



NASDAQ: DARE  
[www.darebioscience.com](http://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

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- ✓ Diverse pipeline – including four clinical development stage candidates
- ✓ Independent outcomes – product candidates utilize different APIs and target different indications
- ✓ Large market potential – first-line and first-in-category product opportunities
- ✓ 505(b)(2) FDA pathway planned for multiple candidates – novel delivery of well-characterized APIs to address unmet needs
- ✓ Commercial value in women's health evidenced by recent transformational pharma transactions

## Anticipated Program Milestones\*

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- 2021** ☐ DARE-BV1 NDA submission to FDA
  - ☐ DARE-HRT1 Phase 1 study topline data
  - ☐ DARE-BV1 PDUFA date<sup>^</sup>
  - ☐ Sildenafil Cream, 3.6% topline data for FSAD Phase 2b study
- 2022** ☐ DARE-BV1 U.S. commercial launch
  - ☐ Ovaprene<sup>®</sup> data from pivotal Phase 3 study

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

<sup>^</sup> 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 with Industry Leaders

## We partner to...

Drive **innovation** and develop new solutions

**Accelerate** novel products to **address persistent unmet needs**

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

## 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<sup>^</sup>** Bacterial Vaginosis- **Phase 3 Topline Data Announced December 2020**

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



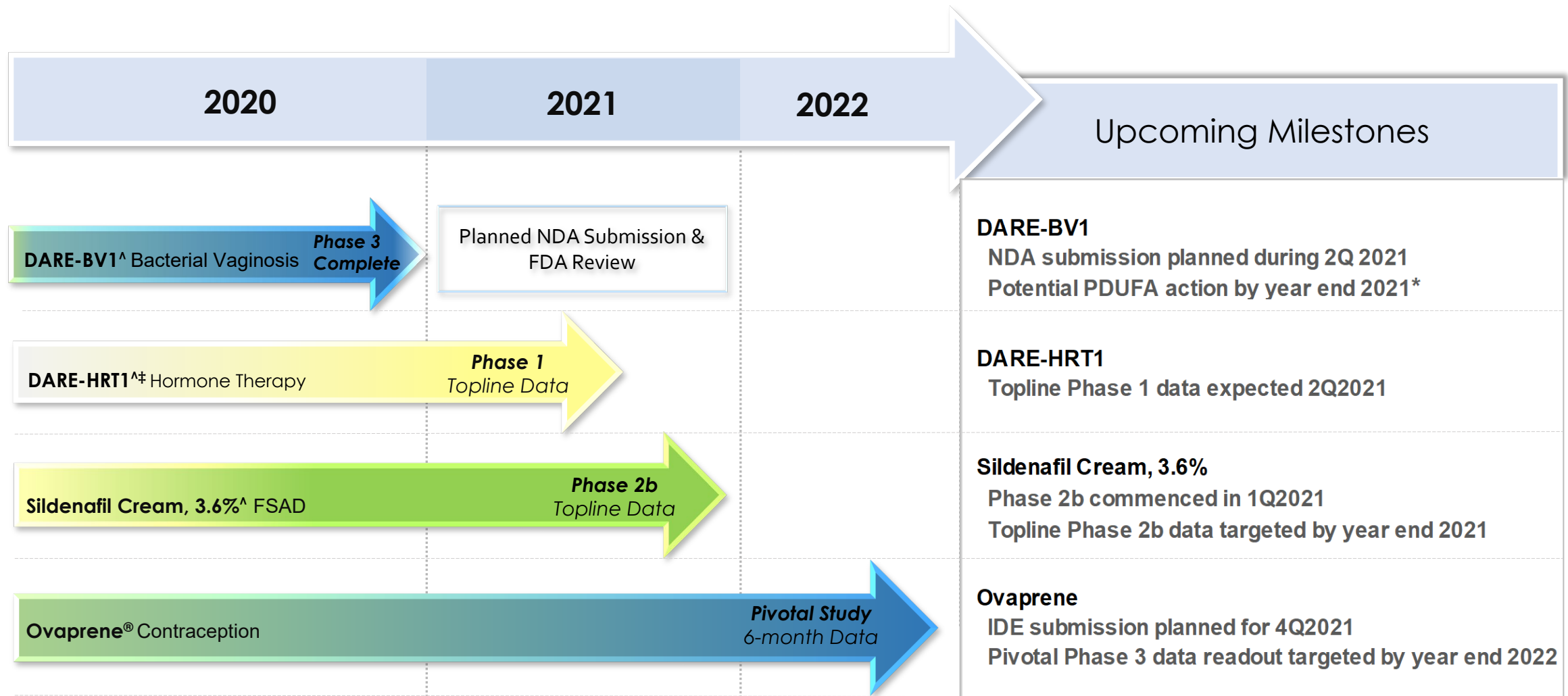
## **Ovaprene<sup>®</sup>** Hormone-Free, Monthly Contraception- **Pivotal Phase 3 Study 6-Month Data 2022\***

First-in-category Hormone-Free Monthly Contraception  
*Self-administered intravaginal drug/device*

