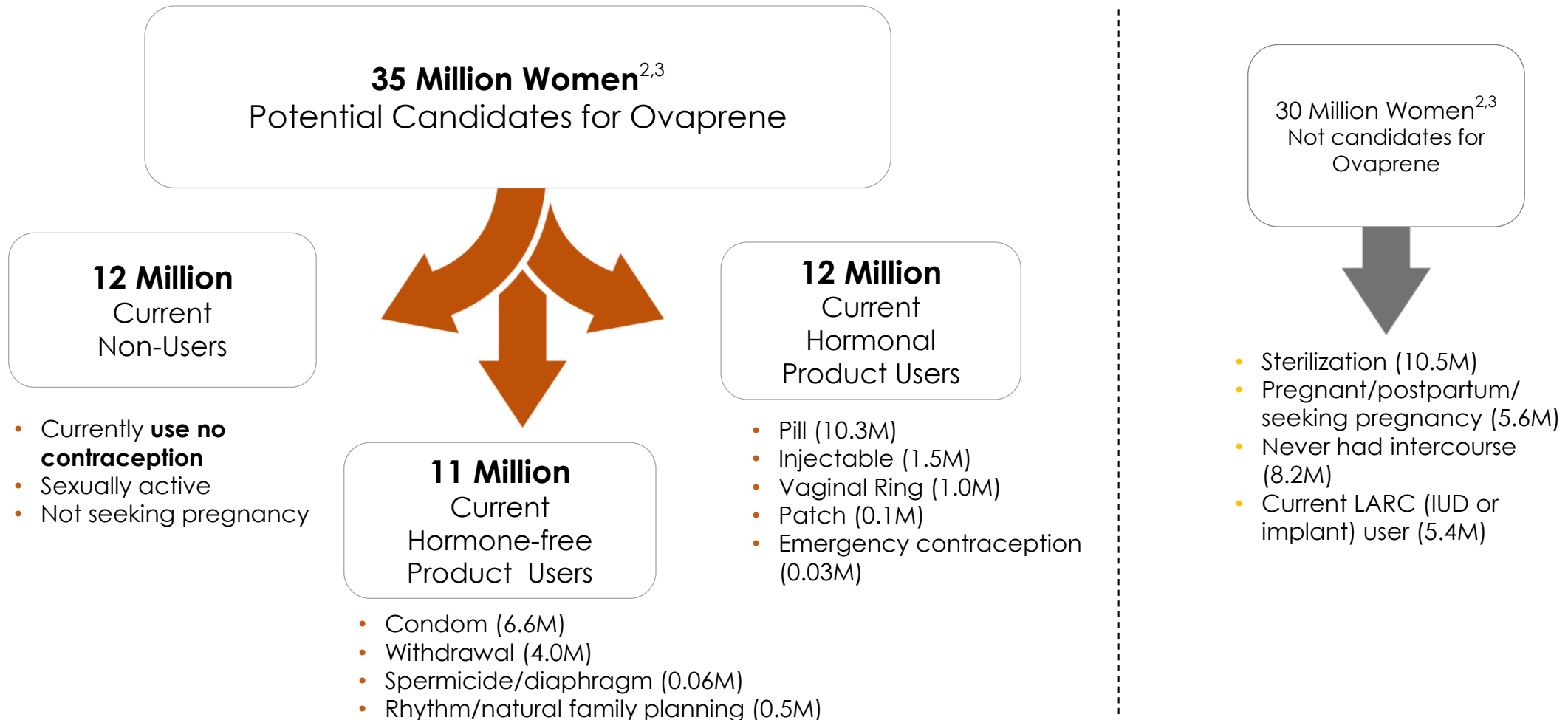


NuvaRing®
(etonogestrel/ethinyl estradiol vaginal ring)
Monthly vaginal ring
2019 worldwide sales: \$879 million (Merck)³

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.







Ovaprene® - Potential Market Opportunity

There are approximately 65 million women in the US Aged 15-44¹



Contraception: What's Missing from Current Hormone-Free Options?



Hormone-free Options	Pregnancies Expected (per 100 women) ^{1,*}	Least Effective
 Spermicides & Vaginal Gels ²	>27	
 Condoms (male)	18	
 Diaphragms (with a spermicide)	12	
 Easy-to-use monthly option	Effectiveness approaching hormonal methods	
 Copper IUD	<1	
		Most Effective

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):74963

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.

