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): January 13, 2025

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 January 13, 2025, 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 securities market participants and others, commencing on January 13, 2025.

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 and Exhibit 99.1 to this report is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation by reference language in any such filing, except as the Company expressly sets forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Daré Bioscience corporate presentation, dated January 13, 2025
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: January 13, 2025

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

Exhibit 99.1

January 13, 2025

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 need and deserve.

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

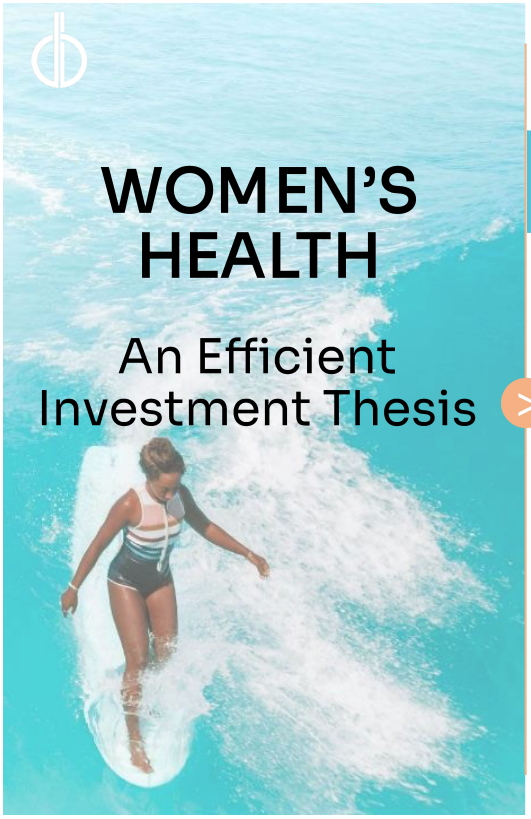
DARÉ
bioscience

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 potential of and market opportunities for 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, U.S. Food and Drug Administration (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 need for additional capital to fund operations and execute its business strategy; the inherent uncertainty of outcomes of clinical trials of investigational drug products; Daré's ability to successfully develop, obtain regulatory approval for and monetize its product candidates; Daré's reliance on third parties to manufacture and conduct clinical trials and preclinical studies of its product candidates and commercialize XACIATO and future products; 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; the effects of macroeconomic conditions, geopolitical events, public health emergencies, major disruptions in government operations, and developments impacting the regulation of the pharmaceutical and health care industries on Daré's operations and potential commercial success; 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.



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

What is
INNOVATION
in
WOMEN'S HEALTH?

INNOVATION is:

Listening to doctors and women
when they talk about what they need.

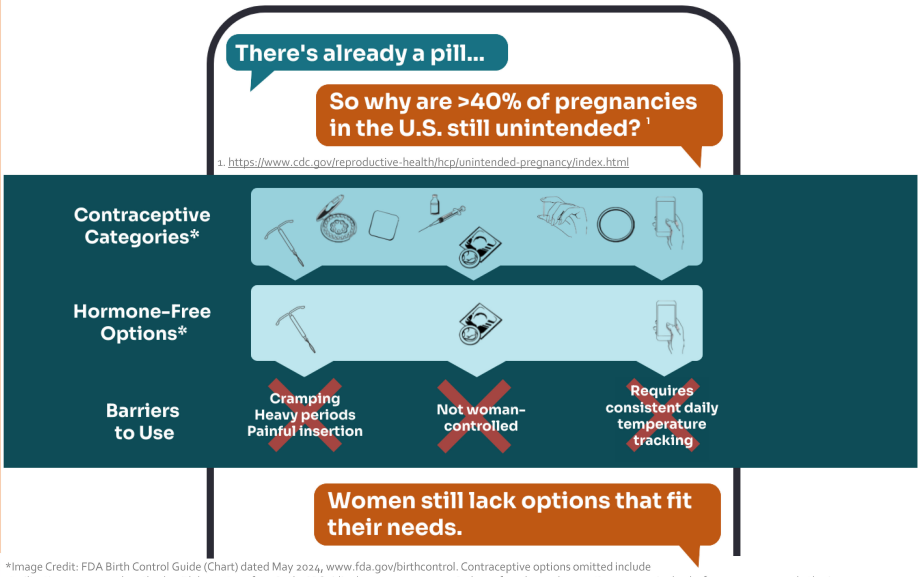
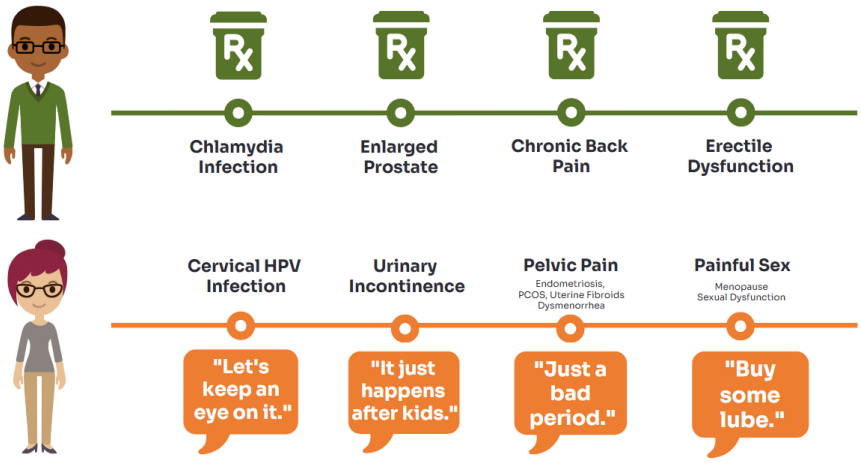


*Image Credit: FDA Birth Control Guide (Chart) dated May 2024, www.fda.gov/birthcontrol. Contraceptive options omitted include sterilization surgery and methods with low rates of use in the U.S. (diaphragm, sponge, cervical cap, female condom, anti-sperm vaginal gels, foams, creams, and other).

