UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 25, 2024

DARÉ BIOSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36395**	**20-4139823**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3655 Nobel Drive, Suite 260
San Diego, CA 92122
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(858) 926-7655**

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock	**DARE**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Exhibit 99.1 to this report is a copy of a corporate presentation dated October 25, 2024, which is incorporated herein by reference. Daré Bioscience, Inc. ("Daré" or the "Company") intends to use the presentation and its contents in various meetings with investors, securities analysts and others, commencing on October 25, 2024.

The Company also plans to make a copy of the presentation available in the "Investors" section of its website (https://ir.darebioscience.com), on the page titled "Presentations, Events & Webcasts," under the heading "Presentations." Information contained in, or that can be accessed through, the Company's website is not incorporated by reference into this report.

The information in this Item 7.01, including Exhibit 99.1 to this report, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 7.01 and Exhibit 99.1 shall not be incorporated by reference into any filing under the Exchange Act or the Securities Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Daré Bioscience corporate presentation, dated October 25, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DARÉ BIOSCIENCE, INC.

Dated: October 25, 2024

By: */s/ Sabrina Martucci Johnson*
Name: Sabrina Martucci Johnson
Title: President and Chief Executive Officer

October 25, 2024

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.

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

DARÉ
bioscience

Forward-Looking Statements; Disclaimers

This presentation is for informational purposes only and is not an offer to sell or a solicitation of an offer to buy any securities of Daré Bioscience, Inc. ("Daré" or the "Company"). This presentation includes certain information obtained from trade and statistical services, third-party publications, and other sources. Daré has not independently verified such information and there can be no assurance as to its accuracy.

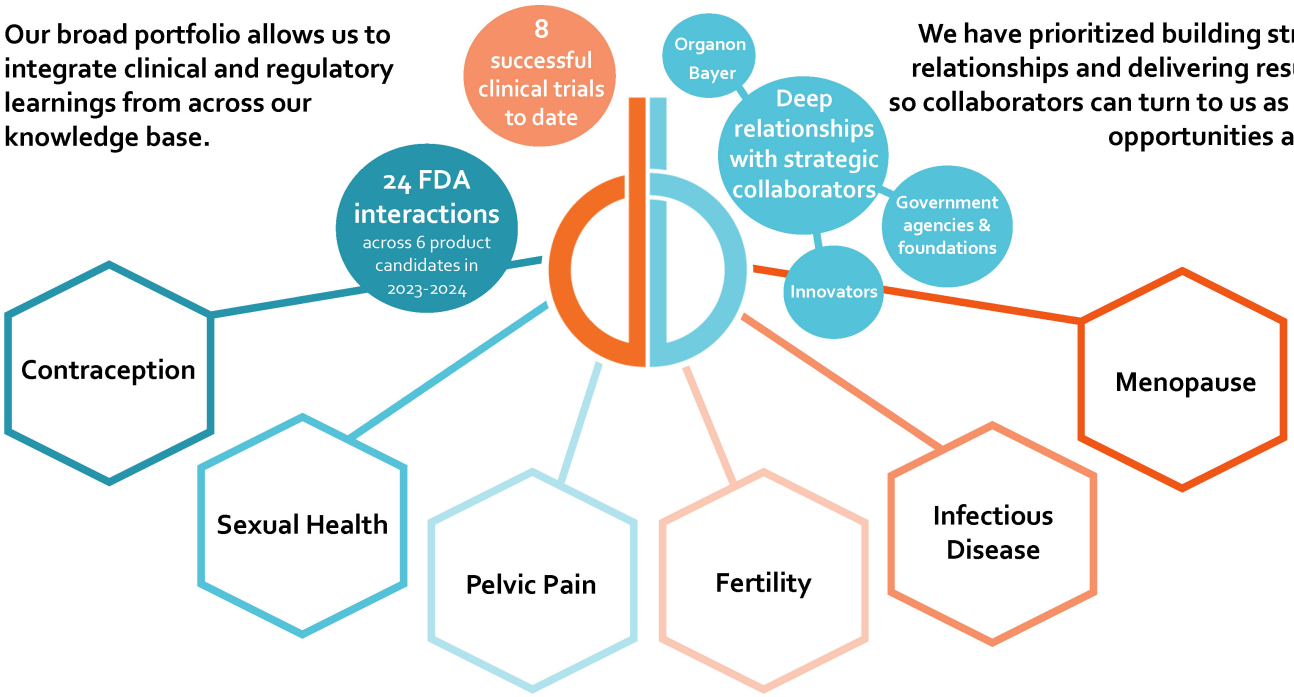
All statements in this presentation, other than statements of historical fact, are forward-looking statements within the meaning of federal securities laws. In some cases, you can identify forward-looking statements by terms such as "may," "will," "expect," "plan," "anticipate," "strategy," "designed," "could," "intend," "believe," "estimate," "target," or "potential," or the negative of these terms and other similar expressions. Such statements include, but are not limited to, statements relating to the clinical and market potential of Daré's product candidates, the advancement of and plans and timelines related to development, including clinical investigation, of Daré's product candidates, Daré's regulatory and commercialization strategy, potential collaborations, expectations regarding existing collaborations, including potential payments under its collaborations, potential pipeline expansion, and potential funding and financing transactions. As used in this presentation, "first-in-category" is a forward-looking statement relating to the potential of a product candidate to represent a new category of product if it were to receive marketing approval for the indication(s) for which it is being developed. None of the product candidates presented herein are approved for use outside of clinical trials. The timing of clinical trials, receipt and announcement of clinical trial data, FDA review and approval, collaborations and other milestones and events relating to development and commercialization of XACIATO™ (clindamycin phosphate) vaginal gel 2% and Daré's product candidates, other than those having occurred prior to the date of this presentation, are forward-looking statements. Forward-looking statements reflect management's estimates and expectations based on current information and involve risks, uncertainties and assumptions that may cause Daré's actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements, including, without limitation: Daré's reliance on third parties to commercialize XACIATO and to manufacture and conduct clinical trials and preclinical studies of its product candidates; the degree of market acceptance that XACIATO and any future product achieves; the coverage, pricing and reimbursement that XACIATO and any future product obtains from third-party payors; risks and uncertainties inherent in Daré's ability to successfully develop, obtain regulatory approval for and monetize its product candidates; Daré's need for additional capital to fund operations and execute its business strategy; and those risks and uncertainties described under the heading "Risk Factors" in Daré's most recent annual report on Form 10-K and quarterly report on Form 10-Q filed with the Securities and Exchange Commission. All forward-looking statements are current only as of the date of this presentation. Daré does not undertake any obligation to update any forward-looking statement in this presentation to reflect new information, future developments or otherwise, except as required by law.