Early-Stage Portfolio

Innovative prescription drug delivery programs

DARE-HRT1

DARE-FRT1

DARE-VVA1

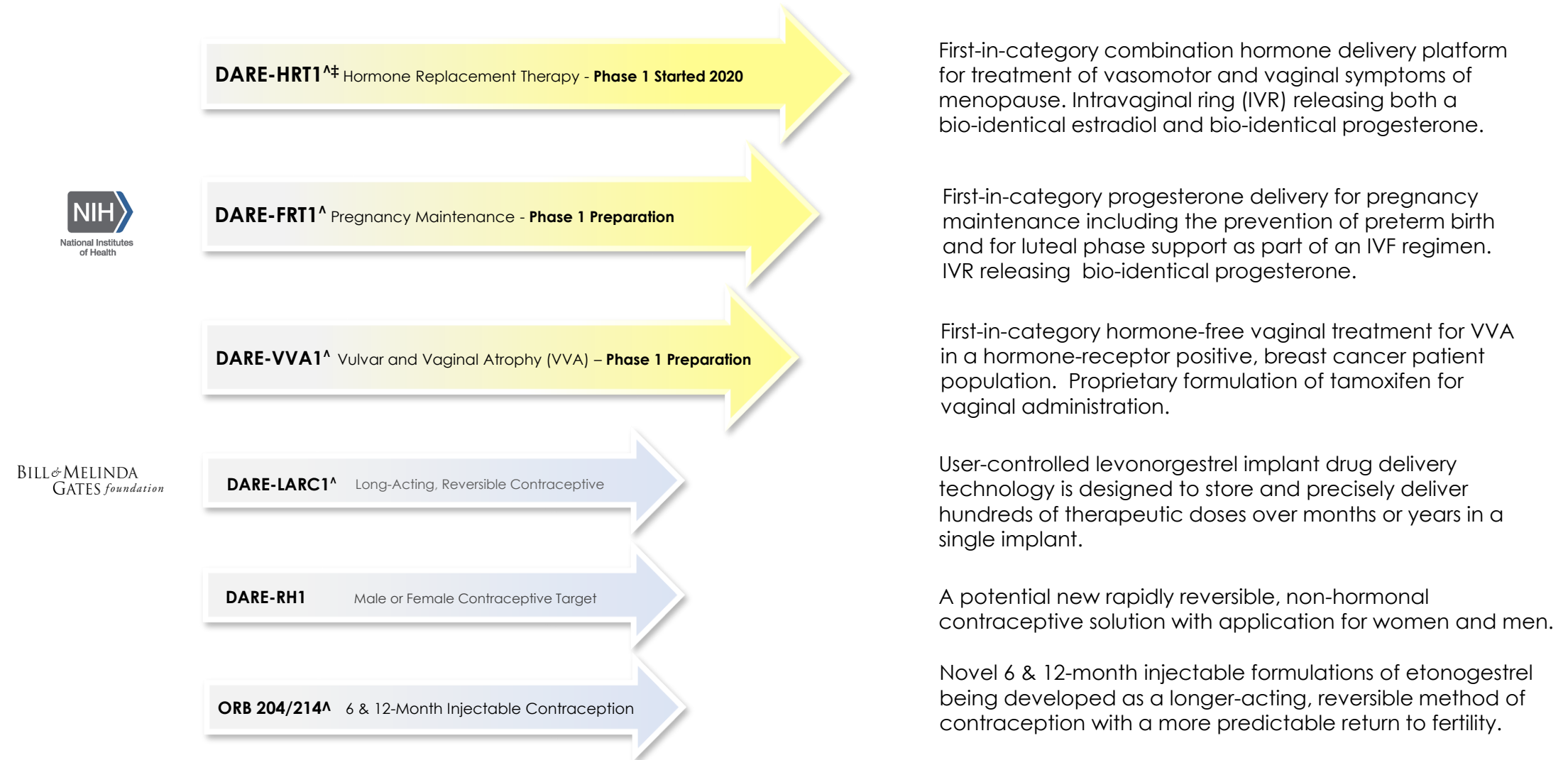
DARE-LARC1

DARE-RH1

ORB 204 & 214

Advancing Products Women Want

PARTNERS	Product Candidate	PRE-CLINICAL	PHASE 1	PHASE 2
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Daré – Advancing Products Women Want