What is INNOVATION in WOMEN'S HEALTH?

INNOVATION is:

Recognizing women's health issues as **treatable health conditions**, not dismissing them as a "normal" part of life.



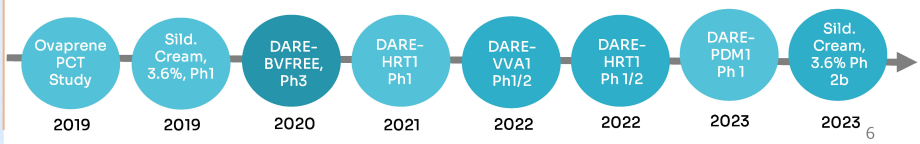
INNOVATION is:

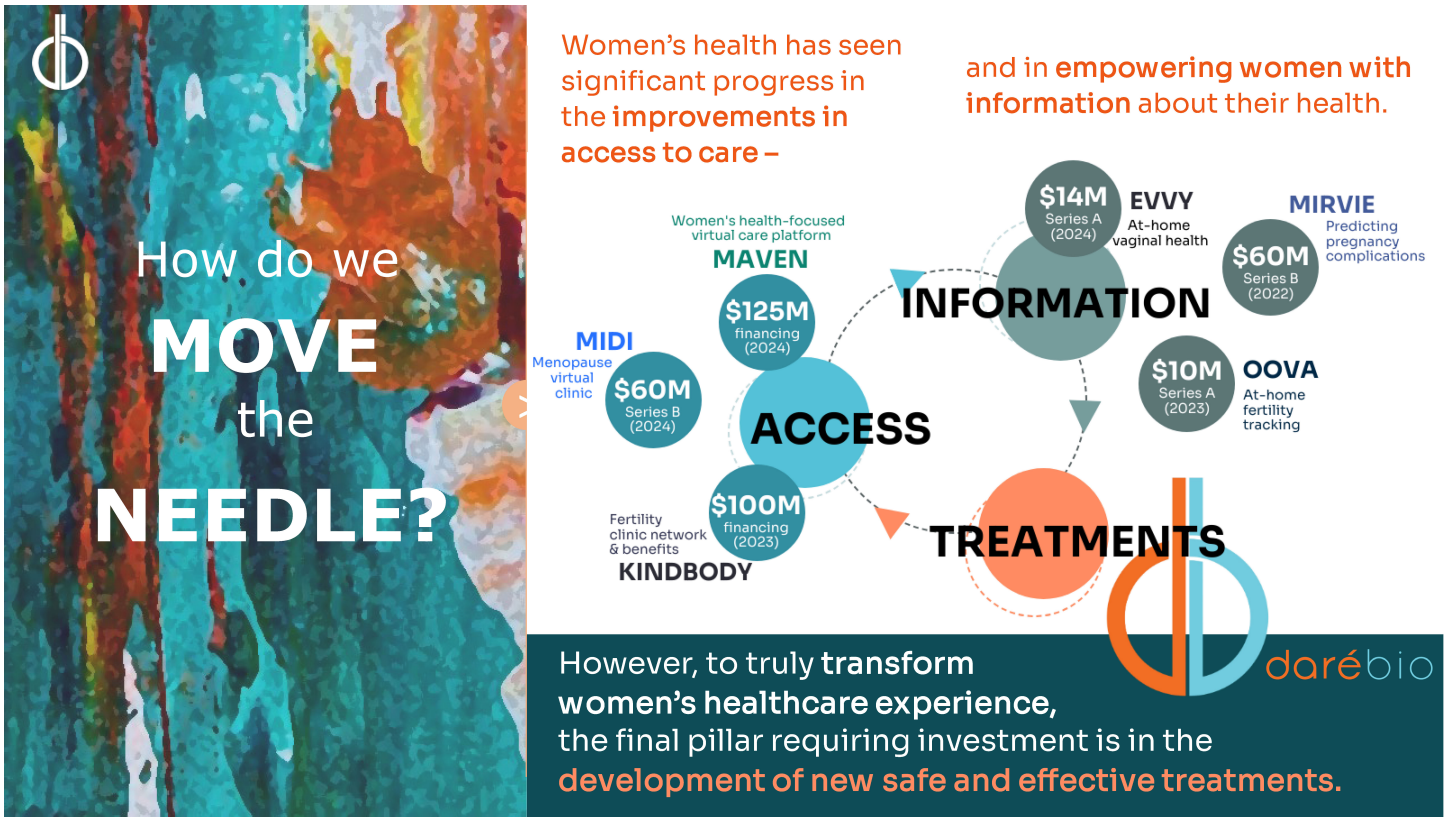
Leveraging the learnings from existing therapeutics to **accelerate our path to market.**

We deploy established active pharmaceutical ingredients (APIs) in first-in-category candidates, allowing us to leverage the derisked 505(b)(2) regulatory pathway.

API	Original FDA Approval		Daré Product Candidate
Sildenafil	Erectile dysfunction (oral)	→	Topical treatment for **female sexual arousal disorder**
Tamoxifen	Breast cancer (oral)	→	Hormone-free vaginal treatment for **sexual pain associated with menopause**
Ritonavir	HIV (oral)	→	Vaginal HPV therapy to **prevent cervical cancer**

Our Track Record: 8 successful clinical trials with six assets in the portfolio, up to and including a Phase 3 trial that led to an FDA approval.