## **Sildenafil Cream, 3.6% <sup>^</sup>** 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<sup>®</sup>*
































































# Near Term Catalysts to Drive Value



**DARE-BV1** NDA filing and **two** top-line data readouts targeted for **2021**



# Experienced Management & Board of Directors

Management Team		Board of Directors	
	<b>Sabrina Martucci Johnson MSc, MIM</b> President & CEO		<b>William Rastetter, PhD</b> Chairman
	   		    
	<b>John Fair</b> Chief Strategy Officer		<b>Cheryl Blanchard, PhD</b>
	  		  
	<b>Lisa Walters-Hoffert</b> Chief Financial Officer		<b>Jessica Grossman, MD</b>
	   		  
	<b>David Friend, PhD</b> Chief Scientific Officer		<b>Susan Kelley, MD</b>
	   		  
	<b>Mary Jarosz, RPh, RAC, FTOPRA</b> Global Head of Regulatory Affairs		<b>Greg Matz, CPA</b>
	  		  
	<b>Mark Walters</b> Vice President of Operations		<b>Robin Steele, JD, LLM</b>
	   		  
	<b>Christine Mauck, MD, MPH</b> Medical Director		<b>Sabrina Martucci Johnson MSc, MIM</b> 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**<sup>1</sup> vaginal infection in women of reproductive age, designed for convenient, one-time administration

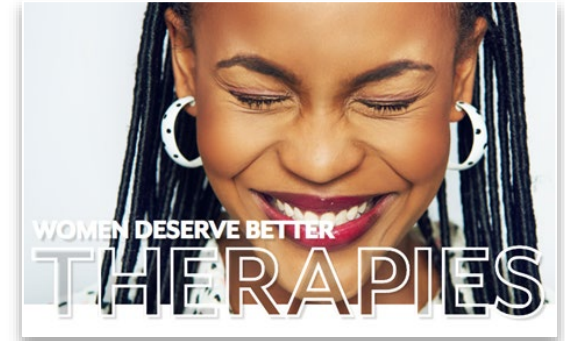
Planned **NDA submission 2Q 2021**

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 US<sup>1</sup>
- Current Rx suboptimal: clinical cure rates of 37-68%<sup>2</sup>



## Bacterial Vaginosis increases health risk<sup>3</sup>

- 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); [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
<b>DARE-BV1</b> (Investigational) (clindamycin phosphate vaginal gel, 2%)	1 time, 5g applicator, applied vaginally	Randomized Placebo-Controlled Phase 3 Trial <sup>1</sup>		
		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)	<b>70.2%</b> 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)	<b>76.0%</b> 23.7%
Solosec® (secnidazole 2g oral granules)	1 time, 2g dose, taken orally	Two Randomized, Placebo-Controlled Phase 3 Studies <sup>2</sup>		
		Study 1 (Day 21-30) <i>Modified-Intent-to-Treat Population at 21-30 Days</i>	SOLOSEC (N=62) Placebo (N=62)	<b>67.7%</b> 17.7%
		Study 2 (Day 21-30) <i>Modified-Intent-to-Treat Population at 21-30 Days</i>	SOLOSEC (N=107) Placebo (N=57)	<b>53.3%</b> 19.3%
		Study 2 (Day 7-14) <i>Modified- Intent-to-Treat Population at 7-14 Days</i>	SOLOSEC (N=107) Placebo (N=57)	<b>57.9%</b> 24.6%
Clindesse® (clindamycin phosphate vaginal cream, 2%)	1 time, 5g applicator, applied vaginally	Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study <sup>3</sup>		
		Study 1 (Day 21-30) <i>Modified-Intent-to-Treat Population at 21-30 Days</i>	Clindesse (N=78) Placebo (N=66)	<b>41.0%</b> 19.7%
		Randomized, Investigator-Blind, Active-Controlled Comparative Study		
		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)	<b>53.4%</b> 54.0%
Nu vessa™ (metronidazole vaginal gel 1.3%)	1 time, 5g applicator, applied vaginally	Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study <sup>4</sup>		
		Study 1 (Day 21-30)	NUVESSA (N=292) Vehicle Gel (N=285)	<b>37.0%</b> 26.7%
		Study 1 (Day 7)	NUVESSA (N=292) Vehicle Gel (N=285)	<b>41.1%</b> 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. Nu vessa PRESCRIBING INFORMATION [https://www.nu vessa.com/nu vessa\\_files/Nu vessa%20PI%202018-08.pdf](https://www.nu vessa.com/nu vessa_files/Nu vessa%20PI%202018-08.pdf)

DARE-BV1 delivered **better clinical cure rate values than currently marketed FDA-approved products** for treatment of bacterial vaginosis.<sup>1</sup> 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.<sup>2</sup>
- 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).<sup>3</sup>
- Based on pre-NDA meeting with FDA early 2021, **targeting NDA submission by end of 2Q2021.**
- 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