All trademarks, service marks or trade names appearing in this presentation are the property of their respective owners. Unless specifically identified as such, Daré's use or display of third-party marks is not intended and does not indicate or imply any relationship with or endorsement or sponsorship of Daré by the third-party owner.

We are experts in developing women's health therapeutics

Our broad portfolio allows us to integrate clinical and regulatory learnings from across our knowledge base.

We have prioritized building strong relationships and delivering results, so collaborators can turn to us as new opportunities arise.



Why invest in women?

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

Limited R&D Investment

- Only 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]

Large Commercial Opportunity

- 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

Daré Bioscience Corporate Highlights

Infrastructure-light, partnering model allows the Company to pursue a portfolio approach with several potential commercial products under the Daré umbrella

Derisked regulatory strategy leveraging the 505(b)(2) pathway could accelerate clinical development timelines and allow the Company to generate more data for less capital compared to what is generally required under the traditional 505(b)(1) pathway

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** (in menopause, HPV therapy to prevent cervical cancer & pelvic pain)

Strong leadership team with extensive experience in clinical development, regulatory affairs and commercial

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

	Successful Trials / Completion Date
PHASE 1	Ovaprene PCT Study (2019); Sild. Cream, 3.6%, Ph 1 (2019); DARE-HRT1 Ph 1 (2021); DARE-PDM1 Ph 1 (2023)
PHASE 2	DARE-VVA1 Ph 1/2 (2022); DARE-HRT1 Ph 1/2 (2022); Sild. Cream, 3.6%, Ph 2b (2023)
PHASE 3	DARE-BVFREE (2020)
Total	*8 (1 FDA approval)*

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

BAYER

ORGANON

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™ ORGANON	(clindamycin phosphate) vaginal gel 2% for **bacterial vaginosis (BV)**[2]	23						✓ Launched 4Q-2023
Ovaprene® CARE NIH	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 associated with menopause**	25		IND cleared; Phase 2 study preparation				
DARE-HPV^ ARPA-H Sprint for Women's Health Launchpad Awardee	HPV therapy to **prevent cervical cancer**	6*, (annually)		Phase 1 and proof of concept studies completed				

^505(b)(2) regulatory pathway anticipated.
* Addressable market reflects potential treatment of all cases of high-risk HPV infections in the U.S. See slide 20 for more details.
Timelines represent anticipated timing.

[1] See slide 21 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 40.

Daré's First FDA-Approved Product

In **less than five years**, Daré:

- In-licensed the asset with a 30-patient proof-of-concept study
- Completed the pivotal clinical trial
- Achieved FDA approval
- Ensured product supply to support the U.S. launch

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.

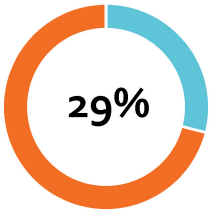
See XACIATO selected safety information on slide 40.

†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.

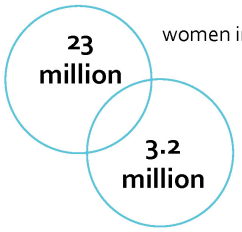
BV Market Opportunity

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]

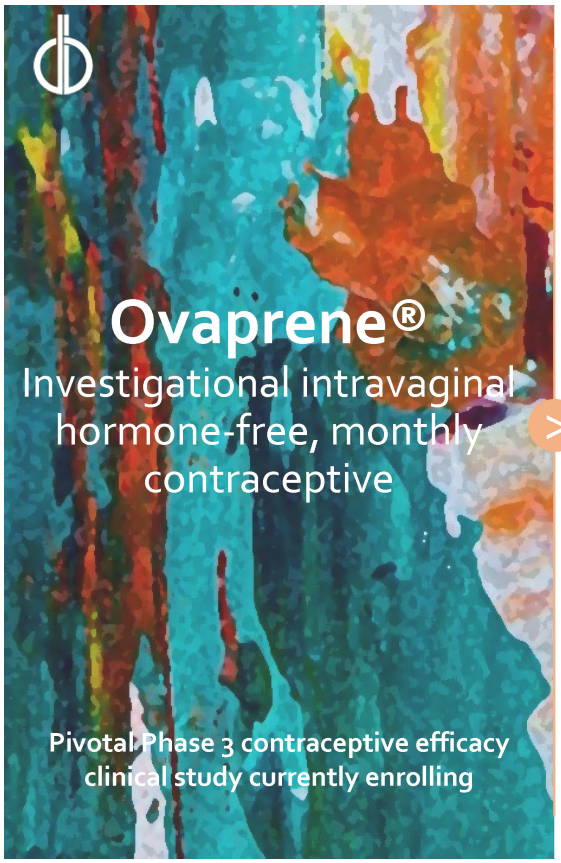
Existing Rx is suboptimal with clinical cure rates of 37-68% (excl. XACIATO™)

$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)



