



TRANSFORMING WOMEN'S HEALTH

We founded Daré Bioscience with the ***sole focus*** of putting women's health first –

to **boldly address** existing therapeutic gaps and **give women** the novel treatment options they want and need.

DARÉ

IN ITALIAN, IT MEANS **"TO GIVE."**

IN ENGLISH, IT MEANS **"TO BE BOLD."**



May 14, 2024



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Daré Bioscience Corporate Highlights

Biopharmaceutical company with a **sole-focus on the advancement of innovative products for the health and wellbeing of women**

- **Infrastructure-light, partnering model** allows the Company to pursue a portfolio approach with several potential commercial products under the Daré umbrella
- Potential **high-impact, first-in-category product candidates** that represent large market opportunities
 - **1 approved product** (XACIATO™ (clindamycin phosphate) vaginal gel 2%, launched by collaborator Organon and widely available in U.S. as of 1Q 2024)
 - **2 late-stage programs** (Ovaprene®, an intravaginal hormone-free monthly contraceptive; Sildenafil Cream, 3.6%, a topical cream to improve genital arousal in women)
 - **4 additional clinical programs** (menopause, sexual pain, HPV therapy to prevent cervical cancer + period pain)
- **Derisked regulatory strategy** leveraging 505(b)(2) development pathway could accelerate clinical timelines and allow the Company to generate more data for less capital compared to what is generally required under the 505(b)(1) pathway
- **Strong leadership team with significant experience** spanning clinical, regulatory, and commercial



Women's Health

An Efficient Investment Thesis



Transforming women's health by advancing **high-impact, first-in-category** product candidates that have **already demonstrated proof of concept**.

Global R&D

- Approximately **1% of healthcare research spending** is invested in non-oncologic female conditions.¹
- The global healthcare pipeline is comprised of **less than 2%** of non-oncologic women's health conditions.²

Commercial opportunity

We believe **investment** in women's health will be efficient and **disproportionately impactful**:

- Women's health products make up **27% of total blockbuster products** while contributing to 35% of total blockbuster sales.³
- **Women control 80% of U.S.** healthcare purchasing decisions.¹

1. [McKinsey & Company, February 14, 2022, Unlocking Opportunities in Women's Healthcare](#)

2. GlobalData Drugs Database and McKinsey & Company

3. IQVIA Monthly Global MIDAS \$ Const-Exchng (MNF) 2013 – 2022

Blockbuster defined as \$500 million dollar sales in a year Women's Health including conditions solely or disproportionately affecting women; excludes oncology conditions in women



The Daré Value Proposition

We leverage the insights and efficiencies of a deep vertical to mitigate risk and efficiently bring high-impact products to market with commercial collaborators

We deploy established active pharmaceutical ingredients (APIs) in first-in-category candidates...

APIs in select Daré candidates	Original FDA approval; established safety record
Clindamycin	1970
Tamoxifen	1977
Levonorgestrel	1982
Ritonavir	1996
Sildenafil	1998
Etonogestrel	2006



...and we have completed successful clinical trials with six assets in the portfolio, up to and including an FDA approval

Number of successful completed trials	
PHASE 1	4
PHASE 2	3
PHASE 3	1
Total	8 (1 FDA approval)




We have established collaborations with two industry leaders, primed to commercialize Daré products at scale





Innovative Treatments That Women Want and Need

Our investigational products are some of the most potentially disruptive therapeutic candidates for women in decades

ASSET ¹		ADDRESSABLE MARKET (millions of women)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	REGULATORY SUBMISSION	FDA APPROVED
XACIATO™ 	(clindamycin phosphate) vaginal gel 2% for bacterial vaginosis (BV) ²	23						 Launched 4Q-2023
Ovaprene® 	Monthly hormone-free contraceptive	35						Pivotal Phase 3 study commenced 4Q-2023
Sildenafil Cream, 3.6% ^	Topical cream to improve arousal	20						End of Phase 2 meeting with FDA completed
DARE-HRT¹ ^	Monthly hormone therapy for menopause symptoms	45						IND and Phase 3 study preparation
DARE-VVA¹ ^	Hormone-free treatment for sexual pain	25						IND cleared; Phase 2 study preparation
DARE-HPV/CIN (formerly R-131-2) ^	HPV therapy to prevent cervical cancer	1 (annually)						Phase 1 and proof of concept studies completed

¹505(b)(2) regulatory pathway anticipated.
Timelines represent anticipated timing.

[1] See slide 16 for earlier stage programs

[2] XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years of age and older. See Full Prescribing Information for the safe and effective use of XACIATO. See XACIATO selected safety information on slide 37.



XACIATO™

(Clindamycin Phosphate)
Vaginal Gel 2%



Daré's first FDA-approved product

XACIATO [zah-she-AH-toe]
(clindamycin phosphate) vaginal gel 2% is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis (BV) in females 12 years of age and older*

In less than five years since licensing the technology, Daré advanced a **pivotal clinical trial**, gained **FDA approval**, and **ensured product supply** to support the U.S. launch of XACIATO

Commercialization Collaborator ORGANON

- **\$12.8 million in payments received through 2023 under the license agreement**
- License agreement provides for **tiered double-digit royalties** and potential milestone payments from Organon of **up to \$180 million.**[†]
- **\$27 million raised in royalty financings**; eligible for upside-sharing milestone payments from XOMA[†]

*XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years and older. See Full Prescribing Information for the safe and effective use of XACIATO.

See XACIATO selected safety information on slide 37.

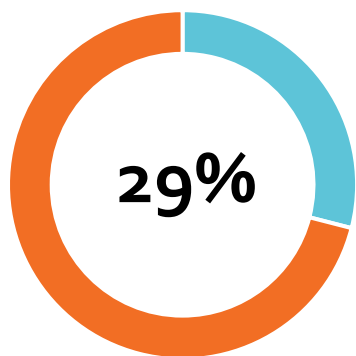
[†]100% of royalties and commercial milestone payments based on XACIATO net sales are subject to a royalty purchase agreement with XOMA (April 2024) and a royalty interest financing agreement (Dec 2023). Upon achieving a pre-specified return threshold, XOMA will make upside-sharing milestone payments to Daré representing 50% of the future payments otherwise payable to XOMA.