Supports  
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.\*



**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.<sup>1,2</sup>

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

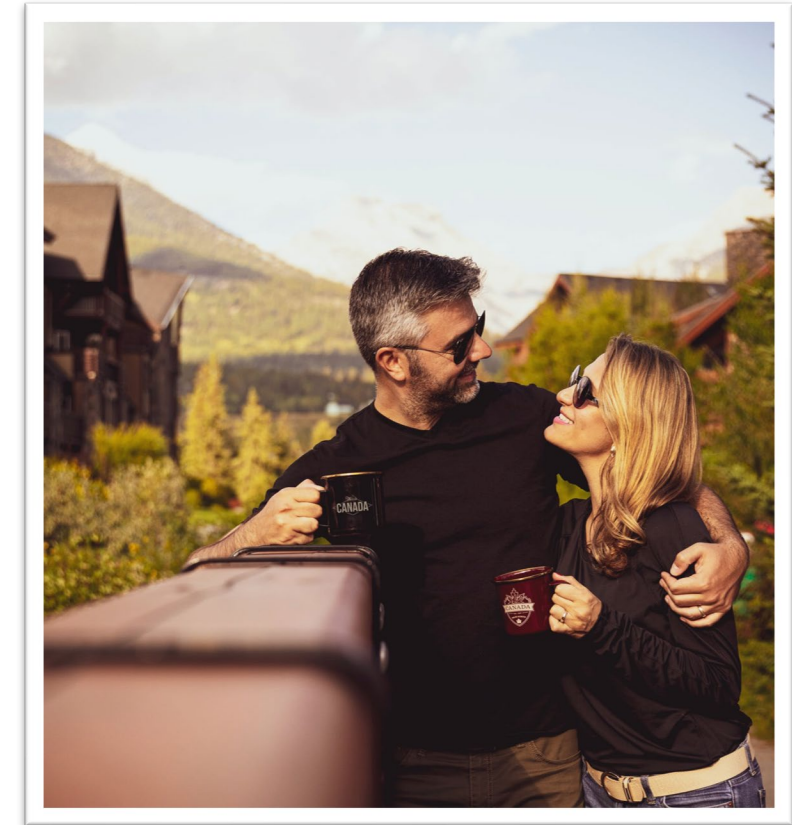
1. <https://drgeo.com/womens-sexual-health-overview/>;  
2. <https://health.usnews.com/conditions/sexual-disorder-dysfunction>

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

Market research estimates:

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





Topically administered investigational Sildenafil Cream<sup>1</sup> is...

- A PDE5 inhibitor utilized in ED medications for men – ED product Viagra<sup>®</sup> peaked at \$2.05 billion in sales in 2012.<sup>2</sup>
- 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<sup>®</sup>
- Given **similarities between ED and FSAD**, sildenafil - the active ingredient in Viagra<sup>®</sup> - 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

Ongoing 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 used 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 Bayer<sup>1</sup>



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.

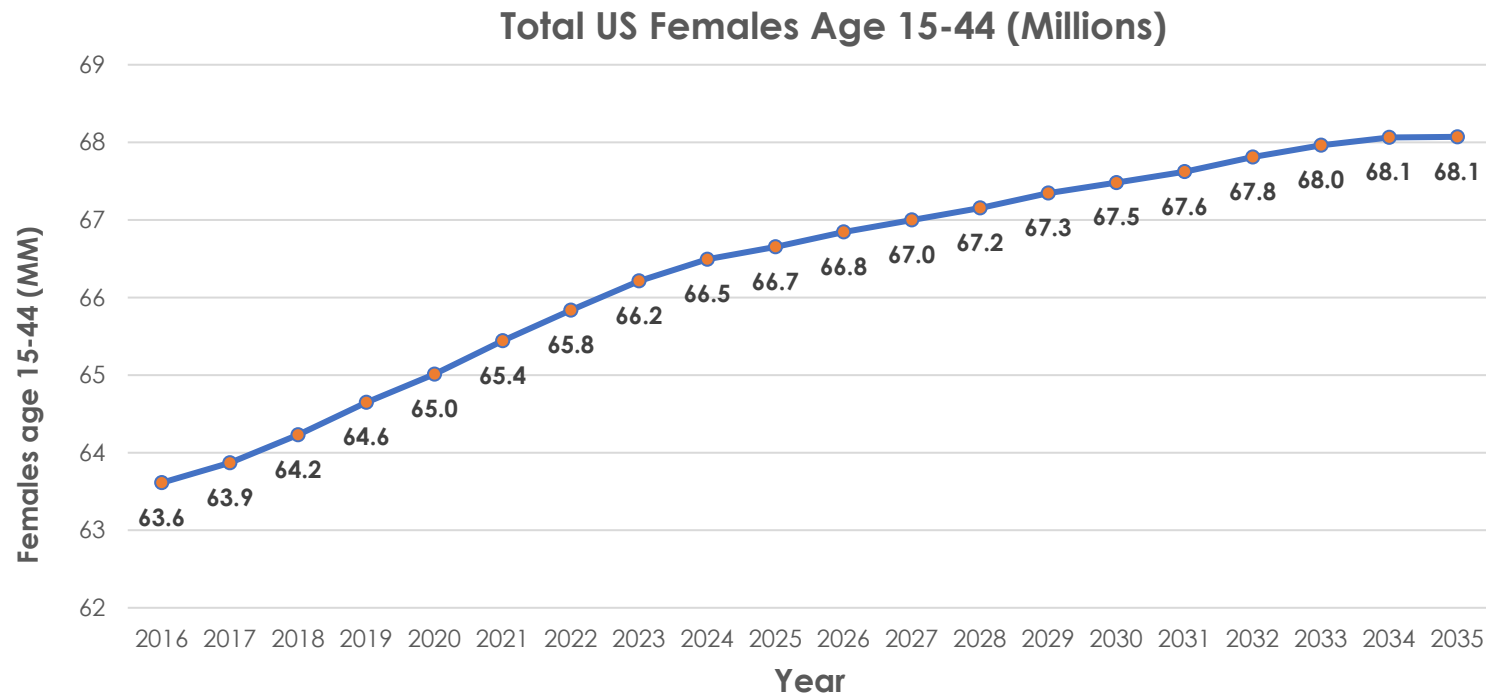
*We believe the licensing agreement with Bayer is validation of our broader corporate strategy and confirmation of Ovaprene's market potential, if approved, as the first monthly non-hormonal contraceptive product in the US market.*