- Innovative women's health pipeline with multiple clinical, regulatory and commercial milestones anticipated in 2021-2022.
- Every program, if approved, represents a potential first-line or first-in-class product opportunity.
- Experienced Board of Directors and Management Team with demonstrated success in clinical and product development, regulatory affairs, corporate strategy and financial operations.
- **Women's health generating more interest as evidenced by transformational transactions:**¹⁻⁷



Licensed **Ovaprene** from **Daré Bioscience**. Deal includes up to \$310 million in potential commercial milestone payments, plus double-digit, tiered royalties on net sales.

KaNDY acquisition for upfront consideration of \$425 million.



AbbVie \$63 billion acquisition of Allergan plc (creates women's health franchise - Lo Loestrin, Liletta and Elagolix).



Acquisition of Ogeda for €500 million upfront and the potential for up to another €300 million in milestone payments.



Acquired global rights to PARAGARD® Intrauterine Device (IUD) from Teva in a \$1.1 billion cash transaction.



Spinoff Organon, a new firm focused on women's health (including NuvaRing) and other drugs with projected revenues of \$6-\$6.5 billion (expected completion in 2021).



Myovant to receive up to \$4.2 B in collaboration to develop and commercialize relugolix in oncology and women's health including up to \$200m in regulatory milestones for the women's health product candidate.

Pharmaceutical companies will continue to seek new and differentiated products to supplement their branded women's health offerings.

1. <https://www.businesswire.com/Dare-Bioscience>
2. <https://www.businesswire.com/KaNDy-Therapeutics-Ltd>
3. http://www.pharmatimes.com/acquisition_of_allergan
4. <https://www.biopharmadive.com/news/astellas-ogeda-womens-health-deal>
5. <https://www.globenewswire.com/The-Cooper-Companies-Announces-Definitive-Agreement-to-Acquire-PARAGARD-IUD-From-Teva>
6. <https://www.statnews.com/merck-to-spin-off-new-6-5-billion-firm-focused-on-womens-health-older-drugs/>
7. <https://www.pfizer.com/news/press-release/press-release-detail/myovant-sciences-and-pfizer-announce-collaboration-develop>

Appendix



DARING TO BE DIFFERENT® AND ADVANCING PRODUCTS WOMEN WANT

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DARE-BV1

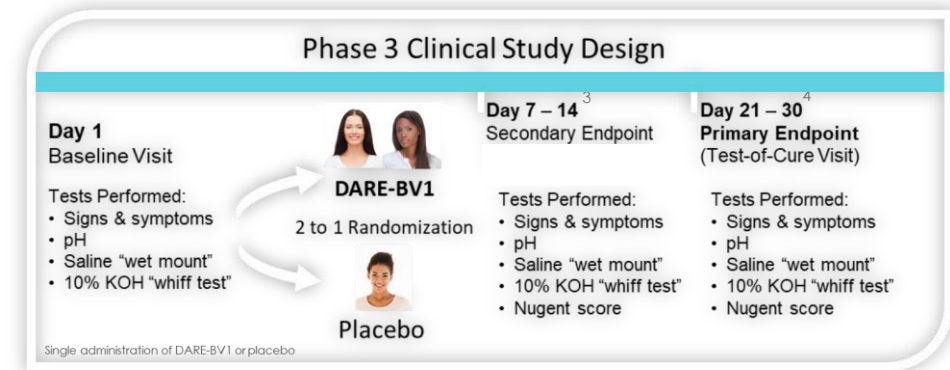
Clindamycin 2% gel for Bacterial Vaginosis

DARE-BV1- Phase 3 Study Design & Demographics¹

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

- DARE-BVFREE randomized 307 women at 32 centers across the US in a 2:1 ratio to receive a single vaginal dose of DARE-BV1 (N=204) or a single vaginal dose of placebo gel (N=103).
- The intent to treat (ITT)² population comprised primarily patients aged 15 to 59 years, with a mean age of 34.8 (SD=8.8) and median age of 35. Over 53% of the ITT population qualified as obese (BMI ≥30.0), with a mean BMI of 31.50 (SD=8.5).
- In the ITT population, 56.0% of women identified as Black or African American, 41% identified as white and 25.5% identified as of Hispanic or Latino origin (compared to 74.5% as not of Hispanic or Latino origin).
- In addition, more than 75% of women in the ITT population reported one or more episodes of bacterial vaginosis diagnosed in the 12 months before they were randomized into the study (77.4% in the DARE-BV1 group and 73.8% in the placebo group).