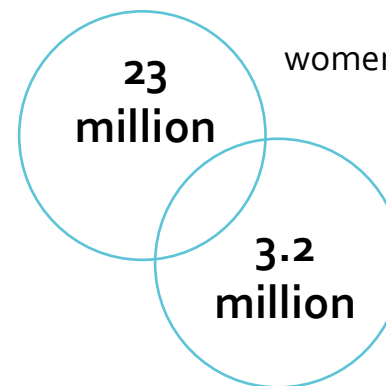
BV Market Opportunity

Bacterial vaginosis is **the most common cause of vaginal symptoms** among women^[1]

BV Prevalence



of U.S. women of reproductive age (14-49) are affected by BV^[1]



women in the US are affected by BV ^[1,2]

drug treated population^[3]

BV Market

Approximately 50% of women with bacterial vaginosis experience recurrence within 1 year of treatment^[4]

Existing Rx is suboptimal with clinical cure rates of 37-68% (excl. XACIATO™)
\$700M Branded Market Opportunity^[5]

Target Product Profile

- **Single self-administered dose**, any time of day
- Vaginal delivery of the antibiotic, with minimal systemic exposure
- Demonstrated equivalent cure rates in both women having her first occurrence of BV as well as those with a history of multiple prior episodes
- Clear labeling for special populations such as pregnant and lactating women

1. Bacterial vaginosis statistics. Centers for Disease Control and Prevention. <https://www.cdc.gov/std/bv/stats.htm> <https://www.cdc.gov/std/bv/stats.htm>. Accessed 13 May 2024.
2. Based on estimated BV prevalence among U.S. women aged 14-49 of 29.2% and the U.S. Census Bureau's 2017 National Population Projections for all females aged 14-49 for 2024. Dataset 1. Projected Population by Single Year of Age, Sex, Race, and Hispanic Origin for the United States: 2016 to 2060 (Main Series). Release date: September 2018. <https://www.census.gov/data/datasets/2017/demo/popproj/2017-popproj.html>
3. Based on 2019 Symphony claims data analysis conducted for Daré Bioscience. Claims data includes commercial plans and some Medicare and Medicaid lives
4. Source: Ellington, Kelly DNP, APRN, WHNP-BC, RNC-OB; Saccomano, Scott J. PhD, RN, GNP-BC. Recurrent bacterial vaginosis. The Nurse Practitioner 45(10):p 27-32, October 2020. | DOI: 10.1097/01.NPR.0000696904.36628.0a
5. 1.5 Rx per drug treated population x \$150/Rx (branded alternatives priced ~\$125-\$285 / Rx)



Ovaprene®

Investigational
intravaginal
hormone-free,
monthly
contraceptive



Daré's potential first-in-category contraceptive product

Designed to be an easy-to-use
monthly option with effectiveness
approaching hormonal methods.

There are currently no FDA-approved
monthly, hormone-free
contraceptives.

Pivotal study collaboration with NICHD



Based on our communications to
date with the FDA, if successful, we
believe **only this single registration
study will be required to support a
premarket approval** application
submission with the FDA



Commercialization Collaborator

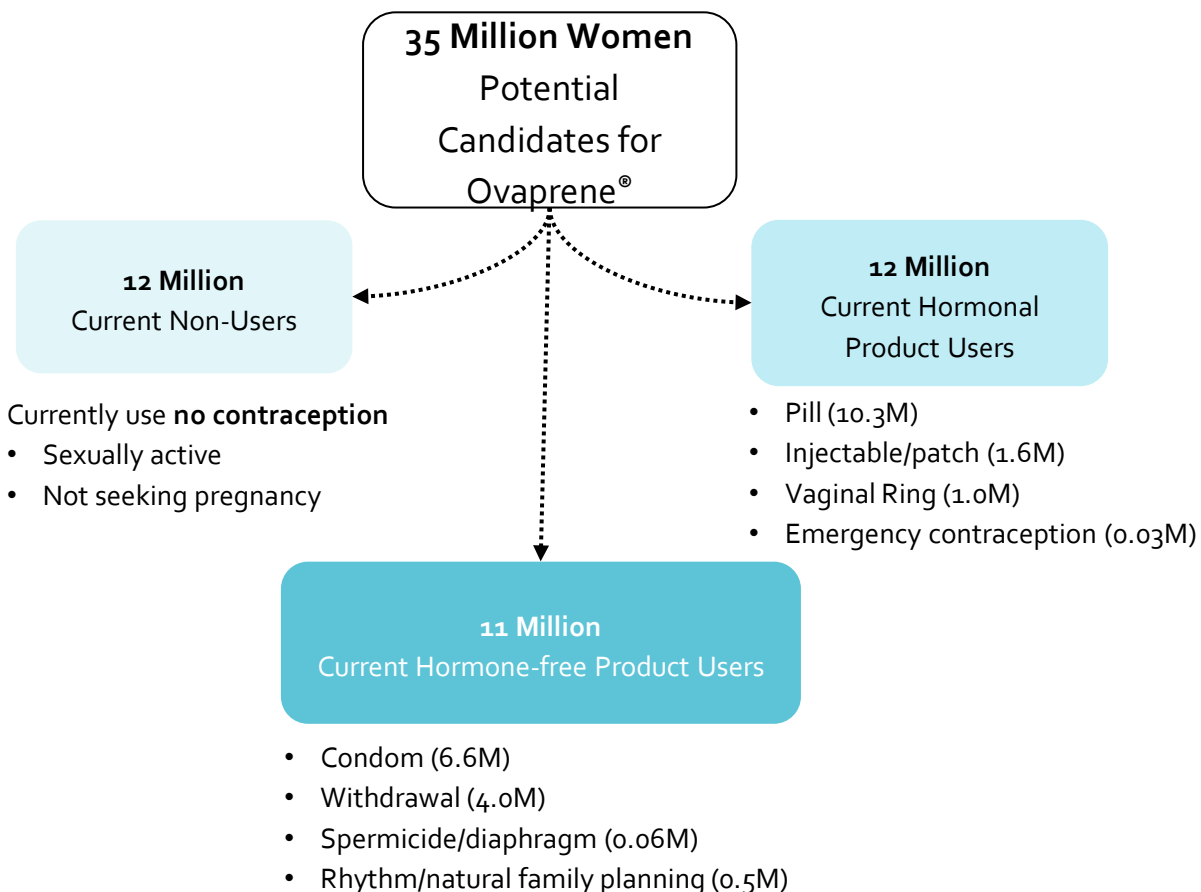


- Bayer received the right to obtain exclusive US rights to commercialize the product, **following completion of the pivotal clinical trial** if Bayer, in its sole discretion, pays Daré **\$20 million**[†]
- Daré may receive up to **\$310 million in commercial milestone payments, plus double-digit, tiered royalties on net sales**[†]

[†] Minority interest in \$20 million payment and royalties on Ovaprene net sales subject to synthetic royalty purchase agreement (April 2024)



Ovaprene® - Potential Market Opportunity^{1,2}



NuvaRing®: \$900M peak sales³

- 91% typical use effectiveness⁴
- Convenience of a monthly ring form
- Fast return to fertility; inserted and removed without a provider
- **Hormonal: contraindicated for VTE risk and for estrogen- or progestin-sensitive cancers**

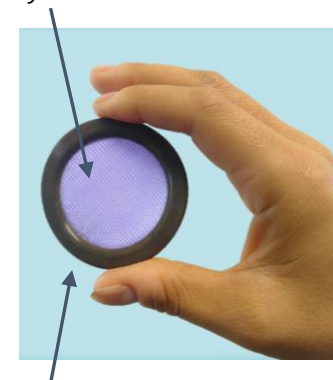


Design Features of Ovaprene® 5-8

- 86% - 91% expected typical use effectiveness
- Convenience of a monthly ring form
- Immediate return to fertility; inserted and removed without a provider
- **Hormone-Free: Unique dual action MOA (spermistatic & barrier), no hormonal contraindications**
- **Safety profile similar to a diaphragm; no significant changes in vaginal flora and no serious adverse events observed in studies to date**

Physical Barrier⁶

Three-dimensional, knitted polymer barrier



Spermistatic Environment⁶

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

1. Market research study conducted in 2019 for Daré Bioscience
2. Contraceptive use data applied to 2019 population data from US Census
3. <https://www.sec.gov/Archives/edgar/data/0000310158/000031015819000014/mrk1231201810k.htm>
4. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021187s022lbl.pdf
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, Polcar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.
8. Mauck, et al. Contraception, Vol. 132, April 2024.