\* <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 Peak Sales:



**Mirena® Hormone IUD**  
(levonorgestrel-releasing intrauterine system) 52mg  
Physician inserted, long-acting.  
low/locally delivered hormone IUS  
**2019 worldwide sales: €1.2 billion (Bayer)**<sup>1</sup>



**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)**<sup>2</sup>

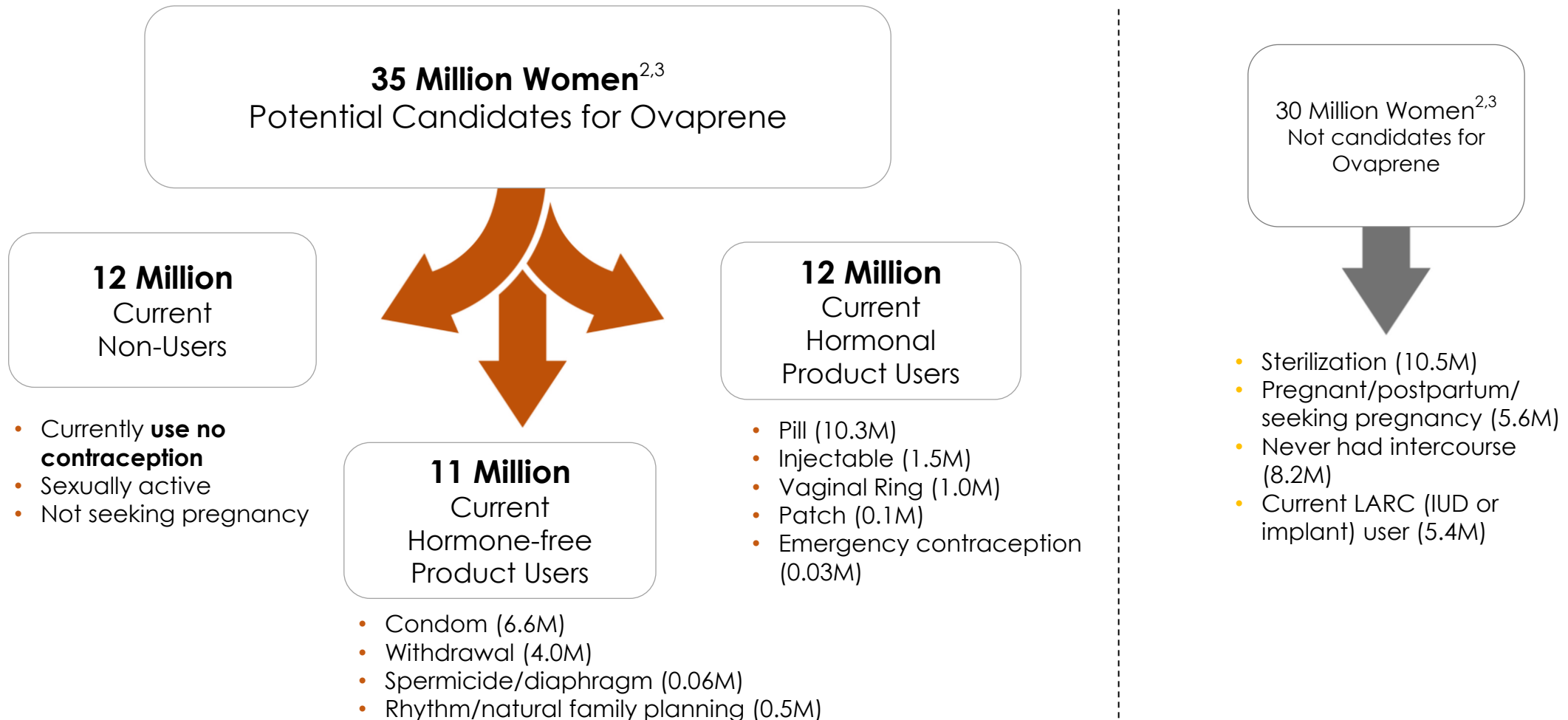


**NuvaRing®**  
(etonogestrel/ethinyl estradiol vaginal ring)  
Monthly vaginal ring  
**2019 worldwide sales: \$879 million (Merck)**<sup>3</sup>

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](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 15-44<sup>1</sup>



1. Source: CDC National Survey for Family Growth, 2013-2015 dataset, cdc.gov.







2. Market research study conducted in 2019 for Daré Bioscience

3. Contraceptive use data applied to 2019 population data from US Census



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



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

1. U.S. Food and Drug Administration Birth Control Guide dated 2/11/2020: <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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208352s000lbl.pdf)

\* 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.