The DARE-BVFREE study's two treatment arms were well balanced in terms of age, race, ethnicity, bacterial vaginosis history, and body mass index (BMI).



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

Definitions:

Primary Endpoint: Clinical Cure (Day 21-30 visit): 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.

1. Data on file.
2. ITT population N=307
3. Visit occurred 7 to 14 days after study drug administration.
4. Visit occurred 21 to 30 days after study drug administration.

DARE-BV1- Phase 3 Study Topline Results

- The study's primary endpoint was clinical cure of bacterial vaginosis determined at Day 21-30 visit in the modified intent-to-treat (mITT) study population (N=180).¹
- **The study met its primary endpoint**, demonstrating single administration of DARE-BV1 proved statistically superior to placebo (p-value < 0.001) at Day 21-30 visit.
- DARE-BV1 also demonstrated statistically significant efficacy in all five pre-specified secondary efficacy assessments.
- Summary of clinical cure results (mITT population), p-value < 0.001:

DARE-BVFREE Phase 3 Study	DARE-BV1 (N = 121)	Placebo (N = 59)
Clinical Cure at Day 7-14 visit	76.0%	23.7%
Clinical Cure at Day 21-30 visit (primary endpoint)	70.2%	35.6%

- DARE-BV1 was well tolerated in the study.

1. In accordance with U.S. Food and Drug Administration (FDA) guidance, the mITT population (N=180) excludes subjects from the intent-to-treat (ITT) population (N=307) who subsequently demonstrated a positive test result for other concomitant vaginal or cervical infections at baseline.



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

Ovaprene® - U.S Regulatory Strategy ¹

Premarket approval (PMA) strategy

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 1Q2022 pivotal study start.
- Conduct pivotal study
 - Six-month efficacy and safety 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 Endpoint ²

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

Sildenafil Cream, 3.6%

Female Sexual Arousal Disorder (FSAD)

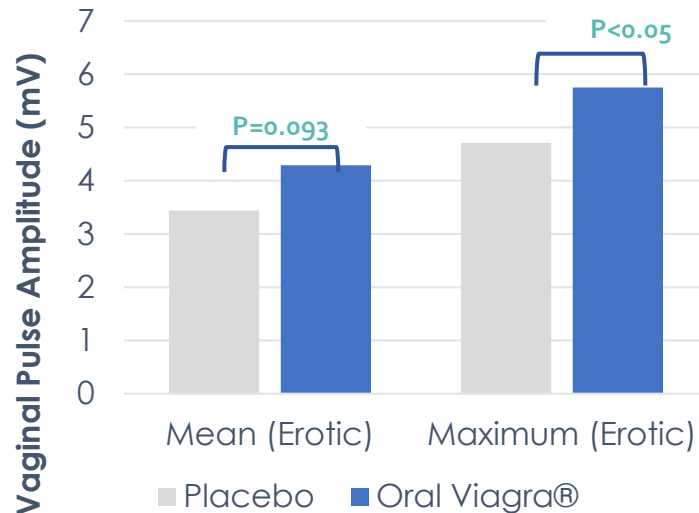
The global female sexual dysfunction treatment market is expected to grow at ~37% CAGR from 2019 - 2023

Oral Sildenafil provided a compelling proof of concept for FSAD

Statistically significant increases in Vaginal Pulse Amplitude (VPA)¹

Pfizer VPA Clinical Lab Study – Oral Viagra

Mean and Maximum VPA[†]

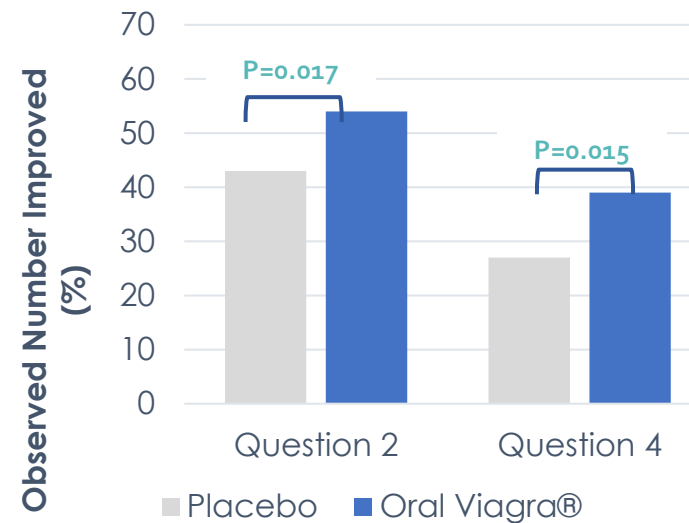


[†] Twelve healthy premenopausal women were studied.