Ovaprene® - U.S. Regulatory Strategy¹

Premarket approval (PMA) strategy

The Center for Devices and Radiological Health (CDRH) as lead review division

*Based on our communications to date with the FDA, if successful, we believe **only this single registration study will be required to support a premarket approval application submission with the FDA***

Pivotal study design²

This is a non-comparative study meaning all women will use Ovaprene – **there is no placebo**

Target approximately 250 subjects to complete ~12 months (13 menstrual cycles) of use

Primary objective

Typical use pregnancy rate over 13 menstrual cycles (estimated Pearl Index)

Secondary objectives

13-cycle typical use cumulative pregnancy rate

Safety, acceptability, product fit/ease of use, vaginal health

1. Anticipated regulatory pathway and timelines.
2. Clinicaltrials.gov ID: NCT06127199



Ovaprene® - Pre-Pivotal Study

The Pre-pivotal Postcoital Test (PCT) Clinical Study Met its Primary Endpoint

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.¹

	Mean <i>Progressively Motile Sperm</i>	Median <i>Progressively Motile Sperm</i>	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

*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.²*

1. Mauck, et al. Contraception, Vol. 132, April 2024

2. Mauck C., Vincent K. Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437-444



Sildenafil Cream, 3.6%

Investigational
topical formulation
of the active
ingredient in Viagra®



Daré's potential first-in-category treatment for female sexual arousal disorder (FSAD)

There are currently no FDA approved treatments for FSAD. FSAD is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity.

Phase 2b Clinical Study

To Daré's knowledge, first study specifically evaluating a potential therapy for treatment of FSAD

- **Characterized sexual response** impacted by the arousal dysfunction;
- **Evaluated the patient population** based on symptoms reported and concomitant diagnoses or medications;
- **Identified endpoints** to take forward into a Phase 3 program

Demonstrated **statistically significant improvement in the proposed patient population** for Phase 3²

Commercial rights not yet partnered:

- Of the various types of female sexual dysfunction disorders, **FSAD is most analogous to erectile dysfunction (ED) in men**
- ED product **Viagra® peaked at \$2.05 billion in sales in 2012¹**

1. <https://qz.com/quartz/1238783/its-the-20th-anniversary-of-viagra-heres-how-its-changed-the-world>

2. Based on informal post-hoc analyses. See slide 27.



FSAD—The Clinical Issue & Prevalence

Female Sexual Arousal Disorder

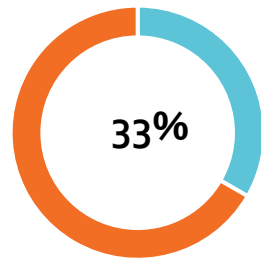
FSAD is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity.¹

Of the various types of female sexual dysfunction disorders, FSAD is most analogous to erectile dysfunction in men.

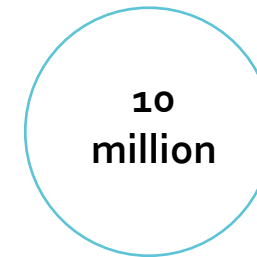
FSAD should be distinguished from other sexual disorders characterized in the DSM, such as orgasmic disorder (anorgasmia) and hypoactive sexual desire disorder (HSDD), which is characterized as lack or absence of sexual fantasies and desire for sexual activity for some period of time.^{2,3}

Market Analysis

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%.⁴



of U.S. women aged 21 to 60 (~ **20 million women**), experience symptoms of low or no sexual arousal.^{5,6}



women are considered distressed and actively seeking treatment.⁵

There are no FDA-approved treatments for FSAD

1. Diagnostic and Statistical Manual (DSM) 4th Edition Text Revision (DSM IV TR) defines FSAD 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.
2. <https://labs.la.utexas.edu/mestonlab/female-sexual-interest-arousal-disorders/>, accessed 6 May 2024
3. <https://my.clevelandclinic.org/health/diseases/24640-anorgasmia>, accessed 6 May 2024
4. McCool et al. Sex Med Rev 2016;4:197-212. DOI: 10.1016/j.sxmr.2016.03.002
5. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.
6. Based on US Census projections for 2016.



Path forward for Sildenafil Cream

Key Takeaways- Phase 2b Clinical Study

- **Phase 2b Clinical Study** designed to evaluate Sildenafil Cream vs. placebo over 12 weeks
 - To Daré's knowledge, first study specifically evaluating a potential therapy for treatment of FSAD
- Post-hoc analyses showed that Sildenafil Cream **met the Ph2b co-primary endpoint** (SFQ28-arousal domain patient reported outcome (PRO)) and **demonstrated clinically meaningful benefit** in patients who have FSAD or FSAD+HSDD¹
 - Secondary and exploratory endpoints saw patients report meaningful improvement

Variable and Subset Population	Sildenafil Cream 3.6%	Placebo Cream	P value
SFQ 28 Responses			
Arousal Sensation Domain	2.03 (0.62)	0.08 (0.71)	0.04
Desire Domain	1.27 (0.76)	-0.89 (0.86)	0.06
Orgasm Domain	1.12 (0.49)	0.186 (0.52)	0.19
FSDS-DAO Responses			
Item 3 Guilt	-0.64 (0.18)	-0.09 (0.20)	0.04
Item 5 Stressed	-0.54 (0.17)	0.02 (0.19)	0.03
Item 10 Embarrassed	-0.59 (0.17)	0.01 (0.19)	0.03






Clinical Development Plan and Commercialization Opportunity

- Sildenafil Cream has potential to be a **first-in-category** option with **significant commercial opportunity** as there currently are no FDA approved treatments for FSAD.
- With the End-of-Phase 2 meeting with the FDA complete, **Sildenafil Cream is preparing to advance toward pivotal studies**
 - Daré intends to leverage the existing safety and efficacy data for sildenafil to utilize the FDA's 505(b)(2) pathway to obtain marketing approval for Sildenafil Cream in the U.S.
- The FDA aligned on key elements of the Phase 3 program to support a **New Drug Application (NDA)** filing and confirmed that:
 - FSAD is an approvable indication
 - The Phase 3 trials could be as short as 12 weeks for the efficacy assessment
- FDA confirmed that it aims to complete its review of the Phase 2b study data and provide comments within the second quarter of 2024 on the proposed primary and secondary PRO endpoints for the planned Phase 3 trials of Sildenafil Cream to support potential product registration and labeling.