# Ovaprene® Investigational Hormone-Free, Monthly Contraceptive

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

## Physical Barrier<sup>6</sup>

Three-dimensional, knitted polymer barrier



## Spermistatic Environment<sup>6</sup>

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.

# Early-Stage Portfolio

Innovative prescription drug delivery programs

DARE-HRT1

DARE-FRT1

DARE-VVA1

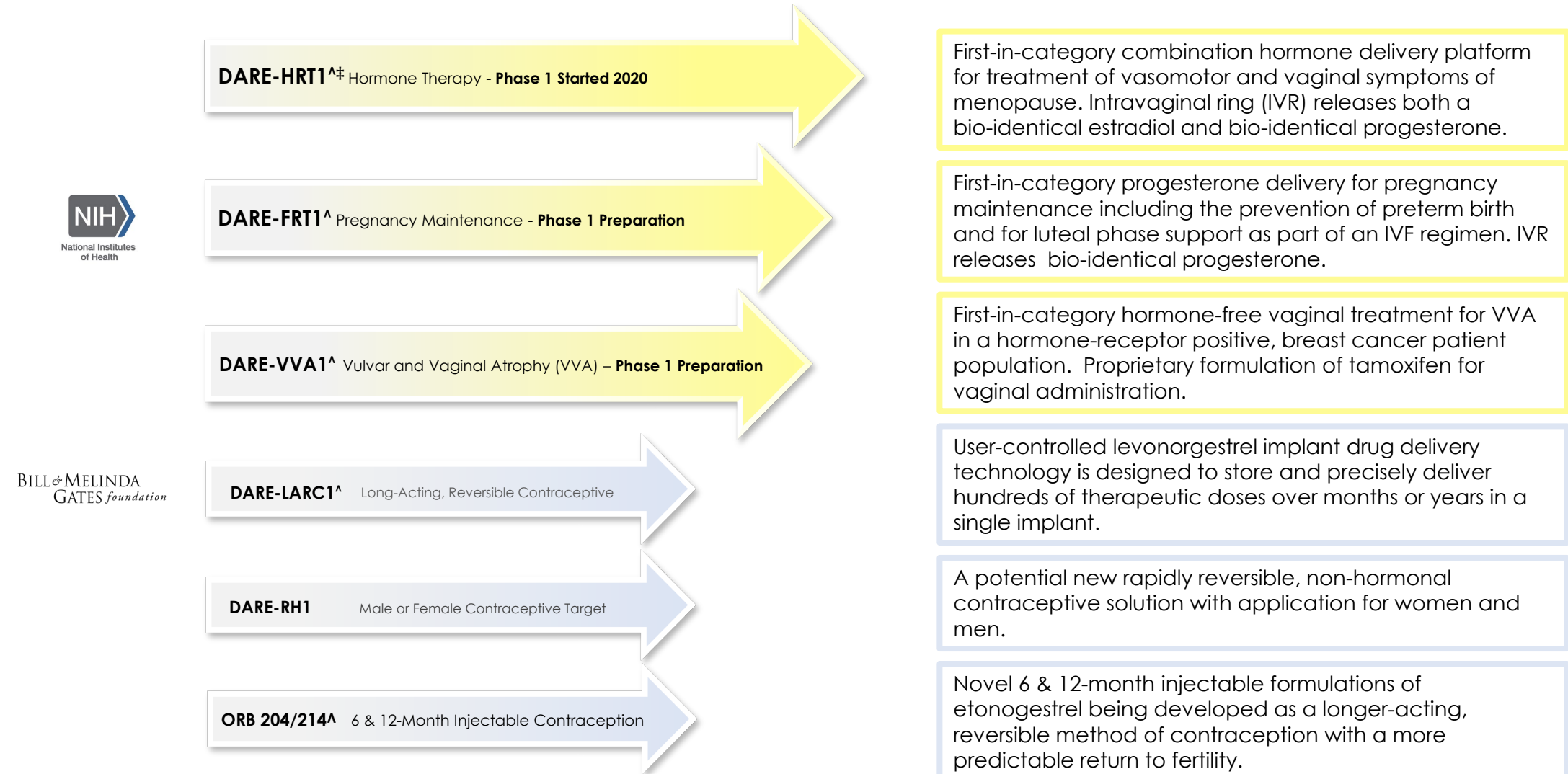
DARE-LARC1

DARE-RH1

ORB 204 & 214

# Advancing Products Women Want

PARTNERS	Product Candidate	PRE-CLINICAL	PHASE 1	PHASE 2
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BILL & MELINDA  
GATES foundation

