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): September 2, 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 September 2, 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 September 2, 2025.

The Company 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 September 2, 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: September 2, 2025

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


DARÉ
bioscience
NASDAQ: DARE
www.darebioscience.com

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 t
discusses potential future drug and medical device products that are or will be under clinical or preclinical investigation and have not been approved for use out
as well as proprietary solutions that may be made available as compounded drugs or consumer health products that the U.S. Food and Drug Administration (FDA
investigational products or potential compounded drugs or consumer health products discussed herein have been approved for marketing by the FDA or any oth
representation is made as to the safety or effectiveness of any investigational product, compounded drug or consumer health product.

All statements in this presentation, other than statements of historical fact, are forward-looking statements within the meaning of federal securities laws. In som
looking statements by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "upcoming," "design," "intend," "expect," "could," "plan," "potent
"should," "would," "contemplate," "project," "target," "objective," "on track," or the negative of these terms and other similar expressions. Such statements includ
relating to Daré's go-to-market strategies; Daré's plans and timing for making proprietary formulations available by prescription in the U.S. as compounded drug
Drug, and Cosmetic Act (503B) and for launching branded consumer health products; expected timing of revenue from sales of those products; market opportuni
ability to gain market acceptance; plans and expectations with respect to Daré's product candidates, including intent to continue to pursue an FDA approval pat
brings to market as compounded drugs under 503B, clinical development plans, trial design, timelines, costs, milestones, targeted indications, clinical trials and
communications, submissions and review of applications; the clinical potential of and market opportunities for Daré's product candidates; potential strategic pa
collaborations; expectations regarding existing collaborations, including potential payments; potential pipeline expansion; the amount and timing of Daré's rece
and other funding awards; and potential funding and financing transactions. As used in this presentation, "first-in-category" is a forward-looking statement relat
candidate to represent a new category of product if it were to receive marketing approval for the indication for which it is being developed because Daré believe
women's health that is not being met by existing FDA-approved products. Forward-looking statements reflect management's estimates and expectations based
risks, uncertainties and assumptions that may cause Daré's actual results, performance or achievements to be materially different from those expressed or implie
statements, including, without limitation, risks and uncertainties related to: Daré's ability to raise additional capital when and as needed to fund operations and e
dependence on grants and other financial awards from governmental entities and a private foundation; limitations on Daré's ability to raise additional capital thr
other equity securities due to restrictions under SEC and Nasdaq rules and regulations or contractual limitations; Daré's inexperience, as a company, in and lack
products; Daré's reliance on 503B-registered outsourcing facilities and other third parties to bring proprietary solutions to market as compounded drugs or as c
facilitate access to such products and the risk that those third parties do not perform as expected; the risk that the FDA could stop permitting 503B-registered c
the drug substances in the proprietary formulations Daré intends to bring or brings to market; the degree of market demand and acceptance for the products Da
on third parties to manufacture and conduct clinical trials and preclinical studies of its product candidates and commercialize XACIATO™ (clindamycin phospha
approved products, if any; Daré's ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on com
in starting, conducting and completing clinical trials of a product candidate and the inherent uncertainty of outcomes of clinical trials; the risk that the current re
FDA's 505(b)(2) pathway for drug product approval in the U.S. is not available for a product candidate as Daré anticipates; Daré's ability to retain its licensed righ
product or product candidate; Daré's and its licensors' ability to obtain and maintain sufficient intellectual property protection; the coverage, pricing and reimbu
future product obtains from third-party payors; product liability claims and actions; cybersecurity incidents; changes in laws and regulations that impact the pha
industries; the effects of macroeconomic conditions, geopolitical events, and major changes and disruptions in U.S. government policies and operations on Dar
or on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; Daré's ability to maintain compliance with Nasdaq's c
continue to have its common stock listed on The Nasdaq Capital Market; and those risks and uncertainties described under the heading "Risk Factors" in Daré's r
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
undertake any obligation to update any forward-looking statement in this presentation to reflect new information, future developments or otherwise, except as r