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

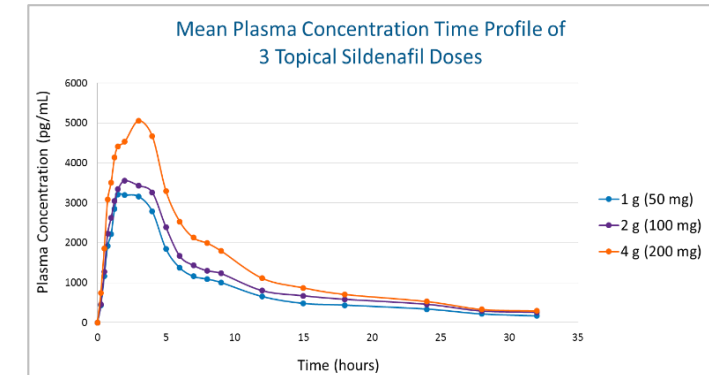
Phase 2a Study of SST-6007 (Sildenafil Cream, 3.6%)¹

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

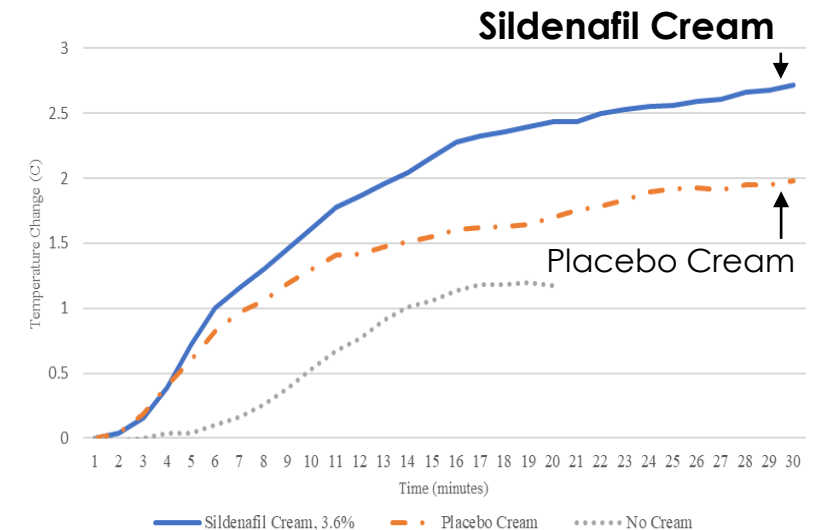
Phase 1 Study



Positive Data- (See 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.

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.

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).

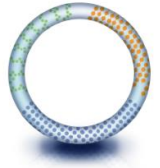


Vaginal Drug Delivery

New investigational prescription drug delivery options for women

The Vaginal Route of Drug Administration¹

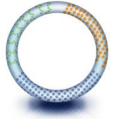
- Vaginal drug delivery offers many potential advantages due to large surface area, dense network of blood vessels and high elasticity due to presence of smooth muscle fibers.
- Recognized advantages include comparable ease of administration and ability to bypass hepatic first-pass metabolism.



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 one or several active drugs,
- No need for membrane or reservoir to contain active drug(s) or control the release.