# 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:**<sup>1-7</sup>



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/DareBioscience>  
2. <https://www.businesswire.com/KaNDy-Therapeutics-Ltd>  
3. [http://www.pharmatimes.com/acquisition\\_of\\_allergan](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

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





# DARE-BV1

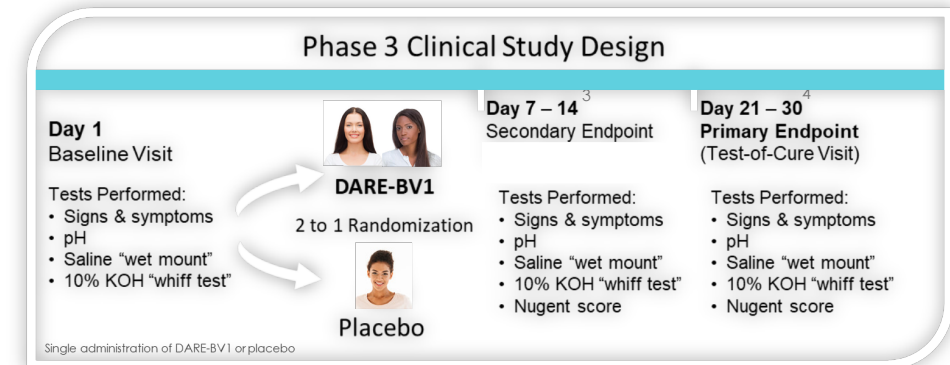
Clindamycin 2% gel for Bacterial Vaginosis

# DARE-BV1- Phase 3 Study Design & Demographics<sup>1</sup>

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)<sup>2</sup> 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).<sup>1</sup>
- **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	<b>DARE-BV1 (N = 121)</b>	Placebo (N = 59)
<b>Clinical Cure at Day 7-14 visit</b>	<b>76.0%</b>	23.7%
<b>Clinical Cure at Day 21-30 visit (primary endpoint)</b>	<b>70.2%</b>	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<sup>®</sup>

## 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%*

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

# Ovaprene® - U.S Regulatory Strategy <sup>1</sup>

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 <sup>2</sup>

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
<b>Baseline PCT's</b>	27.21	23.20	17.88	24.80
<b>Ovaprene PCT's</b>	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)

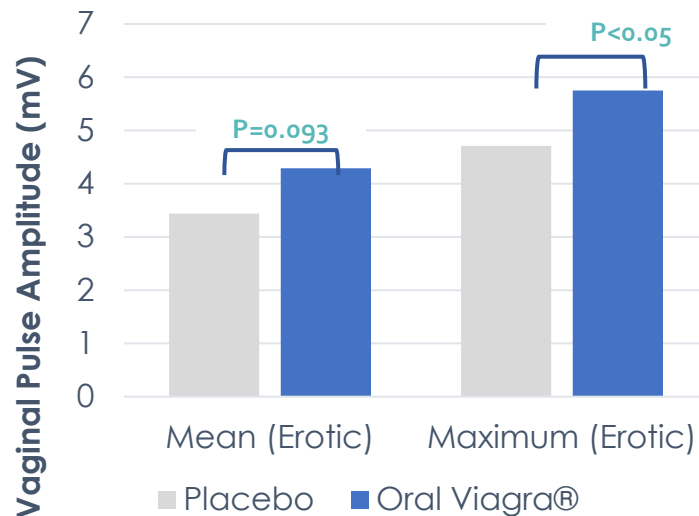
*The global female sexual dysfunction treatment market is expected to grow at  
~37% CAGR from 2019 - 2023*

# Oral Sildenafil provided a compelling proof of concept for FSAD

## Statistically significant increases in Vaginal Pulse Amplitude (VPA)<sup>1</sup>

**Pfizer** VPA Clinical Lab Study – Oral Viagra

Mean and Maximum VPA<sup>†</sup>

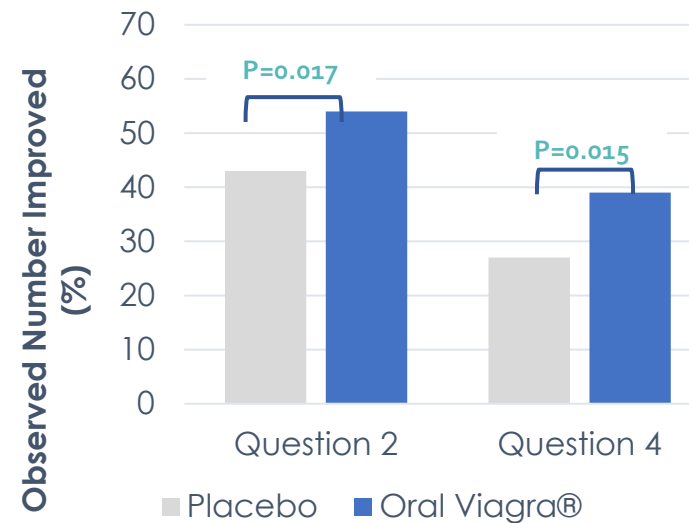


<sup>†</sup> Twelve healthy premenopausal women were studied.