This presentation includes market size and growth data and estimates and other industry information published by independent third parties or based on manag
management's knowledge of the industry and good faith estimates of management. This market and industry data and information involves a number of assumpt
cautioned not to give undue weight to such estimates. Although Daré believes the third-party sources are reliable as of their respective dates, Daré cannot guara
of this information and has not independently verified this information. Projections, assumptions and estimates of the future performance of the industry in whic
opportunities for product candidates Daré develops are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results
expressed in the data and estimates made by the independent parties and by Daré.

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

Daré at a Glance

Sole focus on women's health — from contraception to menopause, sexual health, vaginal health, and fertility

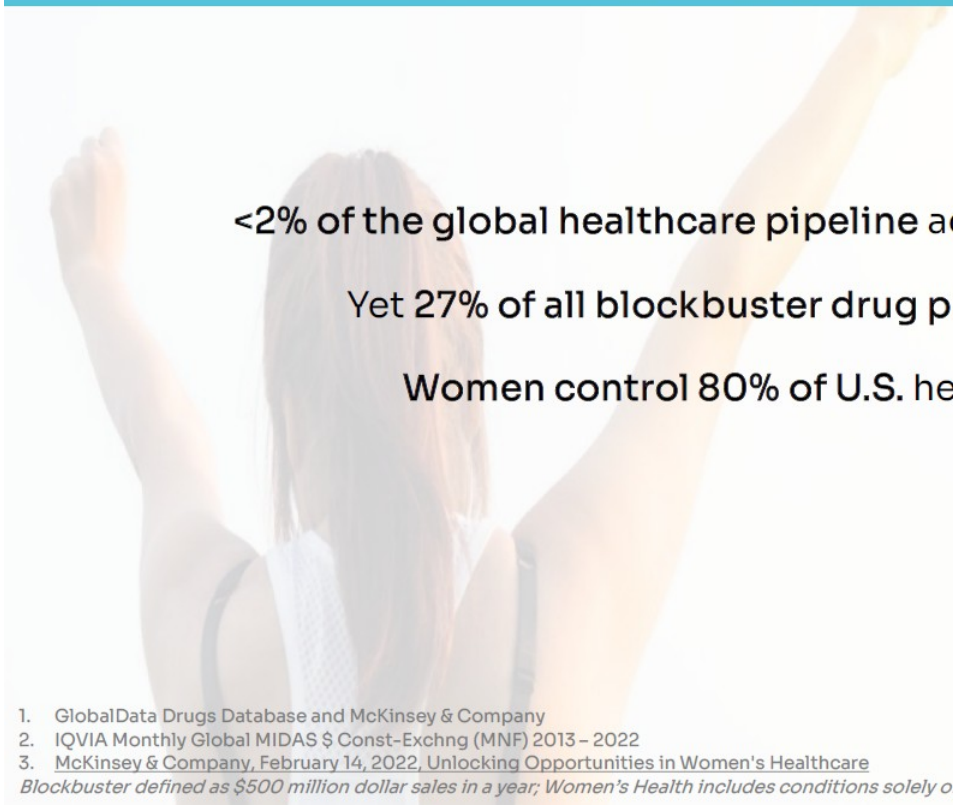
Evidence-based solutions via fastest eligible pathways to market — 503B compounding, FDA approvals, and non-prescription

Strategic collaborations with Organon and Bayer

Capital-efficient model

Significant non-dilutive funding

Why Invest in Women



<2% of the global healthcare pipeline addresses non-oncologic women

Yet **27% of all blockbuster drug products** are women's health dru

Women control 80% of U.S. healthcare purchasing decisions.[3]

1. GlobalData Drugs Database and McKinsey & Company
2. IQVIA Monthly Global MIDAS $ Const-Exchng (MNF) 2013 – 2022
3. McKinsey & Company, February 14, 2022, Unlocking Opportunities in Women's Healthcare