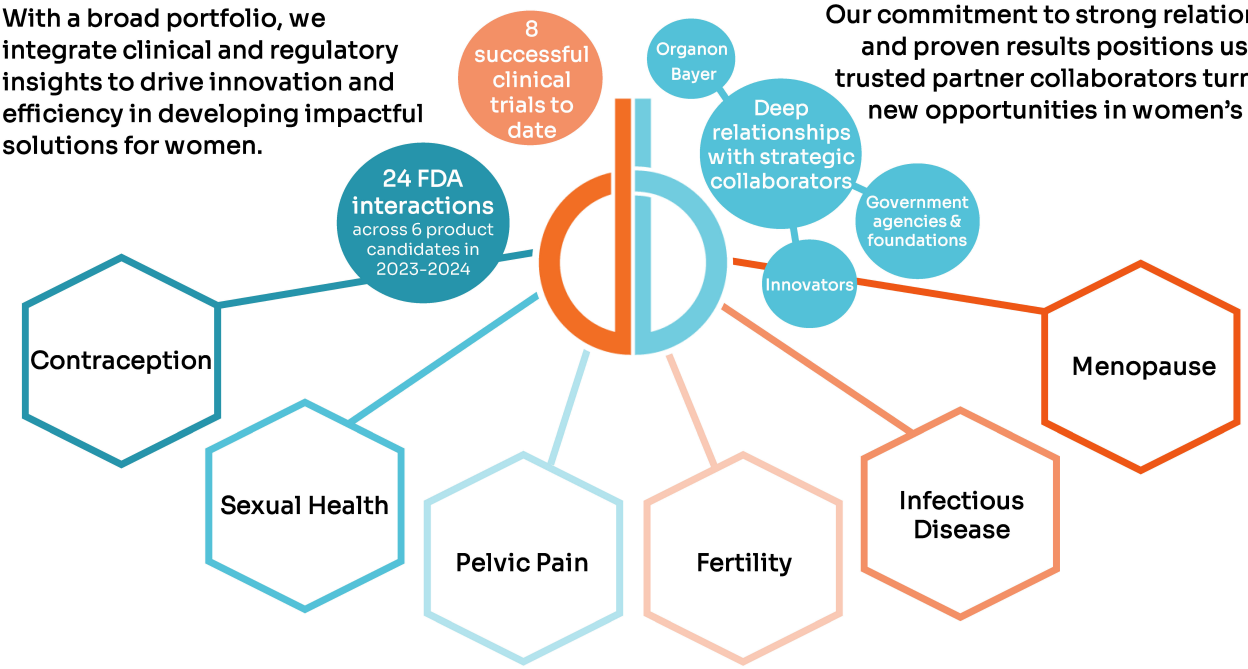



How do we
MOVE
the
NEEDLE?
Women's health has seen significant progress in the improvements in access to care –
and in empowering women with information about their health.
$14M
Series A
(2024)
EVVY
At-home vaginal health
MIRVIE
Predicting pregnancy complications
$60M
Series B
(2022)
INFORMATION
Women's health-focused virtual care platform
MAVEN
$125M
financing
(2024)
MIDI
Menopause virtual clinic
$60M
Series B
(2024)
ACCESS
$10M
Series A
(2023)
OOVA
At-home fertility tracking
$100M
financing
(2023)
Fertility clinic network & benefits
KINDBODY
TREATMENTS
However, to truly transform women's healthcare experience,
the final pillar requiring investment is in the
development of new safe and effective treatments.
darébio

We Are Leading Experts in Women's Health

With a broad portfolio, we integrate clinical and regulatory insights to drive innovation and efficiency in developing impactful solutions for women.

Our commitment to strong relationships and proven results positions us as the trusted partner collaborators turn to for new opportunities in women's health



Revolutionizing Women's Health Therapeutics

Our investigational products are some of the most potentially disruptive therapeutic candidates for women in decades, targeting unmet needs with innovative solutions.

ASSET[1]		ADDRESSABLE MARKET (millions of U.S. 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
Ovaprene® BAYER NIH	Monthly **hormone-free contraceptive**	35				Pivotal Phase 3 study enrolling		
Sildenafil Cream, 3.6% ^	Topical cream to improve **arousal**	20				Phase 3 study preparation		
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 38 for more details.
Timelines represent anticipated timing.

[1] See slide 18 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†

*See Full Prescribing Information for the safe and effective use of XACIATO. See XACIATO selected safety information on slide 38.

†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.

Huge Gaps Remain in the Contraceptive Landscape

We believe that millions of women have not found the contraceptive option that meets their needs.

6% of Americans currently use a GLP-1 (~20 million)

Pills | Other methods | Ring

17 million U.S. women use hormonal contraception

No method	Current Non-Hormonal Users	Current Hormonal Users
(Sexually active women not seeking pregnancy using no contraception)	(Condom, withdrawal, spermicide/ diaphragm, natural family planning)	(Pill, injectable, patch, ring, emergency contraception)

2.5% of all U.S. contraceptive use

35 million[1] U.S. women are potential candidates for Ovaprene®

NuvaRing®: $900M peak global sales

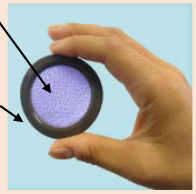
- 93% typical use effectiveness
- Convenience of a monthly ring form
- Fast return to fertility; inserted and removed without a provider
- **Hormonal: contraindicated for VTE risk and for estrogen- or progestin-sensitive cancers**

Design Features of Ovaprene®[2-4]

- 86% - 91% expected typical use effectiveness[2]
- 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 safety concerns**

Physical Barrier[3]
*3D, knitted polymer barrier to **physically block** the passage of sperm*

Spermiostatic Environment[3]
A silicone ring releasing hormone-free ferrous gluconate to chemically impede sperm motility.