1. See slides 26-27 for more information on the exploratory Phase 2b clinical study.



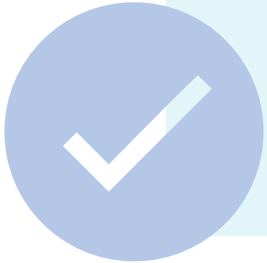
Earlier Stage Programs With Grant Funding Enhance The Pipeline

		ADDRESSABLE MARKET	PRE- CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	
Australia R&D Cash Rebate	DARE-PDM¹^ Primary Dysmenorrhea	50% menstruating women			Phase 1 Study Completed 2023 IND preparations		Vaginal diclofenac once- daily thermosetting hydrogel
 National Institutes of Health	DARE 204/214 ^ 6 & 12-Month Injectable Contraception	12 million women		Phase 1 Study Preparation			Etonogestrel contraceptive injection once every 6-12 months
 National Institutes of Health	DARE-FRT¹/PTB¹^ Preterm birth (DARE-PTB ¹) and for luteal phase support as part of an IVF regimen (DARE-FRT ¹)	1 in 10 births		IND and Phase 1 Study Preparation			Bio-identical progesterone delivery via intravaginal ring
 National Institutes of Health <i>Foundation grant up to ~\$49M</i>	DARE-LARC¹ ^ Long-Acting, Reversible Personal Contraceptive System	17 million women		Pre-IND Activities			Levonorgestrel releasing implant that can be remotely paused and resumed
Foundation Grant	DARE-LBT Novel hydrogel formulation for delivery of live biotherapeutics to support vaginal health	23M+ women		Formulation development			
	DARE-GML Novel Antimicrobial Glycerol Monolaurate	23M+ women		Formulation development			
 UNIVERSITY OF COPENHAGEN	DARE-RH¹ Male or Female Contraceptive Target	35 million women		Hit to lead stage			
 National Institutes of Health	DARE-PTB² Potential New Therapeutic Intervention for the Prevention and Treatment of Idiopathic Preterm Birth	1 in 10 births		Pre-clinical studies			

¹505(b)(2) regulatory pathway anticipated.



Upcoming Milestones



Ovaprene®

- Phase 3 study commenced 4Q 2023
- Phase 3 study recruitment and data updates



Sildenafil Cream, 3.6%

- End of Phase 2 meeting with FDA occurred December 2023
- Phase 3 design, development, and collaboration strategy updates;
FDA indicated target timing for Phase 3 endpoint feedback 2Q2024



APPENDIX



Ovaprene®

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



**U.S. Commercialization
Collaborator**



**Phase 3 Development
Collaborator**



Contraception:

Market Opportunity

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

Population of women 15 – 44 years by age: US, 2020

Age (Years)	US (Percent)	US (Count)
15-19 yrs	15.9	10,266,332
20-29 yrs	24.0	21,918,026
30-39 yrs	34.3	22,159,866
40-44 yrs	15.8	10,199,608
Total	100.0	64,543,832

Sources: US Census Bureau.
Population estimates based on bridged race categories released by the National Center for Health Statistics.
Retrieved June 15, 2023, from www.marchofdimes.org/peristats.

Successful Contraceptive Brands Peak Sales:



Mirena® Hormone IUD

(levonorgestrel-releasing intrauterine system) 52mg.

- Physician inserted, long-acting, low/locally delivered hormone IUS
- **2020 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)

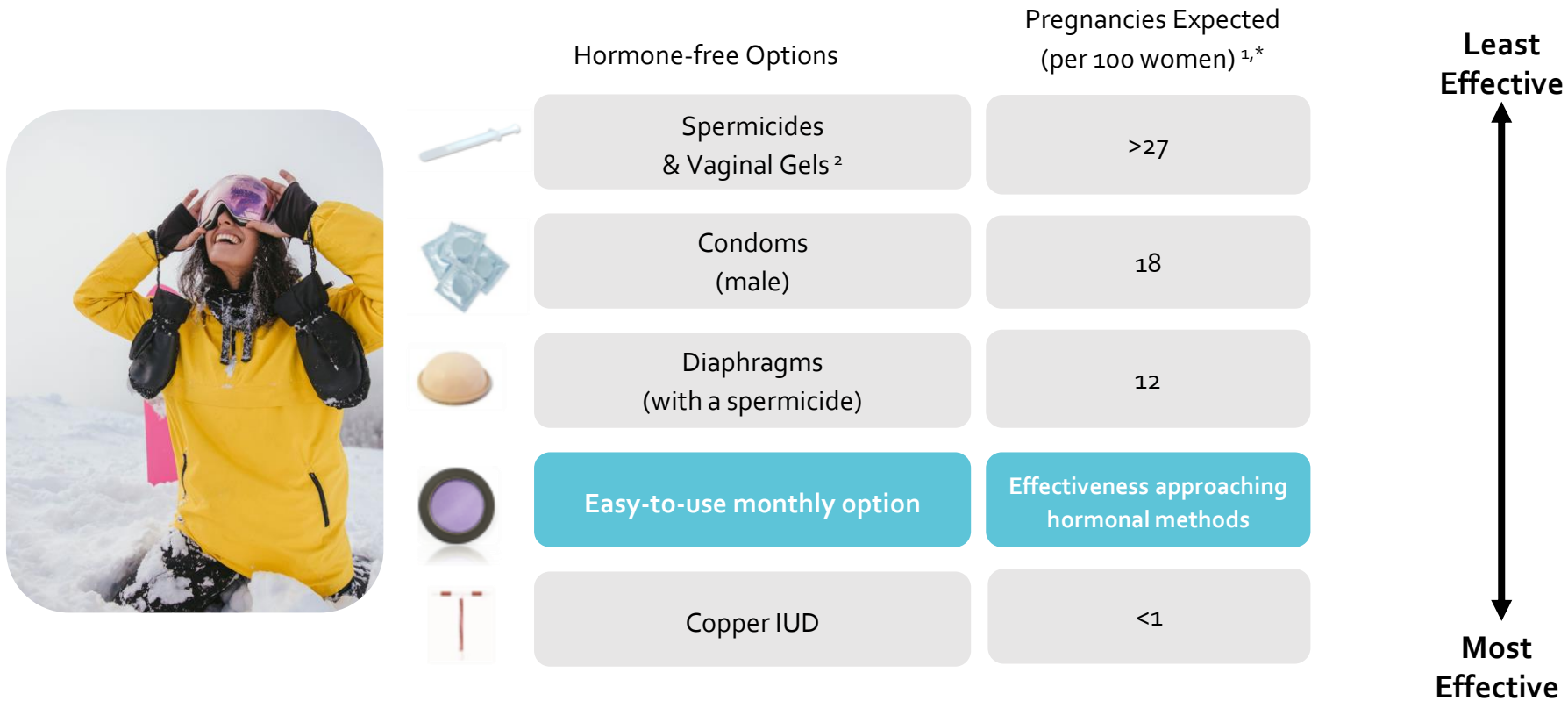
- Monthly vaginal ring
- **2018 worldwide sales: \$900 million (Merck)**³

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://www.sec.gov/Archives/edgar/data/0000310158/000031015819000014/mrk1231201810k.htm>



Contraception:

What's Missing from Current Hormone-Free Options?



1. U.S. Food and Drug Administration Birth Control Guide dated 6/14/2021: <https://www.fda.gov/consumers/free-publications-women/birth-control-chart>

2. U.S. Food and Drug Administration Drug Data Prescribing information for a vaginal gel approved in 2020, PhexxiTM 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

* 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® - Commercial License Agreement with Bayer

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 FDA¹.