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 Collaborator

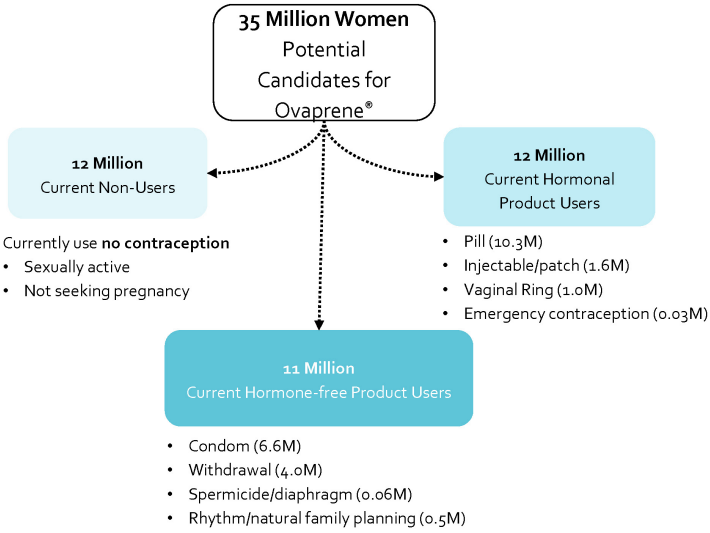
- Our CRADA enables Daré to leverage the contraceptive **clinical trial expertise** of the NICHD while also **sharing the Phase 3 pivotal study costs**.
- If successful, we believe that **the single ongoing registration study will be sufficient to support a premarket approval** application submission 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]



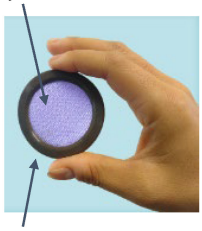
NuvaRing®: $900M peak sales[3]

- 91% typical use effectiveness[4]
- 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 (spermiostatic & 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 Barrier[6]
Three-dimensional, knitted polymer barrier

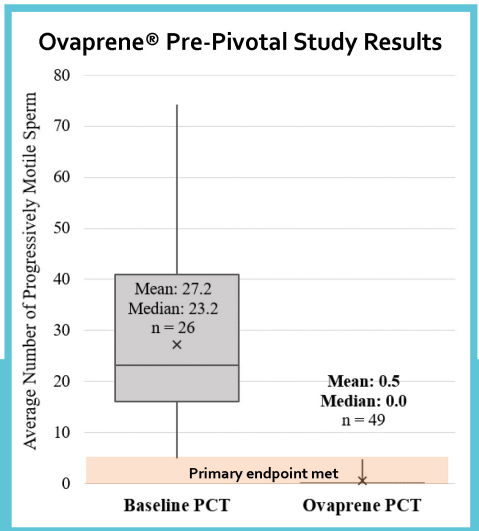


Spermiostatic Environment[6]
Contraceptive-loaded silicone ring releasing non-hormonal active ferrous gluconate

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, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.
8. Mauck, et al. Contraception, Vol. 132, April 2024

Ovaprene® - Pre-Pivotal Study

- **The Ovaprene® Pre-Pivotal Postcoital Test (PCT) study met its primary endpoint**.
  - **In 100% of women and cycles,** Ovaprene prevented the requisite number of sperm from reaching the cervix.
  - A successful cycle was defined as an average of less than five (< 5) progressively motile sperm (PMS) per high-powered field (HPF) being present in the midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place.[1]



Using a surrogate marker for contraceptive effectiveness, the PCT study showed **similar results to products that later demonstrated "typical use" contraceptive effectiveness of 86-91%***

*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

Ovaprene® - U.S. Regulatory Strategy[1]

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

Pivotal study design[2]

- 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)

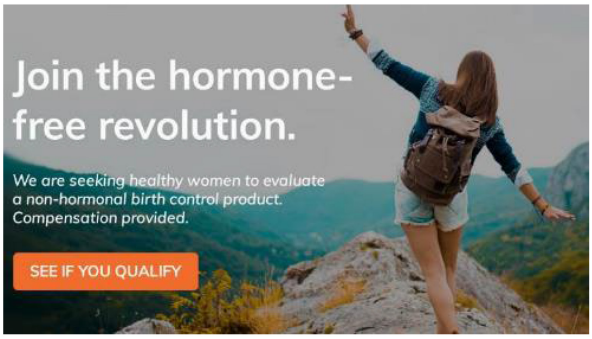
Secondary objectives

- 13-cycle typical use cumulative pregnancy rate
- Safety, acceptability, product fit/ease of use, vaginal health

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

Pivotal study enrollment

- Recruitment is currently underway at 20 sites across the US, supported by a central advertising campaign for the study that launched in March 2024.
- Based on current average enrollment rate, we anticipate ~125 women (50% of our target number of participants to complete the study) will complete ~6 months of product use by the end of Q2 2025.



ovaprenestudy.com

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

Daré's Potential First-in-Category Treatment for Female Sexual Arousal Disorder (FSAD)

- FSAD is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity and is **clinically analogous to erectile dysfunction in men**.
  - As with male erectile dysfunction, FSAD is associated with insufficient blood flow to the genitalia.
- An estimated **20 million women** suffer from low or no arousal, but similar to erectile dysfunction (ED) before Viagra®, **without an effective treatment, the condition is often dismissed and stigmatized**.
  - However, once Viagra was approved, it generated $400M in revenue in the first quarter of sales[1] and peaked at **$2.05 billion in 2012**[2]

There are no FDA-approved treatments for FSAD.

Phase 2b Clinical Study

To Daré's knowledge, this was the first study specifically evaluating a potential therapy for treatment of FSAD which:

- **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; FDA feedback forthcoming

Demonstrated **statistically significant improvement in the proposed Phase 3 patient population**[3]

1. https://www.cnbc.com/2019/05/10/how-viagra-revolutionized-the-erectile-dysfunction-market.html
2. https://qz.com/quartzy/1238783/its-the-20th-anniversary-of-viagra-heres-how-its-changed-the-world
3. An exploratory post-hoc subset of the Phase 2b study intent-to-treat (ITT) population. See slide 32.