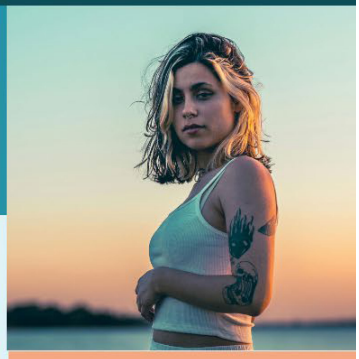


Market Data Sources: Harris, E. (2024). JAMA, 332(1), 8. doi:10.1001/jama.2024.10333; Market research study conducted in 2019 for Daré Bioscience. Contraceptive use data applied to 2019 population data from US Census. See Slide 26 for more details; U.S. Food and Drug Administration Birth Control Guide, May 2024; Merck & Co, Form 10-K for the year ended December 31, 2019.

Ovaprene Data Sources:
1. See Slide 26 for more details.
2. See Slide 23 for more details.
3. Del Priore, et al. Journal of Reproductive Medicine 2009; 54: 685-690
4. Mauck, et al. Contraception, Vol. 132, April 2024

Fighting the Stigma Around 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.



16% or **~10M women** of women in the U.S. ages 21 to 60 are distressed from experiencing no or low sexual arousal, according to market research, and are actively seeking treatment.[1,2]

5% to **15%** of men experience complete ED at age 40, increasing to at age 70[3]

Without effective treatment, the condition is often dismissed and stigmatized.

1. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.
2. Based on US Census projections for 2016. 3. https://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/endocrinology/erectile-dysfunction/

The prevalence of FSAD and ED are similar.

When Fighting Stigma Becomes a Multi-Billion Dollar Industry

Before Viagra®, **erectile dysfunction (ED)** was also dismissed and stigmatized and often **considered to be a normal part of aging.**

1949

SEXUAL BEHAVIOR IN THE HUMAN MALE

ALFRED C. KINSEY

"[Older males] carry on directly the pattern of gradually diminishing activity...**Each male may reach the point where he is, physically, no longer capable of sexual performance.**"

1986

The American Journal of Medicine

May 1986, Vol. 80

"Most practitioners still believe that in the majority of patients, [male] **impotence is psychologic**, with fears, phobias, and feelings of guilt... being responsible for the impotence."

"It is an underlying tenet of this review that ... there is no age at which intercourse is not physiologic and as such **the development of impotence represents a pathologic process requiring treatment.**"

Viagra sales peaked at **$2.05 billion in 2012**[1] and ED is now widely recognized as a **physiological medical condition.**

1998

Los Angeles Times

BUSINESS

Number of Viagra Prescriptions Sets Launch Record

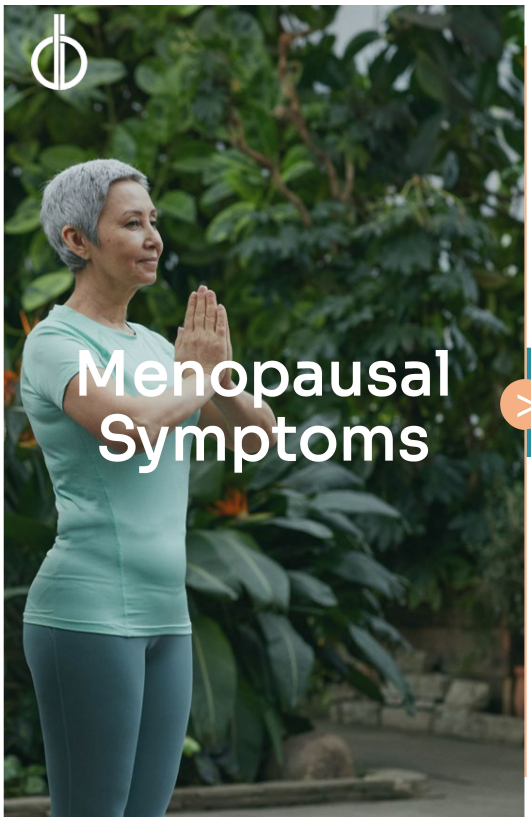
April 21, 1998 12 AM PT

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

However, there are still no FDA-approved treatments for FSAD.

Sildenafil Cream, 3.6% is an investigational topical formulation of the active ingredient in Viagra® for the treatment of FSAD.

Phase 2b RESPOND study has been completed; Phase 3 study preparation is ongoing.



Menopause is Having a Moment

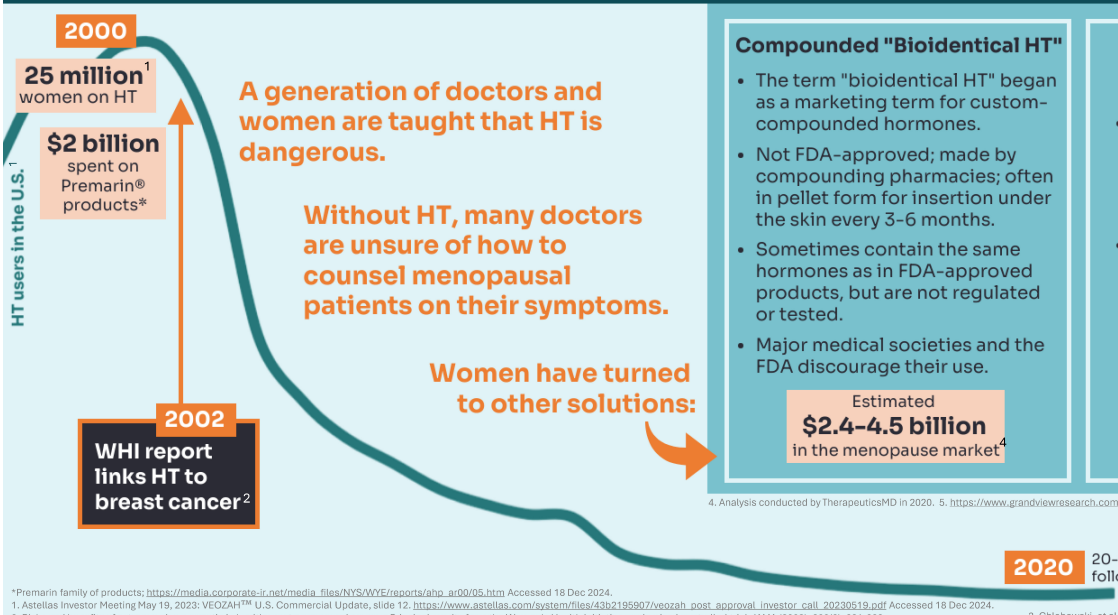
- The menopause market is a large and growing market, with **more than 1 billion people worldwide** expected to be in menopause by 2025[1]. Approximately **51% of menopausal women experience moderate to severe vasomotor symptoms (VMS) or hot flashes.**[2]
- The global market for menopausal products is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