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

Near-Term Commercial Path

ASSET / TARGET AVAILABILITY			UNMET NEED	MARKE
Q4 2025 DARE TO PLAY™	Sildenafil Cream (Rx^)	Designed for her **sexual experience**	There are no FDA-approved treatments for **a problem likely as common as erectile dysfunction** – except that it's in women.[1]	A 2024 analyst repo the **erectile dys opportu** **$11 b**
Post DARE to PLAY DARE TO RESTORE™	Vaginal probiotic suppositories (non-Rx)	Designed to maintain a **healthy vaginal microbiome**	**Vaginal health awareness is growing** – mentions of the microbiome **increased by 54%** in Reddit women's health communities from 1H 2023 to 1H 2024.[3]	Feminine care cor **Honey Pot Compan** have capitalized on t successful exits respec
Late 2026 DARE TO THRIVE™	Monthly estradiol + progesterone vaginal ring (Rx^)	Designed to support her through **menopause**	Gaps in solutions for menopause symptoms have given rise to **an explosion of untested supplements and therapies.**	An analysis conduc estimated the U **hormone thera** **$2.5-4.**

^Proprietary formulations expected to be made available for prescription fulfillment via a 503B-registered outsourcing facility partner.
1. See Slides 23 & 25 for estimated U.S. prevalence of symptoms of low or no sexual arousal in women and erectile dysfunction (ED) in men. 2. Aug 22, 2024 Needham analyst report on HIMS, pg. 24. The analyst's estimated ED market opportunity was based on 26.6 million men at $35/month. The generic and compounded ED drug market opportunity leverages 30 years of market experience with an FDA-approved oral therapy for ED that established tremendous brand awareness and market acceptance.
3. How Reddit Empowers Women's Health published by The Weber Shandwick Collective.
4. CODI 10-K for FY 2024. The Honey Pot Co.'s (THPC) c portfolio includes anti-itch/soothing creams, supposito products, & represented 8% of gross sales in FY2024. TH CODI purchased a controlling interest THPC in Jan 202 includes Clairvee® vaginal probiotic dietary supplemen acquisition of Bonafide Health for $425M in Nov 2023.
6. TD Cowen Therapeutic Categories Outlook, February

DARE to PLAY™ Sildenafil Cream

- DARE to PLAY™ Sildenafil Cream is a proprietary topical formulation of the active ingredient in an erectile dysfunction drug (Viagra®)*
- **An estimated 20 million women experience symptoms of low or no sexual arousal;** ~10 million are considered distressed and actively seeking treatment.[1,2]
- **There are no FDA-approved treatments for female sexual arousal disorder (FSAD).**

We are pursuing a dual path approach:

Targeting prescription launch in Q4 2025 as a compounded drug through a 503B-registered outsourcing facility partner

+

Continuing to **pursue FDA's 505(b)(2) pathway** to obtain marketing approval in the U.S. for FSAD [3]

*DARE to PLAY is a compounded drug. It is not FDA approved.

1. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.
2. Based on US Census projections for 2016.
3. See slides 25-32.

Key Data: DARE to PLAY™ Sildenafil Cream

PK study demonstrated **minimal systemic exposure**: (1–2% C_{max} of oral sildenafil)

Phase 2b study demonstrated **statistically significant arousal improvement in the targe population** (post-hoc analysis).[2]

Sildenafil Cream was **well tolerated by exposed users and their sexual partners** in the Phas There were no differences in the number of treatment-related TEAEs among Sildenafil Cre placebo cream users (p>0.99).[2]