## Statistically significant improvement in genital stimulation (FIEI)<sup>2</sup>

**Pfizer** Clinical Field Study – Oral Viagra

Improvement on FIEI Questions<sup>†</sup>



## Female Intervention Efficacy Index (FIEI)

<sup>†</sup> **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**.

# Sildenafil Cream, 3.6% - Phase 1/2a Study Results

## 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.

- Sildenafil Cream had significantly lower systemic exposure compared to a 50 mg oral sildenafil dose
  - AUC – 3-6%
  - C<sub>max</sub> – 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

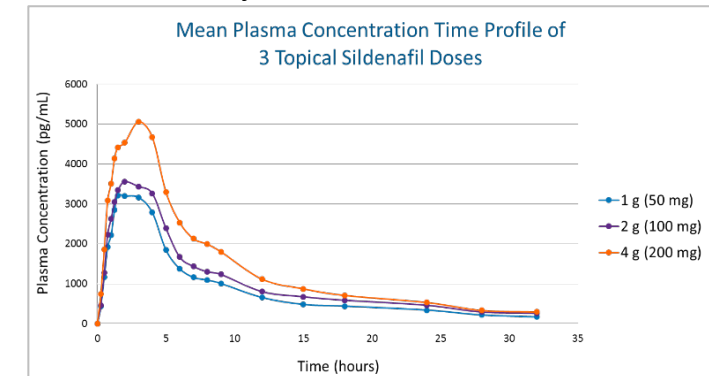
## Phase 2a Study of SST-6007 (Sildenafil Cream, 3.6%)<sup>1</sup>

**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 <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

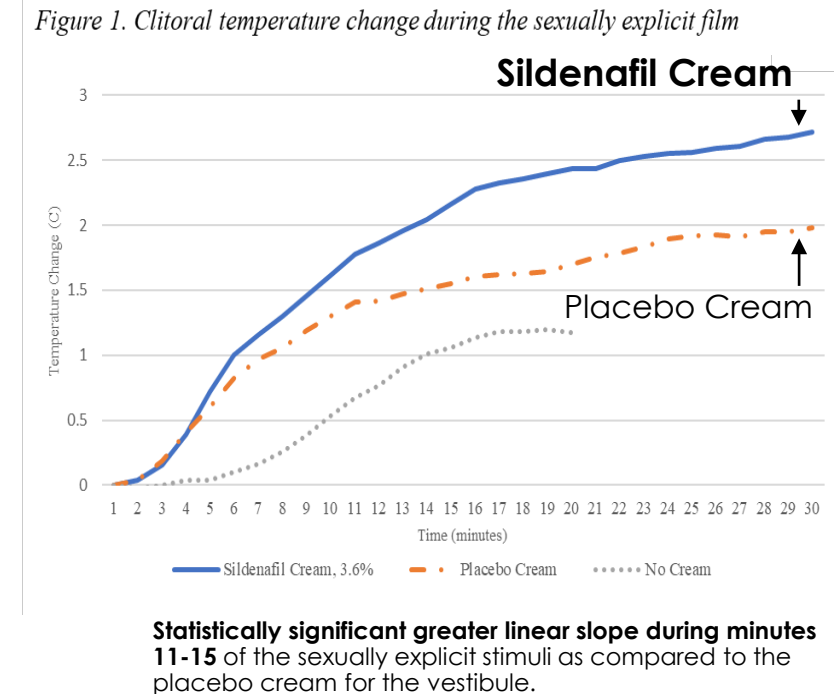
### Phase 1 Study





## 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.



## Thermography Study Design & Methodology <sup>(N=6)</sup><sup>1</sup>

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).



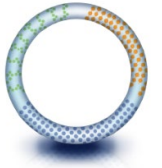


# Vaginal Drug Delivery

New investigational prescription drug  
delivery options for women

## The Vaginal Route of Drug Administration<sup>1</sup>

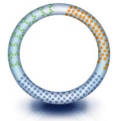
- Vaginal drug delivery offers many potential advantages due to large surface area, dense network of blood vessels and high elasticity due to presence of smooth muscle fibers.
- Recognized advantages include comparable ease of administration and ability to bypass hepatic first-pass metabolism.