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 **significantly improved (P=0.04) arousal sensation** (SFQ28-arousal domain patient reported outcome) and **demonstrated additional clinically meaningful benefits** in a patient population with FSAD with or without concomitant decreased desire, a subset of the ITT population.[1]

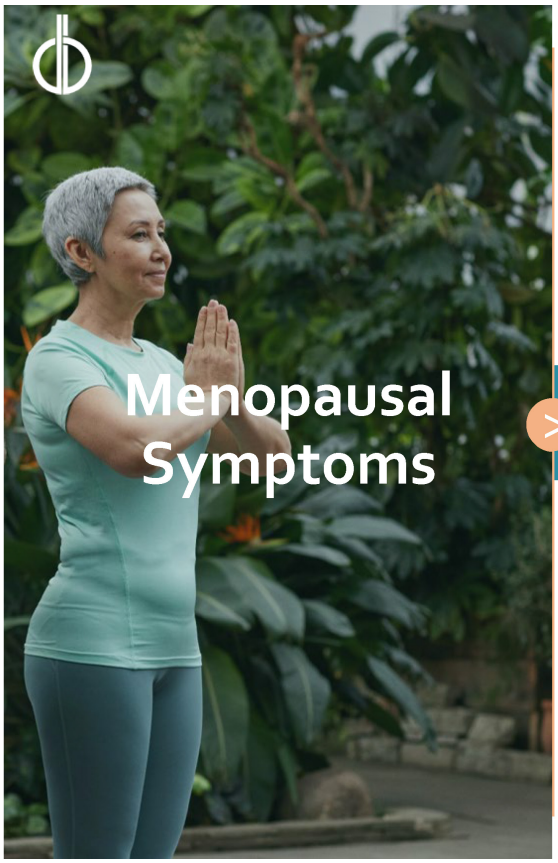
Post-Hoc Analyses for FSAD with or without concomitant decreased desire Subset Population

Endpoint*	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)	0.18 (0.52)	0.19
FSDS-DAO Responses			
Item 3 Guilt	-0.73 (0.16)	-0.23 (0.17)	0.04
Item 5 Stressed	-0.50 (0.16)	-0.02 (0.16)	0.04
Item 10 Embarrassed	-0.51 (0.17)	0.00 (0.17)	0.04
Item 14 Concerned†	-0.21 (0.16)	-0.22 (0.16)	0.95

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 end-of-Phase 2 meeting with the FDA complete, **Sildenafil Cream is preparing to advance toward pivotal studies** for the treatment of FSAD.
  - Daré intends to leverage 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.
  - Based on FDA feedback to date, two successful Phase 3 trials will be required to support a New Drug Application (NDA) submission.
- Reached **alignment with FDA on key elements of the Phase 3 program**:
  - FSAD is an approvable indication
  - Efficacy assessment period in the Phase 3 trials could be as short as 12 weeks
- Additional FDA feedback is forthcoming.
- Daré is executing on operational activities necessary for the planned Phase 3 program.

1. Johnson, et al. Obstetrics & Gynecology 144(2):p 144-152, August 2024. See slides 31-32 for more information on the exploratory Phase 2b clinical study. *All endpoints in this table are least squares mean change (standard error) from baseline to end of study (Week 12). †Co-primary endpoint.



Menopause is Having a Moment

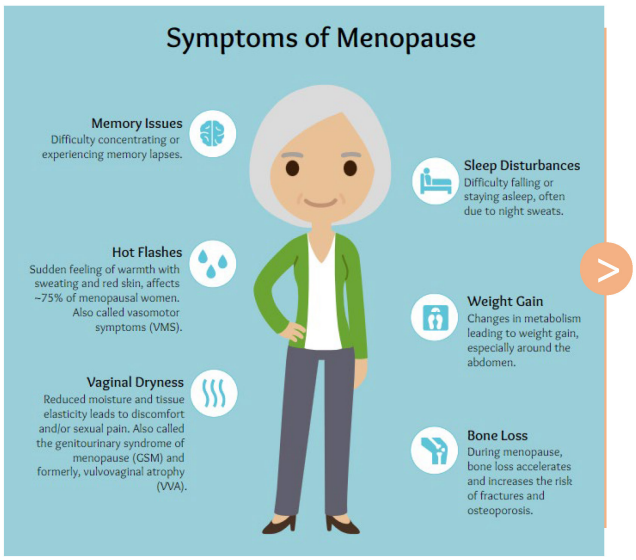
- The menopause market is a large and growing market, with **more than 1 billion people worldwide** expected to be in menopause by 2025[1]. Approximately **51% of menopausal women experience moderate to severe vasomotor symptoms (VMS) or hot flashes**.[2]
- The global market for menopausal products is 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]

With the rise of digital support platforms and virtual care clinics, **menopausal women are looking for solutions.**

However, in a landscape with **few FDA-approved treatment options**, they are turning to the burgeoning industry of compounded products, supplements, and natural remedies – none of which are evaluated by the FDA for safety and efficacy.

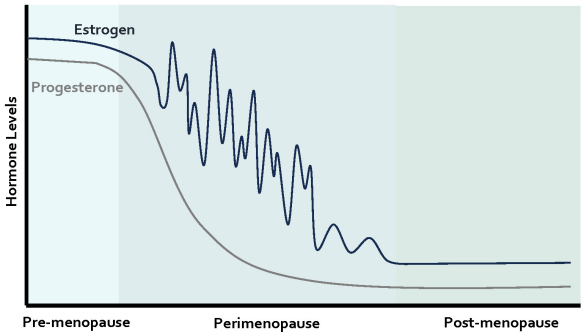
1. https://www.washingtonpost.com/opinions/2022/04/28/menopause-hormone-therapy-nih-went-wrong/
2. Astellas Investor Meeting Dec 14, 2017, slide 21. https://www.astellas.com/system/files/eg_aim-00.pdf , accessed 13 May 2024.

What Causes Menopause?