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

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.

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**.²

Daré may receive up to **\$310 million in commercial milestone payments, plus double-digit, tiered royalties on net sales**.²

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.

* <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>

2. Minority interest in \$20 million payment and royalties on Ovaprene net sales subject to synthetic royalty purchase agreement (April 2024)



Ovaprene® - Collaborative Research Agreement with NIH

"This collaboration between Daré and NICHD marks an important milestone in Women's Healthcare Innovation. Women are at the center of everything we do and we are so pleased to continue to partner with Daré in support of our mission We're For Her to provide women with education and access to contraceptive options," said John Berrios, Bayer's Head of Women's Healthcare.



Cooperative
Research and
Development
Agreement
(CRADA) for the
Pivotal Phase 3
Study

July 2021 – Daré announced that funding and clinical operations support for the Phase 3 will be provided by the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under the CRADA¹

The pivotal Phase 3 study is being **supported by the NICHD's Contraceptive Development Program** which oversees the Contraceptive Clinical Trials Network (CCTN) established in 1996 to conduct studies of investigational contraceptives. The Phase 3 study is being conducted within the CCTN with the NICHD's CRO.

Daré is responsible for providing clinical supplies of Ovaprene® and coordinating interactions with and preparing and submitting supportive regulatory documentation to the FDA.

Under the CRADA, Daré also agreed to contribute **\$5.5 million** toward the total estimated cost to conduct the pivotal Phase 3 study. Three payments totaling \$5 million have been made.

1. <https://ir.darebioscience.com/news-releases/news-release-details/dare-announces-collaborative-research-agreement-crada-pivotal>



Sildenafil Cream, 3.6%

Investigational
topical formulation
of the active
ingredient in Viagra®



Potential First-In-Category treatment for Female Sexual Arousal Disorder (FSAD) – there are no FDA approved treatments for FSAD

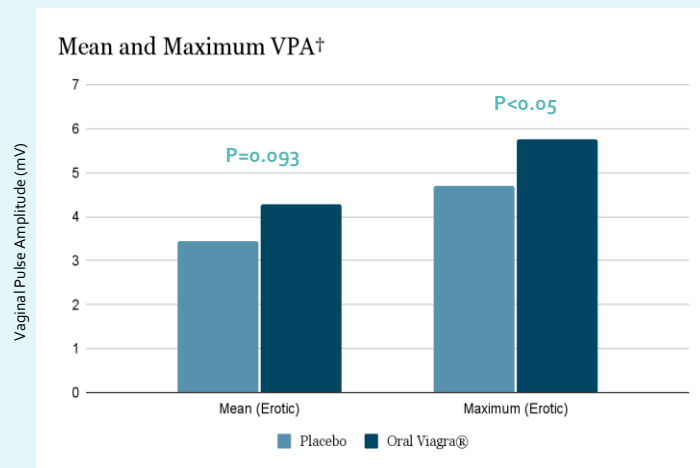
Designed to increase local blood flow to promote improved genital arousal response.

Applied topically, avoiding hepatic first-pass metabolism response, resulting in lower systemic exposure potentially resulting in reduced side effects vs. oral sildenafil, including Viagra®.



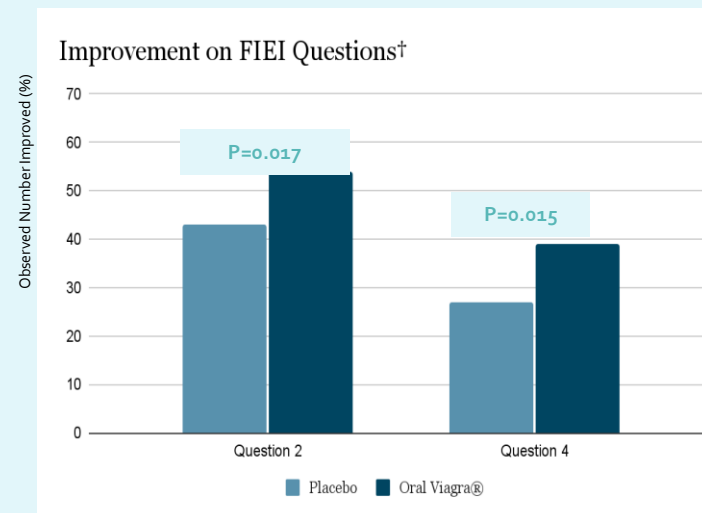
Oral Sildenafil provided a compelling proof of concept for FSAD

Statistically significant increases in Vaginal Pulse Amplitude (VPA)[†] Pfizer VPA Clinical Lab Study – Oral Viagra



[†] Twelve healthy premenopausal women were studied.

Statistically significant improvement in genital stimulation (FIEI)[‡] Pfizer Clinical Field Study – Oral Viagra



[†] 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.

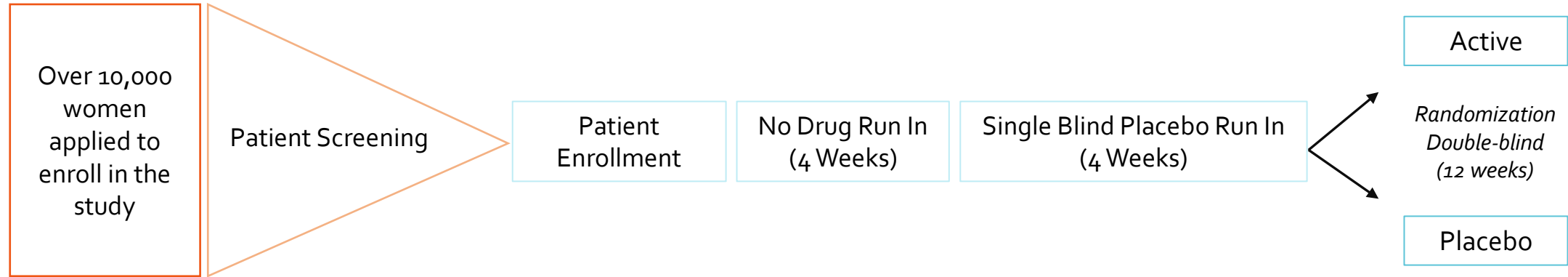
Key Takeaways of Viagra® studies:

- 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.



Overview of Phase 2b Study

Phase 2b, Exploratory, Randomized, Placebo-Controlled, Trial of Sildenafil Cream 3.6% for the Treatment of Female Sexual Arousal Disorder in Healthy Premenopausal Women (#NCT04948151) – N=200 Randomized, 101 Sildenafil Cream vs 99 Placebo



Co-Primary Endpoints: Change from baseline (BL) in SFQ28 Arousal Sensation (AS) Domain and FSDS-DAO Question 14

Secondary Endpoints: Change from BL in number & proportion of satisfactory sexual experiences (SSEs)

Several Exploratory Endpoints: Including SFQ28 Desire and Orgasm Domains, and FSDS-DAO Questions

Exit Interviews (EIs): EIs were performed to better understand qualitatively what constitutes a meaningful change on the SFQ28-AS domain, Arousal Diary AS domain, FSDS-DAO Question 14, Patient Benefit Evaluation (PBE), and what constitutes meaningful improvement on the Patient Global Impression of Change (PGI-C), the PGI-C in Satisfactory Sexual Events (PGI-C SSE), and Patient Global Impression of Severity (PGI-S).