The Changing Perceptions Around Hormone Therapy (HT)



Compounded "Bioidentical HT"

- The term "bioidentical HT" began as a marketing term for custom-compounded hormones.
- Not FDA-approved; made by compounding pharmacies; often in pellet form for insertion under the skin every 3-6 months.
- Sometimes contain the same hormones as in FDA-approved products, but are not regulated or tested.
- Major medical societies and the FDA discourage their use.

Estimated **$2.4-4.5 billion** in the menopause market[4]

Non-HT Supplements for Menopause Symptoms

- Often contain herbal ingredients such as black cohosh, evening primrose oil, and ashwagandha root extract
- Supplements are not FDA-regulated and can cause serious health problems such as liver toxicity

Estimated to be **$16 billion** globally in 2023[5]

*Premarin family of products; https://media.corporate-ir.net/media_files/NYS/WYE/reports/ahp_ar00/05.htm Accessed 18 Dec 2024.

1. 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 18 Dec 2024.

2. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: Principal results from the Women's Health Initiative randomized controlled trial. JAMA (2002), 288(3), 321-333.

3. Chlebowski, et al.(2020). *JAMA*, *324*(4), 369–380.

4. Analysis conducted by TherapeuticsMD in 2020. 5. https://www.grandviewresearch.com/industry-analysis/menopause-market Accessed 06 Jan 2025.

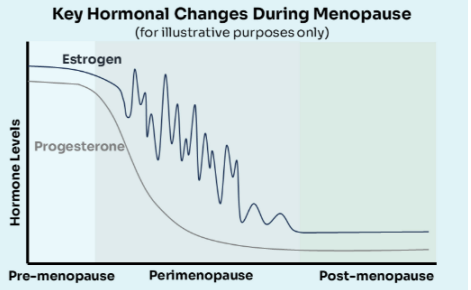
With the WHI findings now thoroughly rebuked, medical societies are actively training their members on the benefits of HT.

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]

1. https://www.hopkinsmedicine.org/health/conditions-and-diseases/introduction-to-menopause



Hormone therapy is recommended as the most effective treatment by the Menopause Society for treatment of the vasomotor symptoms of menopause (VMS) or hot flashes.

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

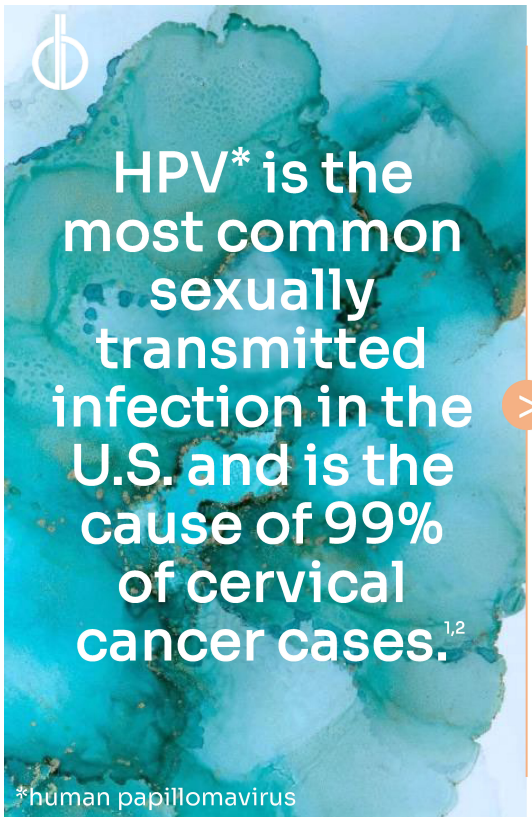
There are no FDA-approved products that combine both **estradiol and progesterone** in a **non-oral monthly form.**

2. https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf

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

Tamoxifen is commonly prescribed by oncologists in the treatment of hormone receptor positive (HR+) breast cancer, as it blocks estrogen activity in breast tissue[3]. 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 the genitourinary syndrome of menopause (GSM).[4]

3. Cleveland Clinic: Tamoxifen. https://my.clevelandclinic.org/health/treatments/9785-tamoxifen
4. Thurman, et al. Climacteric Volume 26, 2023 - Issue 5



>6 million women are diagnosed each year with high-risk HPV infections that could lead to cervical cancer.[3]

While vaccinations and screenings are important tools, **safe and effective HPV treatments remain an unmet need.**

Today, HPV infections are not treated upon diagnosis.