During perimenopause, the supply of mature eggs in a woman's ovaries diminishes and ovulation becomes irregular. The **production of estrogen and progesterone also decreases**. The changes in estrogen in particular cause most of the symptoms of menopause.[1]

Key Hormonal Changes During Menopause
(for illustrative purposes only)



For the treatment of VMS, the Menopause Society recommends delivering **both estrogen and progesterone**, simultaneously, for women with an intact uteri, and states that **non-oral routes of administration** may offer potential advantages.[2]

There are **no FDA-approved products** that combine both **estradiol and progesterone in a non-oral monthly form.**

1. https://www.hopkinsmedicine.org/health/conditions-and-diseases/introduction-to-menopause
2. https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf

Daré Menopause Programs

Hormone Therapy Product Candidate

DARE-HRT1 Monthly Vaginal Ring for the Vasomotor Symptoms of Menopause

*Phase 1 / 2 study completed; IND related activities to support a single Phase 3 study underway.^*

- ☑ Bioidentical estradiol & progesterone in one product
- ☑ Highly acceptable, non-oral dosage form

- In the Ph1/2 study, DARE-HRT1 demonstrated statistically significant improvement in VMS as well as the genitourinary symptoms of menopause, and vaginal pH and maturation index.[1]
- DARE-HRT1 had a high level of acceptability in the Ph1/2 study, with over 80% of subjects on the lower and higher dose versions of DARE-HRT1 reporting the IVR as comfortable or very comfortable. Additionally, over 80% of subjects in each IVR dose group stated they were either somewhat or very likely to use the IVR for a women's health condition or disease if needed.[1]

Hormone-Free Product Candidate

DARE-VVA1 Vaginal Inserts for Painful Intercourse Associated with GSM

Phase 1 / 2 study completed; IND cleared. Activities to support Phase 2 study underway.

For women who cannot or choose not to use hormones, there is interest in non-hormonal products, especially targeting to the **breast cancer population**.

Bayer and Astellas are pursuing studies of their non-hormonal VMS products specifically in breast cancer populations.

Tamoxifen is commonly prescribed by oncologists in the treatment of hormone receptor positive (HR+) breast cancer, as it blocks estrogen activity in breast tissue.[2] However, studies have shown an inverse effect in vaginal tissue where it **has demonstrated estrogen-like effects on vaginal epithelium which could counter the physiological changes that lead to GSM.**

- The Ph1/2 study demonstrated safety and tolerability of DARE-VVA1, as well as improvement in vaginal cytology & the bothersome vaginal symptoms associated with GSM.[3]

^ Daré believes FDA approval is achievable via the 505(b)(2) pathway supported by a single, placebo-controlled, Phase 3 clinical trial and a scientifically justified PK "bridge" (via a relative bioavailability trial) between DARE-HRT1 and the selected listed estradiol and progesterone drugs.

1. Thurman, et al. Menopause 30(8):p 817-823, August 2023.
2. Cleveland Clinic: Tamoxifen. https://my.clevelandclinic.org/health/treatments/9785-tamoxifen
3. Thurman, et al. Climacteric Volume 26, 2023 - Issue 5

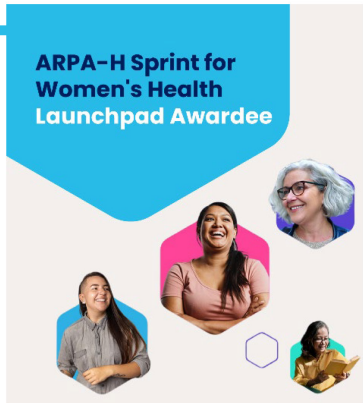
DARE-HPV^

Investigational antiviral vaginal insert for human papillomavirus (HPV)-related cervical diseases

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

- There are currently **no FDA-approved, non-surgical pharmaceutical interventions** to treat **HPV-related cervical dysplasia.**
- There are **no FDA-approved treatments for HPV infection.**

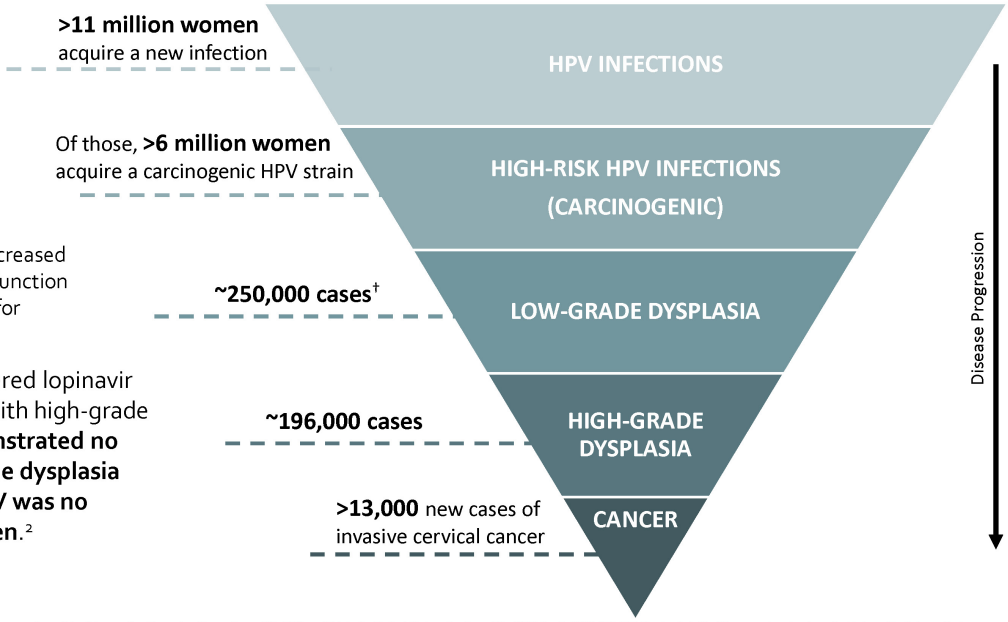
- DARE-HPV is a proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert.
- Phase 1 and proof-of-concept studies have been completed.
- Activities to support IND filing to enable progression to Phase 2 clinical development underway supported by a two-year **ARPA-H Launchpad Award**.