1. See slide 31.
2. See slides 27-30.

Ovaprene®

Investigational Hormone-free Monthly Intravaginal Contraceptive

- **Phase 3 pivotal study is enrolling**; positive interim data and Data Safety Monitoring Board (DSMB) recommendation reported in Q3 2025. [1]
- There are currently **no FDA-approved monthly, hormone-free contraceptives**.
- **Bayer** received the right to obtain **exclusive US rights to commercialize** the product if Bayer, in its sole discretion, pays Daré **$20 million** following completion of the pivotal clinical trial. [2,3]

1. See Slide 36
2. https://ir.darebioscience.com/news-releases/news-release-details/bayer-and-dare-bioscience-announce-exclusive-licensing-agreement
3. Minority interest in $20 million payment and royalties on Ovaprene net sales subject to synthetic royalty purchase agreement (April 2024)

Menopause Franchise

The global market for menopausal products is expected to reach >$24 billio

DARE-VVA1*

Hormone-free tamoxifen inserts for painful intercourse associated with menopause

Investigational New Drug (IND) application cleared for Phase 2 start

DARE-HRT1*

Monthly estradiol + progesterone intravagi

We are pursuing a dual path approach:

Targeting prescription launch in late 2026 as a compounded drug through a 503B-registered outsourcing facility partner

+

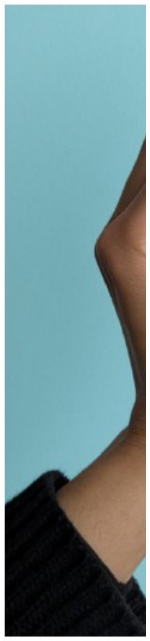
Continui
505(b)(2
marketing
for the vas
mer

*DARE-VVA1 and DARE-HRT1 are investigational products. They are not FDA approved. See slide 41.

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

DARE-HPV

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

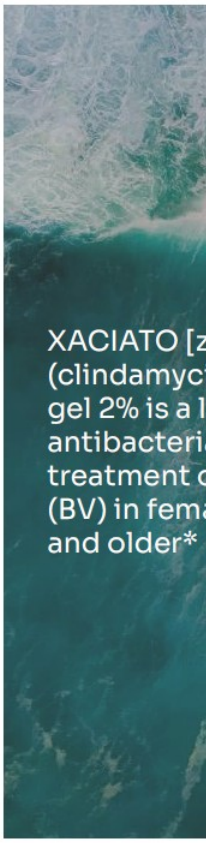


- A proprietary fixed-dose formulation of **lopinavir and ritonavir[1] in a soft gel vaginal insert**.
- In a **pilot study** of vaginally-administered lopinavir and ritonavir in 23 women in Kenya with high-grade cervical dysplasia, the majority demonstrated no dysplasia and undetectable HPV after 12 weeks of treatment.[2]
- **Up to $10 million non-dilutive funding award** to support U.S. IND filing and enable progression to Phase 2 clinical development

1. Lopinavir and ritonavir are the active pharmaceutical ingredients in the FDA-approved drug Kaletra® for the treatment of HIV-1 infection.
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.

FDA Approved Product: XACIATO™

(Clindamycin Phosphate) Vaginal Gel 2%



- **Available nationwide via commercial collaboration with Organon;** royalties and potential milestones payable by Organon of up to **$180 million.**†
- **$27 million raised in royalty financings**; Daré is eligible for upside-sharing milestone payments from XOMA†
- Demonstrates validation of **partnership-driven commercialization strategy** where appropriate

*See Full Prescribing Information for the safe and effective use of XACIATO. See XACIATO selected safety information on slide 46

†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
(Dec 2023). Upon achieving a pre-specified return threshold, XOMA will make upside-sharing milestone payments to Daré representing 50% of the future payments o

Pipeline Overview

Diverse, strategically balanced portfolio of **late-, mid-, and early-stage assets** targeting n
oncologic conditions across women's health

Large addressable U.S. and global markets

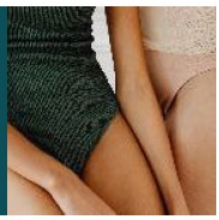
DARE TO PLAY™ — Designed for her sexual experience