HPV infections and cervical precancers (dysplasia) are monitored using a **"watch and wait"** approach 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.**

1. CDC Cancer Statistics: Cancers Associated with Human Papillomavirus. https://www.cdc.gov/vaccine-safety/vaccines/hpv.html. Accessed 18 Dec 2024.
2. WHO Cervical Cancer. https://www.who.int/health-topics/cervical-cancer. Accessed 18 Dec 2024.
3. 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.

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 enrollment ongoing
- Phase 3 study updates

Sildenafil Cream, 3.6%

- Phase 3 protocol submission reflecting the FDA's recommendations planned for Q1 2025
- Phase 3 study start targeted for mid-2025
- Collaboration strategy

DARE-HPV

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

APPENDIX

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 advance programs in a more capital efficient way compared to 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.)
- **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

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 Cooperative Research and Development Agreement (CRADA) enables Daré to leverage the contraceptive **clinical trial expertise** of the NICHD.
- If successful, we believe that **the single ongoing registration study will be sufficient to support a premarket approval** application submission with the FDA.

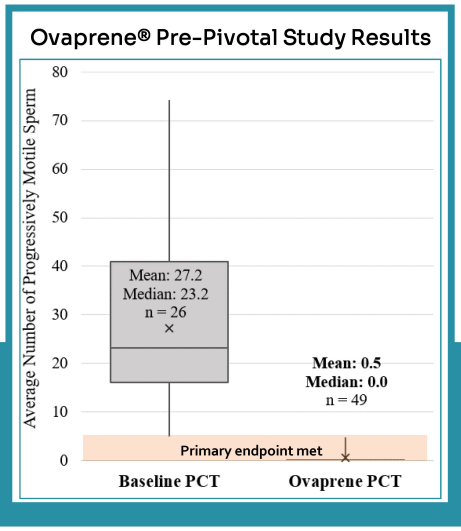
Commercialization Collaborator

- 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® - 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)

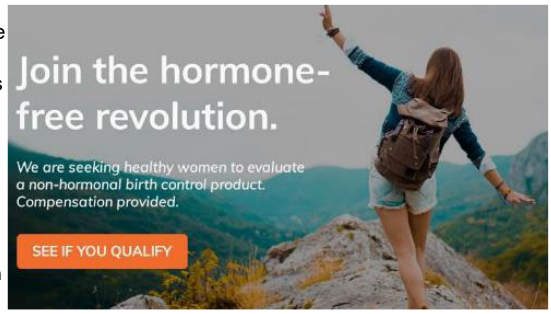
Secondary objectives

- 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 10 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.
- Foundation grant announced in November 2024 will fund additional clinical sites which is expected to accelerate the overall study timeline.



ovaprenestudy.com

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

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.

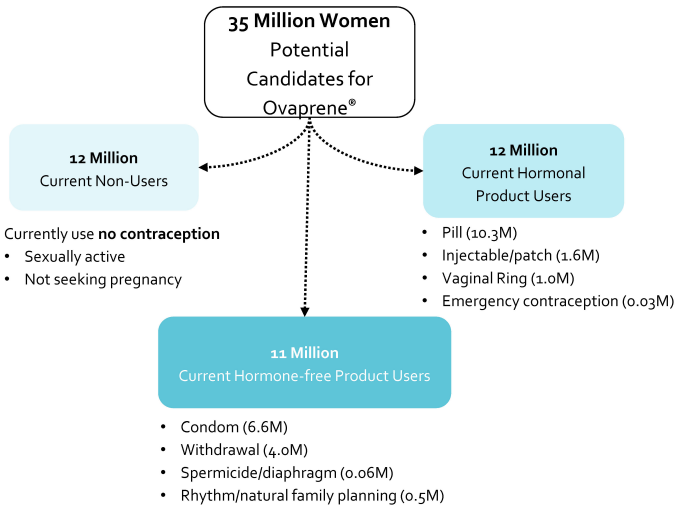
Bayer received the right to obtain exclusive US rights to commercialize the product, **following completion of the pivotal clinical trial** if Bayer, in its sole discretion, pays Daré **$20 million.**[2]

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® - Potential U.S. Market Opportunity[1,2]



1. Market research study conducted in 2019 for Daré Bioscience
2. Contraceptive use data applied to 2019 population data from US Census

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

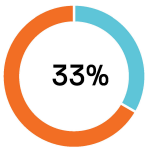
Female Sexual Arousal Disorder

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

FSAD 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.

Path Forward for Sildenafil Cream

Key Takeaways- Phase 2b Clinical Study

- The **Phase 2b Clinical Study** was designed to evaluate Sildenafil Cream vs. placebo over 12 weeks.
  - To Daré's knowledge, this was the 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†‡	-0.27 (0.18)	-0.12 (0.20)	0.58

Clinical Development Plan and Commercialization Opportunity

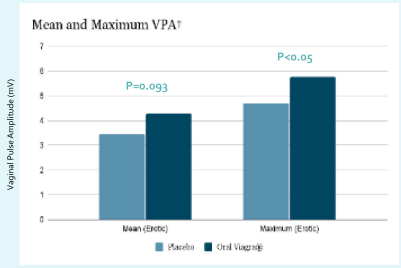
- Sildenafil Cream has potential to be **a first-in-category** option with **significant commercial opportunity** as there currently are no FDA approved treatments for FSAD.
- Daré intends to leverage existing safety data for sildenafil to utilize the FDA's 505(b)(2) pathway to obtain marketing approval for Sildenafil Cream in the U.S.
- End-of-Phase 2 meeting with the FDA completed**, Phase 3 plans announced in Q4 2024**.
  - Two successful Phase 3 trials will be required to support a New Drug Application (NDA) submission for the treatment of FSAD.
  - Phase 3 study protocol and statistical analysis plan submission reflecting the FDA's recommendations planned for Q1 2025:
    - *Patients with FSAD with or without concomitant decreased desire*
    - *12-week double-blind treatment period evaluating Sildenafil Cream compared to placebo cream*
    - *Co-primary efficacy endpoints assessing (1) arousal sensations and (2) associated distress; the same co-primary endpoints used in the Phase 2b RESPOND study*
    - *Secondary endpoints to assess improvement in orgasm, desire, and distress and interpersonal difficulties will be included, as they were in the Phase 2b RESPOND study*
- **Targeting mid-2025 for Phase 3 study start**