Safe and Effective HPV Treatments Remain an Unmet Need

- HPV is the most common sexually transmitted infection in the United States.
- Today, cervical precancers (dysplasia) are monitored until they reach a late stage, since the most common treatment is a surgery which removes part of the cervix.
  - This surgery is associated with an increased risk of preterm birth and sexual dysfunction and therefore is not recommended for patients with fertility concerns.
- In a pilot study of vaginally-administered lopinavir and ritonavir in 23 women in Kenya with high-grade dysplasia, **78% of the women demonstrated no dysplasia or a reduction to low-grade dysplasia** after 12 weeks of treatment, and **HPV was no longer detected in 52% of the women**.[2]

HPV-Related Cervical Diseases per year in the U.S.[1]



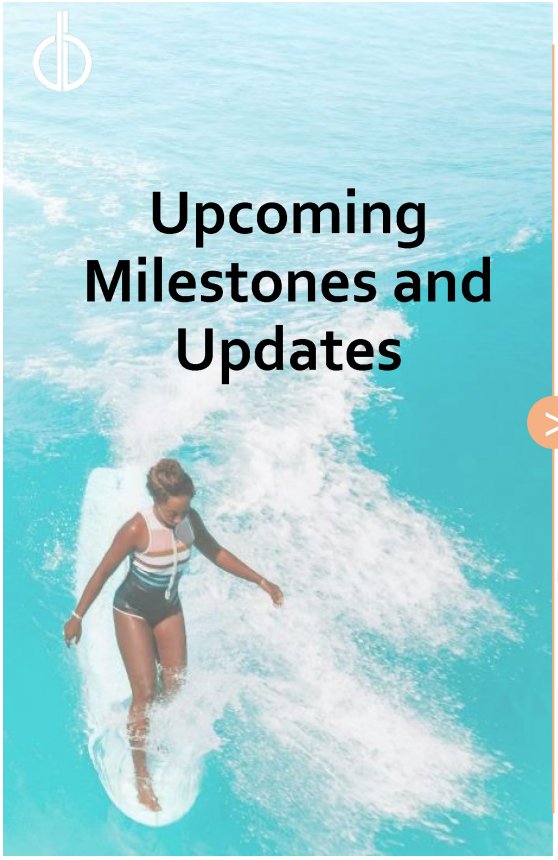
1. Estimates based on the following sources: Lewis, et al. Estimated Prevalence and Incidence of Disease – Associated Human Papillomavirus Types Among 15-59-Year-Olds in the United States. Sex Trans Dis. 2021 Apr 1; 48(4):273-277. Henk, et al. "Incidence and costs of cervical intraepithelial neoplasia in a US commercially insured population." J Low Genit Tract Dis. 2010 Jan;14(1):29-36. CDC: Estimated Number of Cases of High-Grade Cervical Lesions Diagnosed Among Women — United States, 2008 and 2016 https://www.cdc.gov/mmwr/volumes/68/wr/mm6815a1.htm Accessed 16 Oct 2024. American Cancer Society: Key Statistics on Cervical Cancer. https://www.cancer.org/cancer/types/cervical-cancer/about/key-statistics.html Accessed 16 Oct 2024.
2. Hampson, et al. "A Single-Arm, Proof-of-Concept Trial of Lopimune (Lopinavir/Ritonavir) as a Treatment for HPV-Related Pre-Invasive Cervical Disease." PLoS One. 2016 Jan 29.
†Estimate calculated from CIN1 and CIN2/3 annual incidence of 1.6 and 1.2 per 1,000 women, respectively (Henk, 2010) and CIN2 cases per year (CDC). 196,000 / 1.2 * 1.6 = 261,333 cases of CIN1 per year.

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^** Pelvic Pain	50% menstruating women experience dysmenorrhea			**Phase 1 Study Completed 2023 IND preparations**		Vaginal diclofenac once-daily thermosetting hydrogel
NIH 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
NIH National Institutes of Health	**DARE-FRT1/PTB1^** Preterm birth (DARE-PTB1) and for luteal phase support as part of an IVF regimen (DARE-FRT1)	1 in 10 births		**IND and Phase 1 Study Preparation**			Bio-identical progesterone delivery via intravaginal ring
NIH National Institutes of Health *Foundation grant up to ~$49M*	**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**			
NIH 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**			

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

Upcoming Milestones and Updates



Ovaprene®

- Phase 3 study commenced 4Q 2023
- Phase 3 study updates

Sildenafil Cream, 3.6%

- End-of-Phase 2 meeting with FDA occurred Dec. 2023
- Phase 3 program updates, including additional FDA feedback and initial Phase 3 study timing
- Collaboration strategy

DARE-HPV

- IND and Phase 2 study preparations, being supported by ARPA-H Sprint for Women's Health Launchpad award

APPENDIX

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.

Phase 3 Development Collaborator

U.S. Commercialization 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.pdfx. 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/mrk123120181ok.htm

Contraception:

What's Missing from Current Hormone-Free Options?

Hormone-free Options	Pregnancies Expected (per 100 women) [1,2]
Anti-sperm vaginal contraceptives (includes spermicides and other anti-sperm agents)	21-28
Diaphragms (with spermicide)	17
Condoms (male)	13
Easy-to-use monthly option	**Effectiveness approaching hormonal methods**
Copper IUD	<1

Least Effective

Most Effective

1. U.S. Food and Drug Administration Birth Control Guide dated May, 2024: https://www.fda.gov/media/150290/download
2. 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 specific product or on the risks of a specific product, please check the product label or consult your healthcare provider.

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 FDA[1].

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 CRADA[1]

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, all of which has been paid.