Evaluation of Recall Period: At the end of the no drug run in and at the end of the single blind placebo run in, the correlation between the 24-hour recall period and the 4-week recall period was evaluated for all patients who completed both the Arousal Diary, the FSDS-DAO, and the SFQ28. Additionally, at the same intervals, a subset of patients selected randomly via interactive response technology, who completed the FSDS-DAO and the SFQ28 but did not complete the Arousal Diary, were evaluated to investigate whether completion of the diary questions influences how the patient answers FSDS-DAO Question 14 and the SFQ28 AS domain scores. These patients completed the entire study but did not complete the Arousal Diary throughout the study. These patients did not affect the primary study objectives as they were not included in the analysis of the coprimary endpoints.

Establish Partner Safety: The sexual partners were enrolled in the study such that partner safety could be established.



Phase 2b – Post-Hoc Analyses

- Informal post-hoc analyses were conducted on enrollment FSD diagnosis category so that **efficacy could be evaluated in the study sub-populations based on concomitant diagnoses, such that the patient population most likely to benefit from the mechanism of action of Sildenafil Cream, 3.6% could be determined for the Phase 3 program**
- In the ITT population, although not statistically significant, the Sildenafil Cream, 3.6% group (N=69) demonstrated greater improvement than the Placebo Cream group (N=59) in change from Baseline to end of study in SFQ28 (AS) domain (1.1 versus 0.8 respectively, $p=0.6$)
- When this SFQ28 (AS) domain efficacy assessment was performed excluding study participants with inability to orgasm and subjects suffering from vaginal pain, both indications that could have other underlying causes beyond the arousal dysfunction, **the improvement in the Sildenafil Cream, 3.6% group was above the recommended meaningful within patient change and statistically significant compared to the minimal improvement in the Placebo cream group**

Variable and Subset Population	Sildenafil Cream 3.6% (N=29)	Placebo Cream (N=23)	P value
	Least Squares change (Standard Error) from BL at Week 12	Least Squares change (Standard Error) from BL at Week 12	
Proposed Phase 3 population – FSAD, including women with decreased desire as a result			
SFQ28 Arousal Sensation Domain	2.03 (0.62)	0.08 (0.71)	0.04
SFQ28 Desire Domain	1.27 (0.76)	-0.89 (0.86)	0.06
SFQ28 Orgasm Domain	1.12 (0.49)	0.186 (0.52)	0.19
FSDS-DAO – Item 3 Guilt	-0.64 (0.18)	-0.09 (0.20)	0.04
FSDS-DAO – Item 5 Stressed	-0.54 (0.17)	0.02 (0.19)	0.03
FSDS-DAO – Item 10 Embarrassed	-0.59 (0.17)	0.01 (0.19)	0.03



Sildenafil Cream, 3.6%

Phase 1 and Phase 2a Study Results

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%
- Cmax – 1-2%

Sildenafil Cream was safe and well tolerated at clinically relevant doses (1-2g):

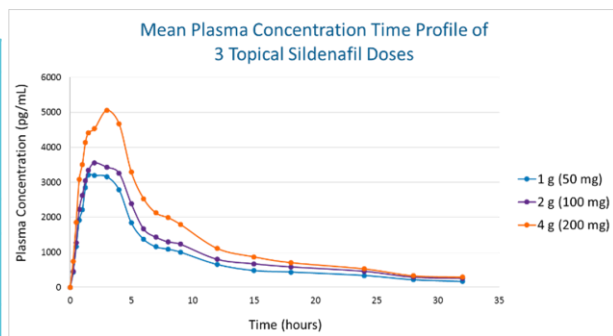
- Favorable product characteristics as self-reported by subjects
- Easy to use
- Readily absorbed

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

Parameter	Treatment Level		
	1 g cream (36mg sildenafil), n=20	2 g cream (71mg sildenafil), n=20	4 g cream (142mg sildenafil), n=19
Cmax (ng/mL)	3.61	4.10	5.65
AUCo-t (h*ng/mL)	27.45	33.32	45.33
Tmax (hr)	2.56	2.60	2.42

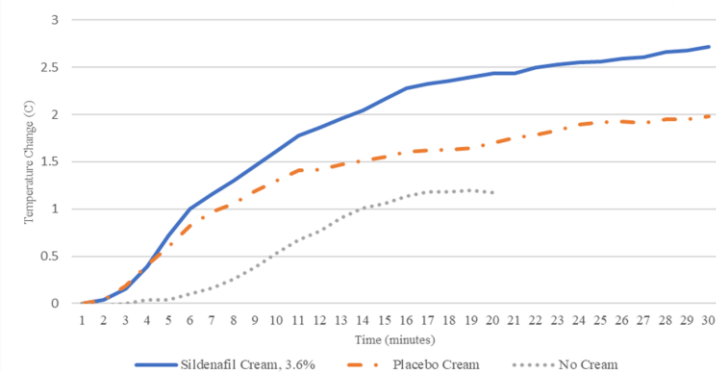


Thermography Study Results*

- Demonstrated **time to effect (11-15 minutes)**
- Positive cognitive arousal responses were noted
- Significantly **greater increases in genital temperature** after application of Sildenafil Cream compared to placebo cream
- Significantly **greater self-reported arousal** responses reported during Sildenafil Cream visits compared to placebo cream visits

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

Figure 1. Clitoral temperature change during the sexually explicit film



Thermography Study Design & Methodology (N=6)²

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).

1. Data on file. Sildenafil Cream, 3.6% was previously known as SST-6007.

2. 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.



DARE-HRT^{1^}

Investigational
monthly menopausal
hormone therapy



Potential first-in-category vaginal combination hormone delivery for treatment of vasomotor symptoms due to menopause.

Intravaginal ring (IVR) designed to release bio-identical estradiol and bio-identical progesterone over 28 days.

Self-administered 28-day IVR.

There are **no FDA-approved options** with both hormones in one monthly IVR.

Potential to be the first convenient monthly format product with both hormones.

Phase 1 / 2 study completed; IND related activities to support Phase 3 study underway.

^{1^}505(b)(2) regulatory pathway anticipated.



Vasomotor Symptoms of Menopause

Daré Innovation: DARE-HRT₁ Monthly Vaginal Ring



Clinical Issue

- In the US, over 45M women are estimated to be in or approaching menopause; symptoms can last up to 10 years¹
- ~75% of menopausal women experience hot flashes²
- 3 in 5 menopausal women felt that they were adversely affected by symptoms while at work³
- 35% of menopausal women reported that they had experienced 4+ symptoms of menopause, but only 44% said they had discussed their symptoms with a doctor⁴



Limitations with current standards of care

- Hormone therapy is the most effective treatment for vasomotor symptoms (VMS) and other symptoms of menopause according to The Menopause Society⁵.
- The Menopause Society recommends delivering both estrogen and progesterone, simultaneously, for women with an intact uteri and The Menopause Society states that non-oral routes of administration may offer potential advantages.
- There are no FDA-approved products that combine both estradiol and progesterone in a non-oral monthly form.
- Many treatments do not offer bioidentical hormones to most closely mimic the natural hormones in a woman's body.