Combination bio-identical estradiol + bio-identical progesterone IVR for hormone replacement therapy following menopause



★ 45M women in U.S. approaching or in menopause¹

Hormone Replacement Therapy (HRT)

HRT remains the most effective treatment for vasomotor symptoms (VMS) and 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

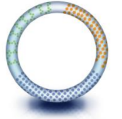
NAMS observes: **non-oral routes may offer advantages** over oral routes of administration.²

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

Bio-identical progesterone IVR for prevention of preterm birth and luteal phase support as part of an IVF treatment plan



Prevention of Preterm Birth (PTB)

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



NIH Grant Funding for DARE-FRT1 PTB Program

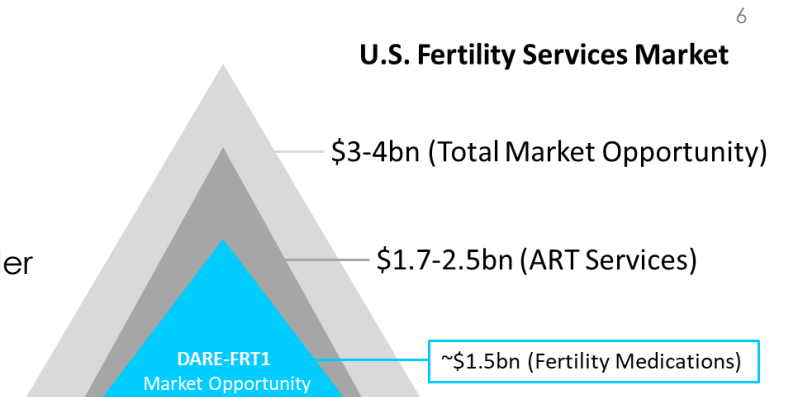
Potential for up to \$2.3 million in NIH grant funding to support DARE-FRT1 development

- 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, infertility risk increases

- ~12-15% of couples cannot conceive after 1-year of unprotected sex.⁴
- ~20% of US women have their first child after age 35; ~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. <https://www.nichd.nih.gov/health/topics/infertility/conditioninfo/common> accessed January 8, 2021
5. <https://www.cdc.gov/reproductivehealth/infertility/index.htm> accessed January 8, 2021
6. Harris Williams & Co. Fertility market overview. May 2015.

Proprietary tamoxifen formulation for vaginal administration for vulvar and vaginal atrophy (VVA)

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

Potential to be the first therapeutic specifically approved for treatment of vulvar and vaginal atrophy (VVA) in patients with hormone-receptor positive (HR+) breast cancer.

- Approximately 3.8 million US women have a history of breast cancer; 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 at **42 to 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.

DARE-VVA1 Proof of Concept

This exploratory study¹ 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, 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

1. Clin. Exp. Obstet. Gynecol. - ISSN: 0390-6663 XLVI, n. 2, 2019

2. <https://www.medicalnewstoday.com/articles/322537.php>

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



User-Controlled Long-Acting Reversible Contraception

(UC-LARC) / Microchips Technology

User-Controlled Long-Acting Reversible Contraception

- Drug Storage
 - Individual doses 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 initiated automatically on schedule or wirelessly on-demand by the patient
 - Reservoirs are opened via electrothermal ablation of membranes
 - Upon opening, interstitial fluid diffuses in and drug diffuses out

DARE-LARC1 Grant Funding

The Bill & Melinda Gates Foundation has strong interest in family planning

~215 million women in developing countries lack access to contraception

Grant funding
to date: \$20.5m

Funding 2013

Grant to understand user needs and define the product concept

Favorable response from Sub-Saharan Africa

- Sub-dermal implant use is growing
- **87% of women surveyed said they would use the proposed implant**
- 74% of healthcare workers said they would use the proposed implant in their practice

Funding 2014 – 2021

Grant to develop implant concept and technology

Currently executing a 4th supplemental grant funding to demonstrate multiple drug releases *in vivo*, after successfully completing additional market research and concept development in the 3rd supplemental grant funding



Financial Summary

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

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

Non-Dilutive Funding Sources

Grant funding:

- \$1.9 million grant for Ovaraprene R&D expenses from Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of 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 Bill & Melinda Gates Foundation.
- **Potential for up to \$2.3 million grant from 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; agreement will provide dedicated resources and new pricing structures, which with Health Decisions' expertise and established relationships, should accelerate development of key programs in a capital-efficient manner.
- Avomeen, an accredited, independent contract R&D and manufacturing organization specializing in chemical analysis and product development; our agreement provides a preferred discounted price structure and access to Avomeen's scientific expertise, including advanced instrumentation and development techniques.
- Australia's R&D tax incentive currently allows refundable cash credit of up to 43.5% of investments made by eligible companies in eligible R&D activity. We intend to apply for the maximum amount allowable under our DARE-HRT1 program.



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