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

Daré's Potential First-in-Category Treatment for Female Sexual Arousal Disorder (FSAD)

Female Sexual Arousal Disorder

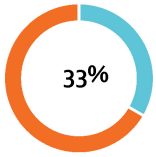
FSAD is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity.[1]

FSAD is clinically analogous to erectile dysfunction in men. As with male erectile dysfunction, FSAD is associated with insufficient blood flow to the genitalia.

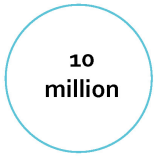
FSAD should be distinguished from other sexual disorders characterized in the DSM, such as orgasmic disorder (anorgasmia) and hypoactive sexual desire disorder (HSDD), which is characterized as lack or absence of sexual fantasies and desire for sexual activity for some period of time.[2,3]

FSAD 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]



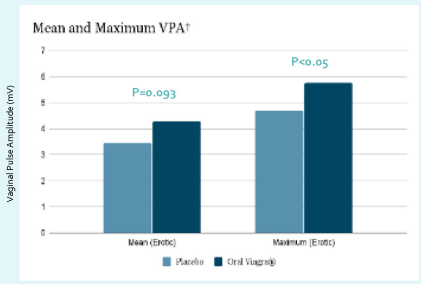
women are considered distressed and actively seeking treatment.[5]

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-interestarousal-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.

Oral Sildenafil provided a compelling proof of concept for FSAD

Statistically significant increases in Vaginal Pulse Amplitude (VPA)[1]

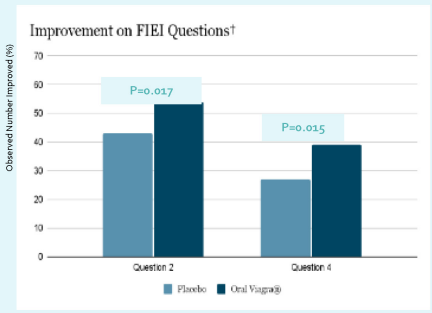
***Pfizer** VPA Clinical Lab Study – Oral Viagra*



† Twelve healthy premenopausal women were studied.

Statistically significant improvement in genital stimulation (FIEI)[2]

***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.

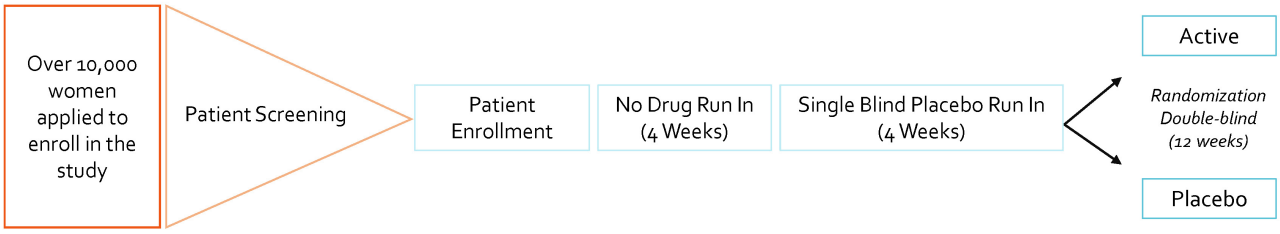
Key Takeaways of Viagra® studies:

- 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.

1. The Enhancement of Vaginal Vasocongestion by Sildenafil in Healthy Premenopausal Women. Journal of Women's Health & Gender-Based Medicine. Vol. 11, No. 4. 2002
2. Safety and Efficacy of Sildenafil Citrate for the Treatment of FSAD: A Double-Blind, Placebo Controlled Study. The Journal of Urology. Vol 170, 2333-2338, December 2003.

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 Sexual Function Questionnaire (SFQ28) Arousal Sensation (AS) Domain and Female Sexual Distress Scale-Desire, Arousal, Orgasm (FSDS-DAO) Question 14

Secondary Endpoints: Change from BL in number & proportion of satisfactory sexual events (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 – Exploratory Post-Hoc Analyses*

- Post-hoc analyses were conducted on enrollment female sexual dysfunction 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 (BL) to end of study (Week 12) in SFQ28 Arousal Sensation (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**

Post-Hoc Analysis Results from Proposed Phase 3 population: FSAD with or without concomitant decreased desire

Endpoint	Sildenafil Cream 3.6% (N=33)	Placebo Cream (N=32)	P value
	LS change (SE) from BL to Week 12	*LS change (SE) from BL to Week 12*	
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)	0.18 (0.52)	0.19
FSDS-DAO – Item 3 Guilt	-0.73 (0.16)	-0.23 (0.17)	0.04
FSDS-DAO – Item 5 Stressed	-0.50 (0.16)	-0.02 (0.16)	0.04
FSDS-DAO – Item 10 Embarrassed	-0.51 (0.17)	0.00 (0.17)	0.04
FSDS-DAO – Item 14 Concerned*	-0.21 (0.16)	-0.22 (0.16)	0.95

LS, least squares; SE, standard error
*Co-primary endpoint.

*See also Johnson, et al. Obstetrics & Gynecology 144(2):p 144-152, August 2024.