Target Product Profile

- A single, non-oral, non-daily, monthly product that can deliver both bioidentical estradiol and progesterone.
- Non-oral routes of administration bypass the liver⁵ and may reduce the risk of blood clots⁶.
- A vaginal ring is a preferred form factor, due to the convenience, discrete administration, and ease of use.⁷
- According to a survey of women who switched from an oral contraceptive to an intravaginal ring (IVR), 71% of reported they would continue to use the IVR after the study⁸.

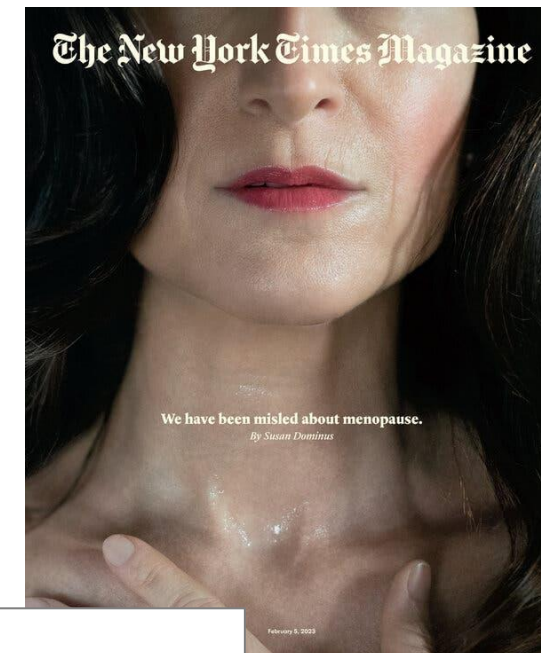
1. <https://my.clevelandclinic.org/health/diseases/21841-menopause>
2. <https://www.hopkinsmedicine.org/health/conditions-and-diseases/introduction-to-menopause>
3. OPINIUM RESEARCH <https://www.vodafone.com/sites/default/files/2021-10/menopause-global-research-report-2021.pdf>
4. <https://www.healthyagingpoll.org/reports-more/report/womens-health-sex-intimacy-and-menopause>

5. <https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf>
6. <https://www.reuters.com/article/us-blood-clot/study-finds-no-blood-clot-risk-with-hormone-patch-idINTRE6BU1ZJ20101231>
7. Source: Internal Qualitative Market Research, Mar-Apr 2017
8. Creinin MD, Multicenter comparison of the contraceptive ring and patch: a randomized controlled trial. Obstet Gynecol. 2008;111(2 Pt 1): 267-77.



Menopause is Having a Moment

- The menopause market is a large and growing market, with **more than 1 billion people worldwide** expected to be in menopause by 2025¹. Approximately **51% of menopausal women experience moderate to severe VMS**.²
- The global market for menopausal products is growing rapidly, at a rate of more than 5%, rising from its 2021 level of about \$15 billion to reach **\$24.4 billion by 2030**.¹
- Visibility around menopause and treatment of menopausal symptoms has been elevated by the White House Initiative on Women's Health Research and in prominent media spots and pieces including in Astellas' recent Superbowl ads.
- If approved, DARE-HRT₁ would be **the only monthly product that meets the Menopause Society's recommendations for first-line treatment of VMS for most women*** and recognizes the potential advantages of non-oral dosing.



Improve Women's Health Across the Lifespan

- **Create a Comprehensive Research Agenda on Menopause.** To help women get the answers they need about menopause, NIH will launch its first-ever Pathways to Prevention series on menopause and the treatment of menopausal symptoms. Pathways to Prevention is an independent,



Ad Age | ASTELLAS TO AIR ITS FIRST SUPER BOWL SPOT



Astellas turns up the heat with Super Bowl spot



1. <https://www.washingtonpost.com/opinions/2022/04/28/menopause-hormone-therapy-nih-went-wrong/>

2. Astellas Investor Meeting Dec 14, 2017, slide 21. https://www.astellas.com/system/files/eg_aim-oo.pdf, accessed 13 May 2024.

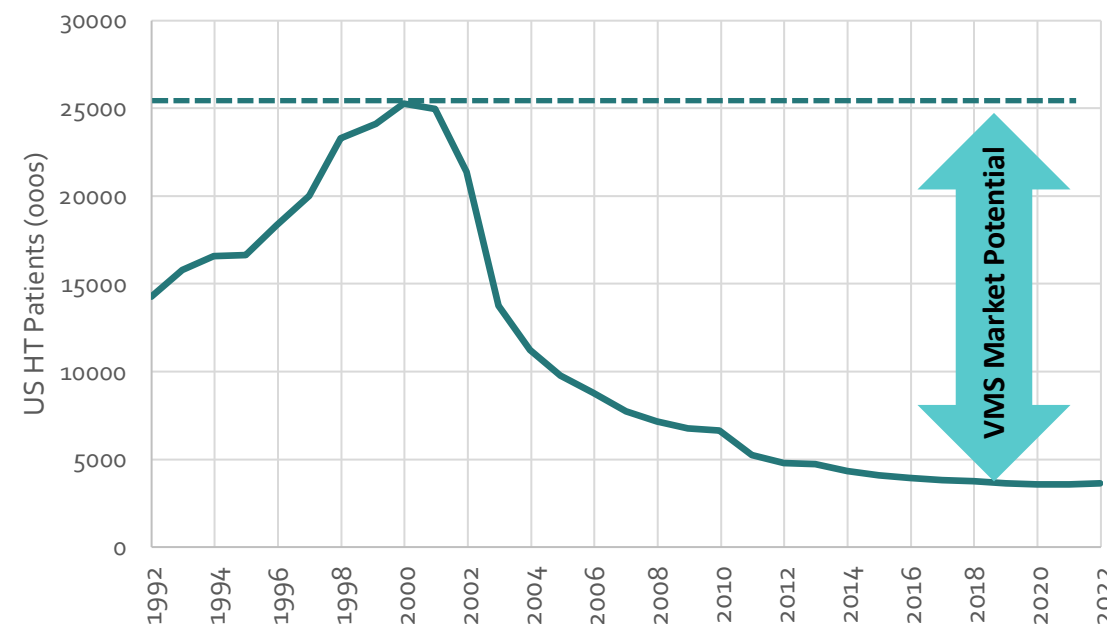
*This recommendation excludes certain women per the 2022 hormone therapy position statement of The Menopause Society (formerly, NAMS), including those without a uterus and those seeking to initiate treatment >60 years of age or >10 years past the onset of menopause. <https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf>.