1. Johnson, et al. Obstetrics & Gynecology 144(2):p 144-152, August 2024. See slides 30-31 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. ‡Previously reported as -0.21 (0.16) / -0.22 (0.16) / 0.95. See slide 31 for more information.

Oral Sildenafil provided a compelling proof of concept for FSAD

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

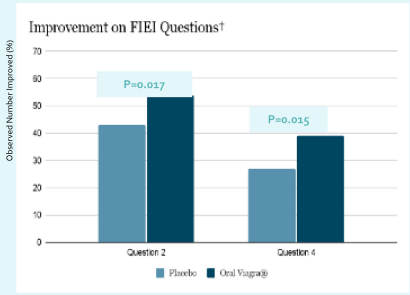
***Pfizer** VPA Clinical Lab Study – Oral Viagra*



† 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.

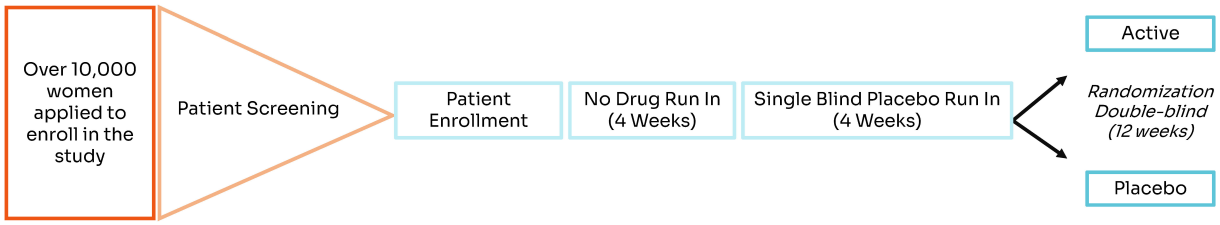
Key Takeaways of Viagra® studies:

- 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**

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

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*‡	-0.27 (0.18)	-0.12 (0.20)	0.58

LS, least squares; SE, standard error
*Co-primary endpoint.
‡Previously reported as -0.21 (0.16) / -0.22 (0.16) / 0.95. New calculations will be used for Phase 3 planning; data on file. New analysis excludes from the calculation a pre-planned Evaluation of Recall Subset (ERS) group of patients who provided patient reported outcomes via the 1-month recall instruments but did not provide data via the 24-hour recall eDiary. This ERS is excluded from the primary endpoint analysis (SFQ28-AS and FSDS-DAO #14).

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):

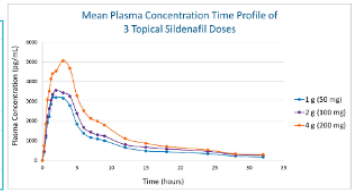
- Favorable product characteristics as self-reported by subjects
- Easy to use
- Readily absorbed

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

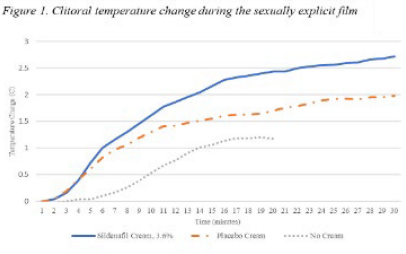


Thermography Study Results*

- 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



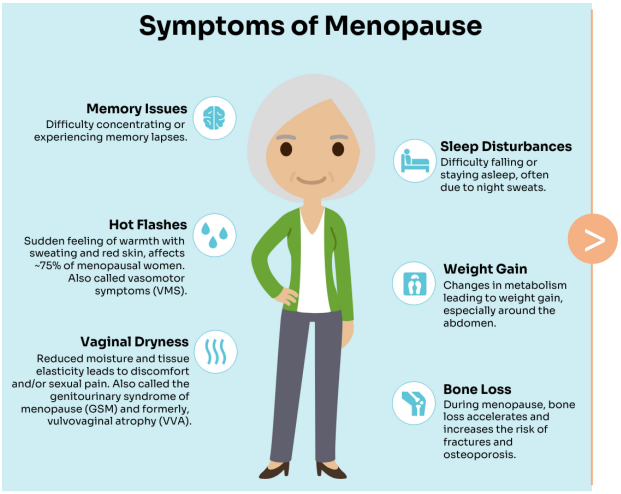
Thermography Study Design & Methodology (N=6)[2]

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.

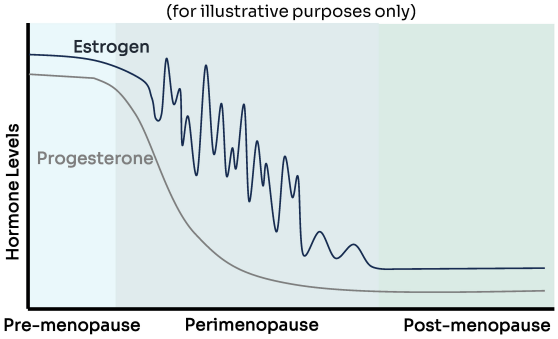
* Thermography utilizes sensitive cameras capable of detecting and recording temperature variations over time. Genital temperature changes are a surrogate for genital blood flow.