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):

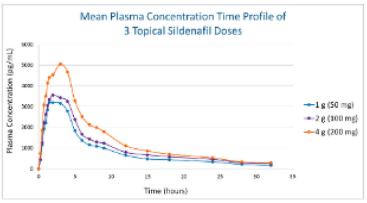
- Favorable product characteristics as self-reported by subjects
- Easy to use
- Readily absorbed

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

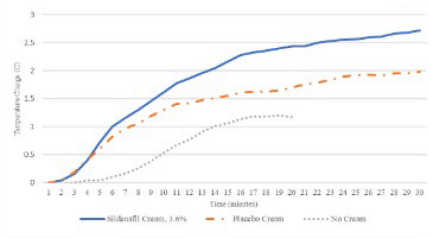


Thermography Study Results*

- 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

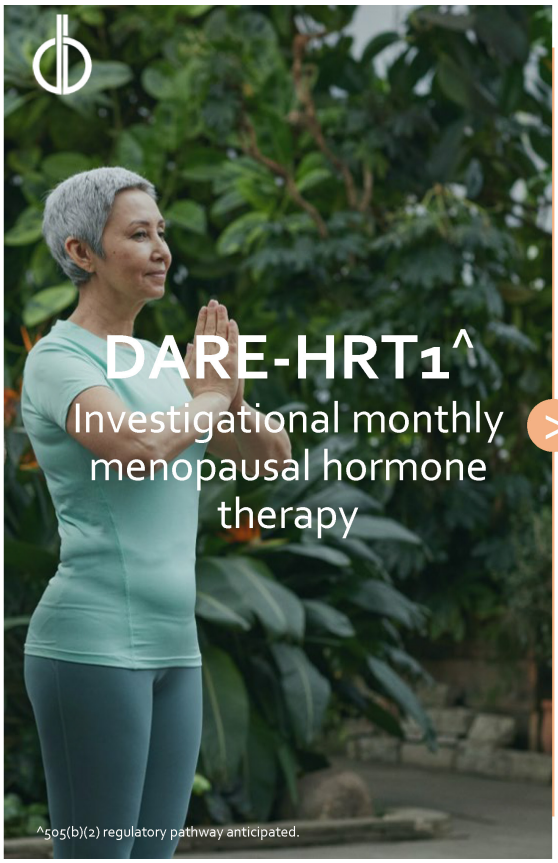


Thermography Study Design & Methodology (N=6)[2]

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.



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.

Vasomotor Symptoms of Menopause

Daré Innovation: DARE-HRT1 Monthly Vaginal Ring

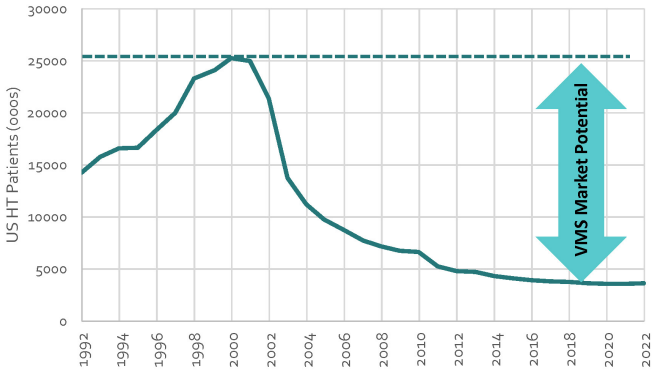
Clinical Issue	• In the US, over **45M women are estimated to be in or approaching menopause**; symptoms can last up to 10 years[1] • ~75% of menopausal women experience hot flashes[2] • 3 in 5 menopausal women felt that they were adversely affected by symptoms while at work[3] • 35% of menopausal women reported that they had experienced 4+ symptoms of menopause, but only 44% said they had discussed their symptoms with a doctor[4]
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 Society[5]. • 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 liver[5] and may reduce the risk of blood clots[6]. • 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 study[8].

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 – Renewing the Market Opportunity

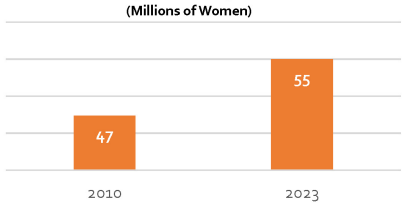
- Prior to the 2002 WHI report, the **Premarin family of products achieved ~$2B in peak revenue,** led by sales of the combination HRT products Prempro and Premphase.[7]
- The WHI report caused hormone therapy market to collapse. While subsequent research and analyses have thoroughly rebuked the WHI's 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 Patients[2]



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.
3. https://pubmed.ncbi.nlm.nih.gov/17405972/
4. https://www.nejm.org/doi/10.1056/NEJM199109123251102?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.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_ar00/05.htm Accessed 24 Oct 2024.

Menopause – Hormone Therapy Position Paper

THE MENOPAUSE SOCIETY POSITION STATEMENT

2022 hormone therapy position statement of The Menopause Society[2]

- 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.

3 in 4[1] **Women**

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

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

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)	NDA submitted	NDA submission anticipated 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.

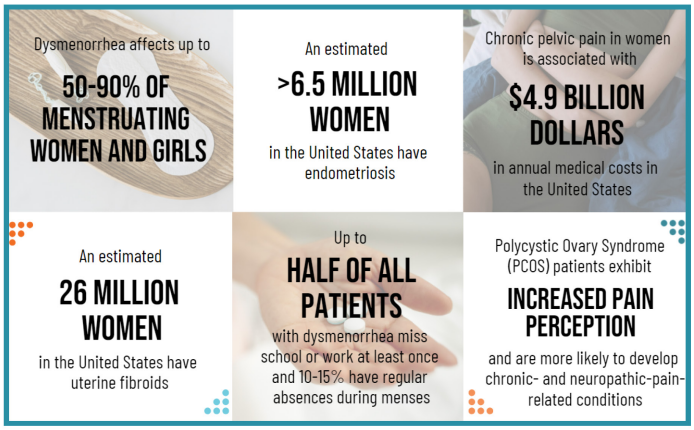
DARE-PDM1^

Investigational nonsteroidal anti-inflammatory drug (NSAID) vaginal gel for use in female pelvic pain

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

Pelvic pain in women is often overlooked and undertreated.

- While DARE-PDM1 is currently being developed for regulatory approval for the indication of primary dysmenorrhea (period pain), NSAIDs are a key component to the multimodal treatment approaches for pelvic pain caused by many gynecologic conditions.



- DARE-PDM1 utilizes Daré's proprietary bioadhesive hydrogel technology, which is designed to increase the vaginal residence of the product.
- **Localized dosing of a vaginal gel** should minimize gastrointestinal side effects associated with oral dosage forms.

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.

darébio

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