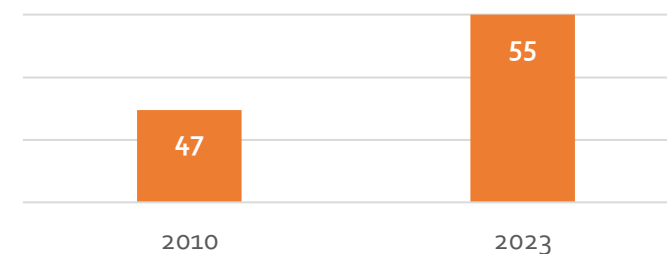
Menopause – Renewing the Market Opportunity

- Prior to the 2002 WHI report, the **Premarin family of products achieved ~\$2B in peak revenue**, led by sales of the combination HRT products Prempro and Premphase.⁷
- The WHI report caused hormone therapy market to collapse. While subsequent research and analyses have thoroughly rebuked the WHI's findings^{3,4}, the **misperceptions from that report still persist, which has created a significant unmet need and market potential.**
- Post WHI, women and healthcare providers shifted to **bio-identical** Hormone Therapy (BHT) containing bio-identical estradiol and progesterone as an alternative to synthetic hormones. These BHT therapies are not approved by the FDA and all the major medical societies and the FDA discourage their use.
- However, due to the lack of FDA-approved options, the largest proportion of script volume today comes from the compounded market and **BHT alone is estimated to represent an additional \$850M** in the menopause market.⁶

US Estimated HT Patients²



US Menopausal Population ^{5,1}
(Millions of Women)



1. <https://www.washingtonpost.com/opinions/2022/04/28/menopause-hormone-therapy-nih-went-wrong/>
2. Astellas Investor Meeting May 19, 2023: VEOZAH™ U.S. Commercial Update, slide 12.
https://www.astellas.com/system/files/43b2195907/veozah_post_approval_investor_call_20230519.pdf. Accessed 13 May 2024.
<https://pubmed.ncbi.nlm.nih.gov/17405972/>
3. https://www.nejm.org/doi/10.1056/NEJM199109123251102?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20www.ncbi.nlm.nih.gov

5. <https://www.census.gov/data/tables/2010/demo/age-and-sex/2010-age-sex-composition.html>, Table 1, Females Age 45-69
6. Cowen Research – Therapeutic Categories Outlook, 2023-03-02. Page 4628
7. https://media.corporate-ir.net/media_files/NYS/WYE/reports/ahp_aroo/05.htm



Menopause – Hormone Therapy Position Paper



THE MENOPAUSE SOCIETY POSITION STATEMENT

2022 hormone therapy position statement of The Menopause Society²

- Hormone therapy remains the **most effective treatment** for VMS and the genitourinary syndrome of menopause and has been shown to prevent bone loss and fracture.
- The risks of hormone therapy differ depending on type, dose, duration of use, route of administration, timing of initiation, and whether a progestogen is used. Treatment should be individualized using the best available evidence to maximize benefits and minimize risks, with periodic reevaluation of the benefits and risks of continuing therapy.
- Non-oral routes of administration (eg, transdermal, vaginal) may offer potential advantages because non-oral routes bypass the first-pass hepatic effect.

Within weeks of approval for a new non-hormonal VMS product (Veoza[®]), NAMS published a 2023 update to their position statement concluding that **hormone therapy should still remain the first line therapy for VMS.**³

3 in 4¹ Women

say menopause has interfered with their lives. **64% of women** say they feel unprepared to handle their symptoms.

1. <https://www.sri.com/story/menopause-goes-high-tech-understanding-your-menopause-journey-by-leveraging-ai-and-wearable-sensing-technology/>
2. <https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf>
3. <https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf>



VMS Competitive Landscape

	DARE-HRT₁	Veozah®	Bijuva®	Elinzanetant	Donesta®
Sponsor / Manufacturer	Daré Bioscience	Astellas Pharma	Mayne Pharma	Bayer	Mithra Pharma
Development Phase	IND and Phase 3 preparations	On Market (approved 2023)	On Market (approved 2018)	Post-Phase 3	Phase 3 completion by Q4 2024
Dose Form	Monthly vaginal ring	Daily oral pill	Daily oral pill	Daily oral pill	Daily oral pill
API	Bioidentical estradiol and progesterone	Fezolinetant (NK-3 receptor antagonist targets temperature regulation in the hypothalamus)	Bioidentical estradiol and progesterone	Elinzanetant (NK-1,3 receptor antagonist targets temperature regulation in the hypothalamus)	Estetrol (synthetic analog of estrogen)
Other Considerations	Hormone therapy remains the most effective treatment for VMS and has been shown to prevent bone loss and fracture	Increased liver function tests required due to liver toxicity concerns			Expect to need supporting progestin to curb endometrial proliferation for non-hysterectomized women

DARE-HRT₁ is the only VMS product in development that could meet the Menopause Society's recommendation for first line treatment.



DARE-VVA^{1^}

Investigational
hormone-free vaginal
insert for dyspareunia



Potential first-in-category hormone-free intravaginal treatment for painful intercourse (dyspareunia) associated with vulvar and vaginal atrophy (VVA).

Proprietary formulation of tamoxifen for vaginal administration.

There are currently no FDA-approved vaginal hormone-free treatments for VVA.

Phase 1 / 2 study completed; IND cleared.

Activities to support Phase 2 study underway.

^{1^}505(b)(2) regulatory pathway anticipated.



DARE-CIN[^]

Investigational anti-viral vaginal insert for HPV infection and cervical intraepithelial neoplasia (CIN)



Potential first-in-category, non-surgical, pharmaceutical intervention for the treatment of CIN and other HPV-related pathologies.

Proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert.

There are currently **no FDA-approved, non-surgical pharmaceutical interventions** to treat **CIN2+.**

There are **no FDA-approved treatments for HPV infection.**

Phase 1 and Proof-of-Concept studies completed; activities to support IND filing to enable progression to Phase 2 clinical development underway.

[^]505(b)(2) regulatory pathway anticipated.



XACIATO Selected Safety Information

- XACIATO is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin.
- Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile may need to be discontinued.
- Polyurethane condoms are not recommended during treatment with XACIATO or for 7 days following treatment. During this time period, polyurethane condoms may not be reliable for preventing pregnancy or for protecting against transmission of HIV and other sexually transmitted diseases. Latex or polyisoprene condoms should be used.
- XACIATO may result in the overgrowth of Candida spp. in the vagina resulting in vulvovaginal candidiasis, which may require antifungal treatment.
- The most common adverse reactions reported in >2% of patients and at a higher rate in the XACIATO group than in the placebo group were vulvovaginal candidiasis and vulvovaginal discomfort.
- XACIATO has not been studied in pregnant women. However, based on the low systemic absorption of XACIATO following the intravaginal route of administration in nonpregnant women, maternal use is not likely to result in significant fetal exposure to the drug.
- There are no data on the effect of clindamycin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for clindamycin and any potential adverse effects on the breastfed child from clindamycin or from the underlying maternal condition.
- Please see the [Prescribing Information](#), [Patient Information](#), and [Instructions for Use](#).



TRANSFORMING WOMEN'S HEALTH

We founded Daré Bioscience with the ***sole focus*** of putting women's health first –

to **boldly address** existing therapeutic gaps and **give women** the novel treatment options they want and need.

DARÉ

IN ITALIAN, IT MEANS **"TO GIVE."**

IN ENGLISH, IT MEANS **"TO BE BOLD."**