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]

^ 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.

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]

2. Cleveland Clinic: Tamoxifen. https://my.clevelandclinic.org/health/treatments/9785-tamoxifen
3. Thurman, et al. Climacteric Volume 26, 2023 - Issue 5

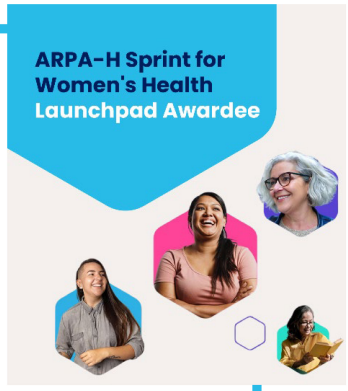
DARE-HPV^

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.**

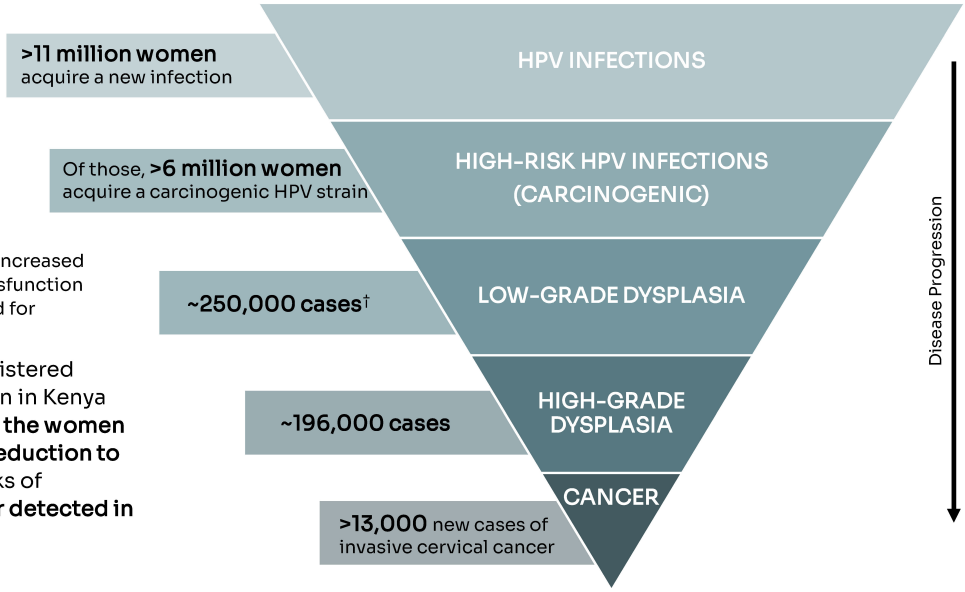
- DARE-HPV is a proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert.
- Phase 1 and proof-of-concept studies have been completed.
- Activities to support IND filing to enable progression to Phase 2 clinical development underway supported by a two-year **ARPA-H Launchpad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



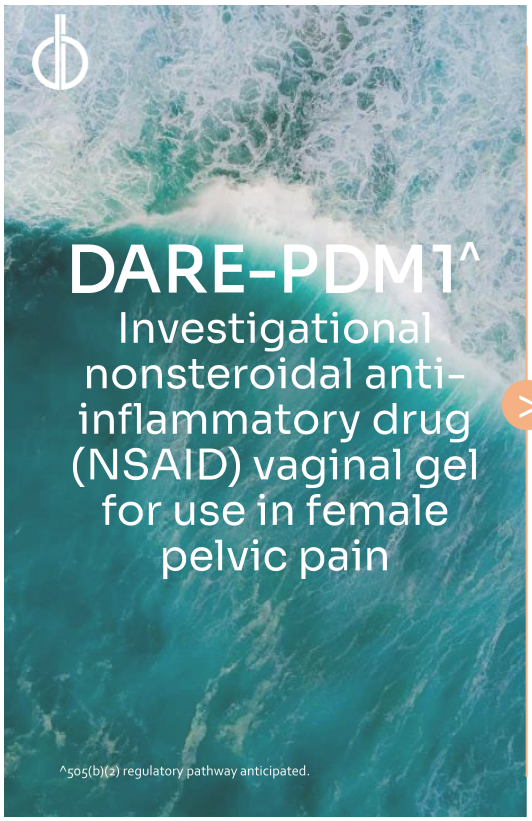
Safe and Effective HPV Treatments Remain an Unmet Need

- 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]

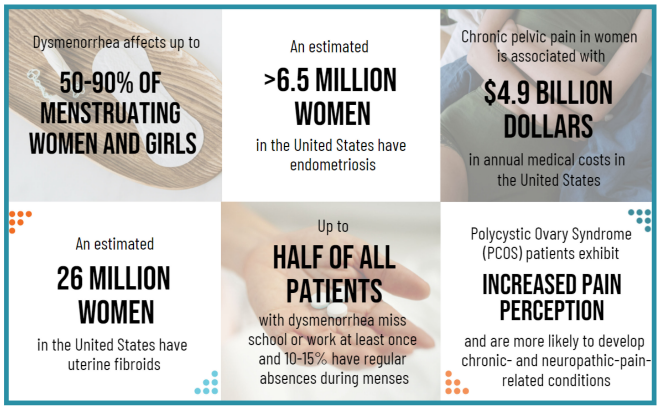


1. Estimates based on the following sources: Lewis, et al. Estimated Prevalence and Incidence of Disease – Associated Human Papillomavirus Types Among 15-59-Year-Olds in the United States. Sex Trans Dis. 2021 Apr 1; 48(4):273-277. Henk, et al. "Incidence and costs of cervical intraepithelial neoplasia 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.



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.

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