## 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 therapy following menopause*



## 45M women in U.S. approaching or in menopause<sup>1</sup>

### Hormone Therapy (HT)

HT 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.<sup>2</sup>

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

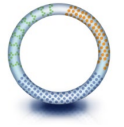
NAMS observes: **non-oral routes may offer advantages** over oral routes of administration.<sup>2</sup>

### 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,<sup>2</sup> the US premature birth rate rose for the fourth straight year in 2018 with ~10% of babies born preterm (<37 weeks).<sup>3</sup>



## NIH Grant Funding for DARE-FRT1 PTB Program

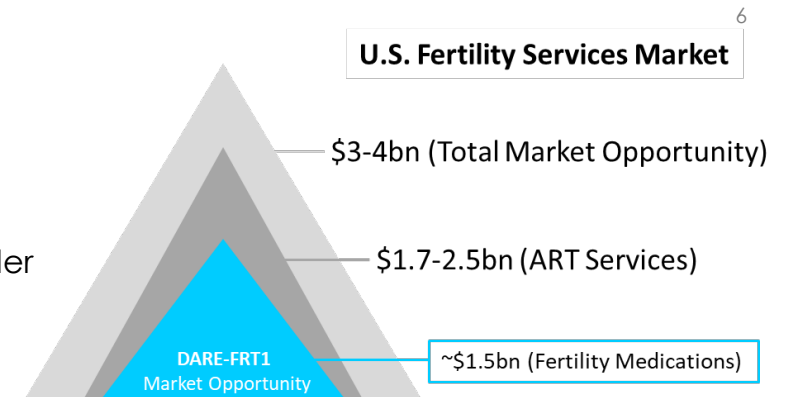
Potential for up to \$2.3 million in NIH grant funding to support DARE-FRT1 development

- 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.<sup>4</sup>
- ~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.<sup>5</sup>



505(b)(2) candidate<sup>1</sup>

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](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.<sup>2</sup>
- 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%.**<sup>3</sup>



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

# DARE-VVA1 Proof of Concept

**This exploratory study<sup>1</sup>** 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)
<b>Median Vaginal pH</b> Normal vaginal pH is usually less than 4.5. <sup>2</sup>	7.1 range 6.5 to 7.5	5.0 range 5.0 to 5.2	<b>-2.0 median range -2.5 to -1.5</b>  Lower pH value is a measure of symptom relief
<b>Vaginal Dryness</b> 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	<b>-5.5 median range -6.0 to -4.5</b>  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),<sup>3</sup> 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](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 4<sup>th</sup> supplemental grant funding to demonstrate multiple drug releases *in vivo*, after successfully completing additional market research and concept development in the 3<sup>rd</sup> supplemental grant funding



# Financial Summary

## FY 2020 Financial Highlights:

- Cash provided from financing activities\* through 12/31/20: \$25.1 million (net of fees)
- Cash and equivalents (as of 12/31/20): \$4.7 million

## 1Q2021 Update (January 1 to March 29, 2021):

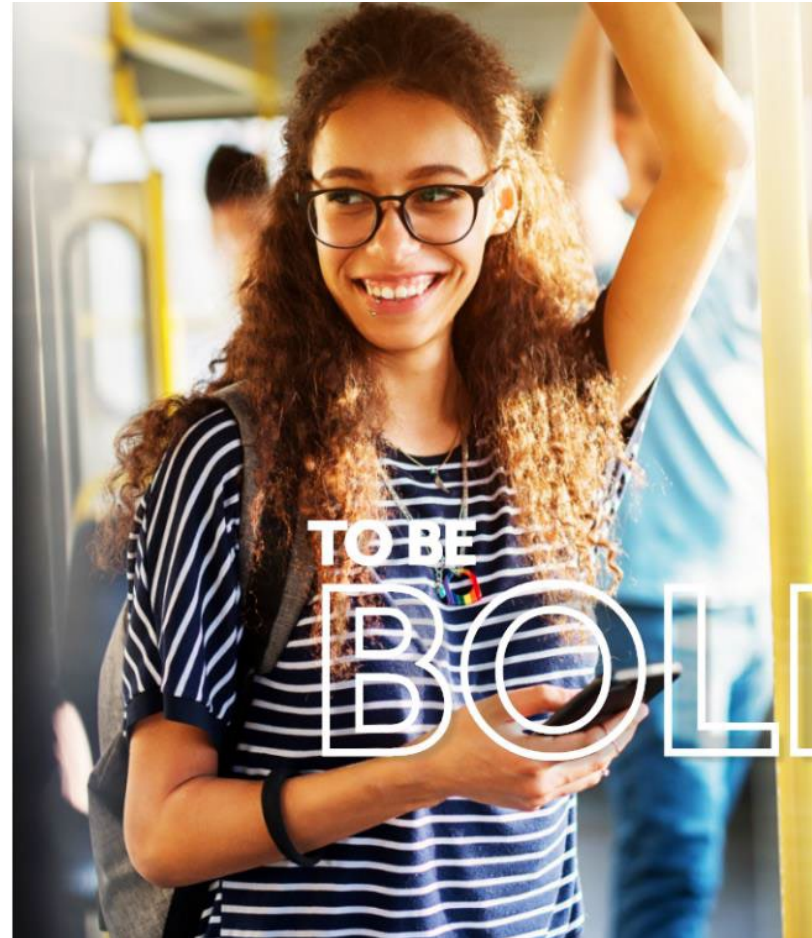
- Cash provided by sales of common stock: \$11.3M (net of fees)
- Common shares o/s: ~ 47.3M shares
- Warrants o/s: ~1.9 million

## 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 year included sales of stock, warrant exercises and proceeds from a PPP loan.





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