DARE TO PLAN™ — Designed for her contraception needs

DARE TO THRIVE™ — Designed to help her keep living her best life

DARE TO FIGHT™ — Designed to treat vaginal infections

DARE TO RESTORE™ — Designed to maintain a healthy vaginal microbiome



DARE TO SUPPORT™ — Designed to support her pregnancy

Strategic Collaborations & Non-Dilutive Funding

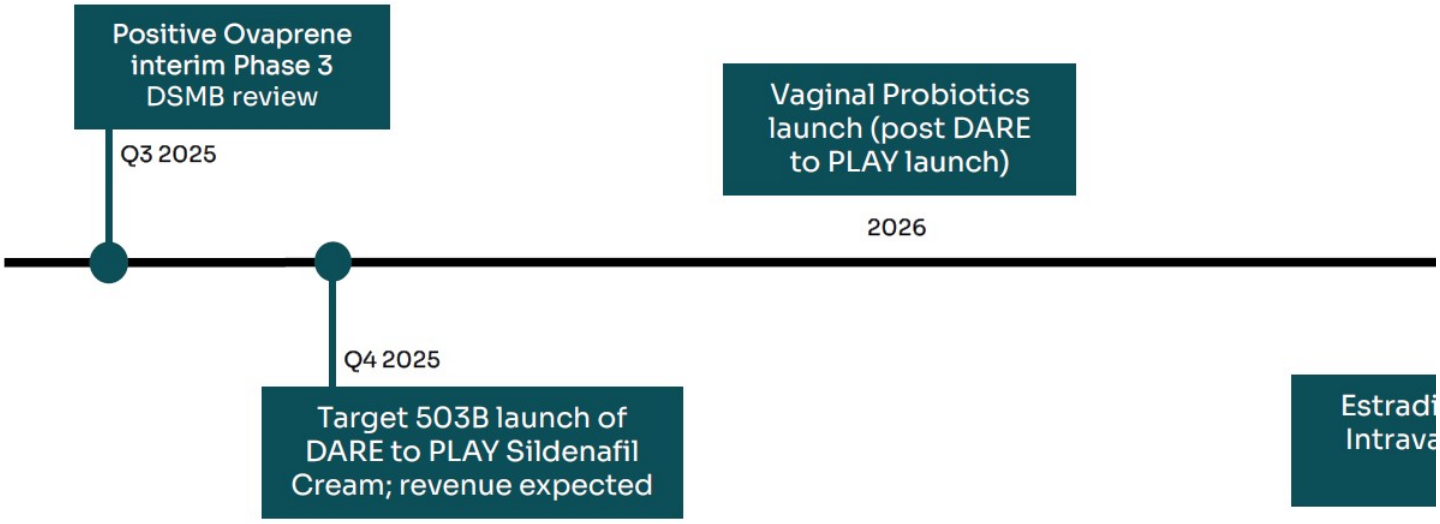
Organon – XACIATO™ commercialization

Bayer – Ovaprene™ commercialization

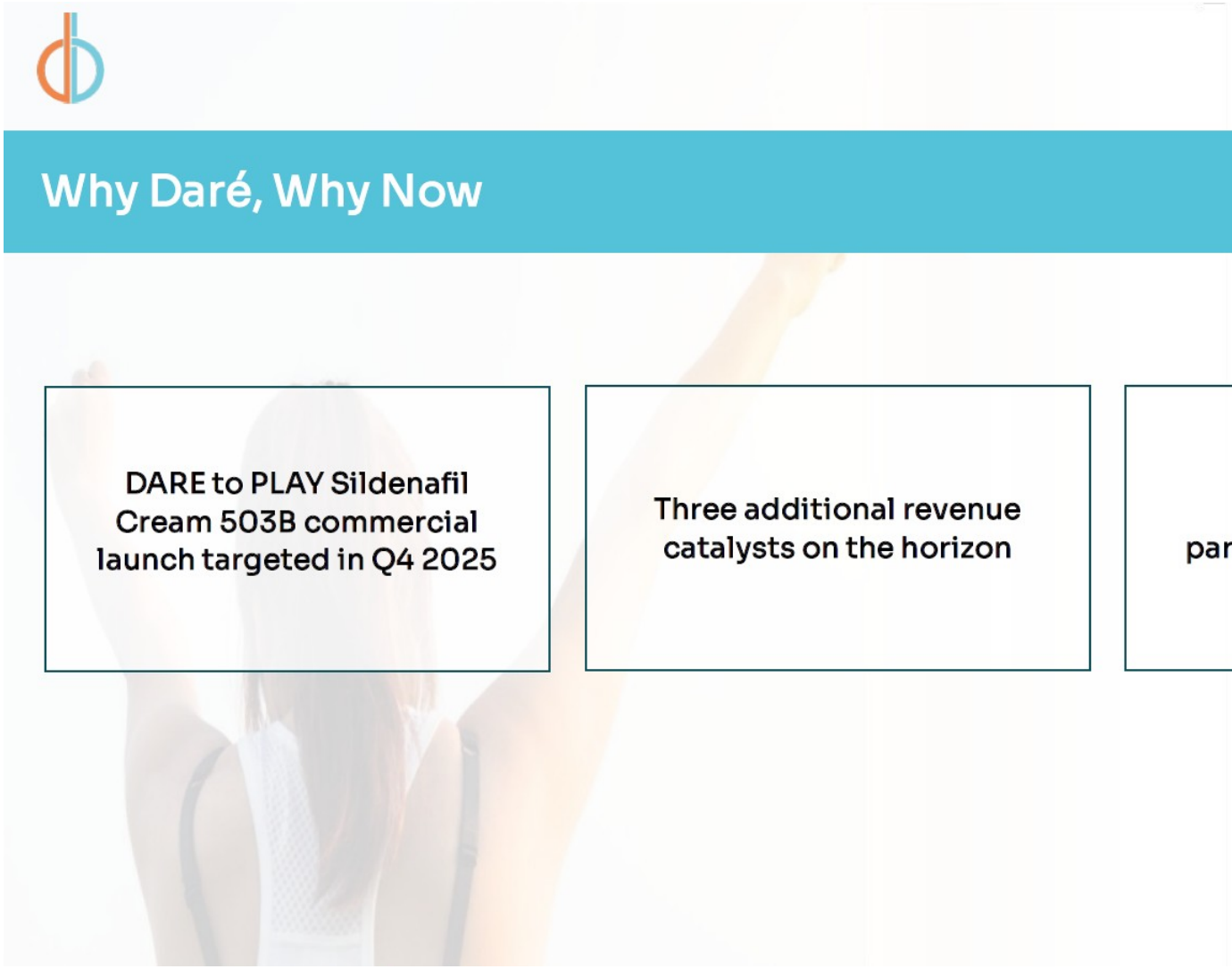
NIH, ARPA-H, Foundation grants and other awards across several portfolio pr

>$75 million awarded since 2018

Recent and Upcoming Catalysts



Why Daré, Why Now



DARE to PLAY Sildenafil Cream 503B commercial launch targeted in Q4 2025

Three additional revenue catalysts on the horizon

Capital partnership


APPEND

Cutting through the noise

We see gaps – where research exists, but solutions are not reaching women.

- We believe innovation does not have to start from scratch. Our core strategy is to **start with the unmet needs**, then identify and acquire the rights to **differentiated** evidence-based solutions in those areas of need.

We aim to deliver real, science-backed options and meet women where they are.

- We understand that **different** needs are served by **different** types of products. This means utilizing **all eligible pathways** to get evidence-based options into the hands of women and **not lost in bureaucracy**.

We are optimizing for access in a fiscally responsible manner.

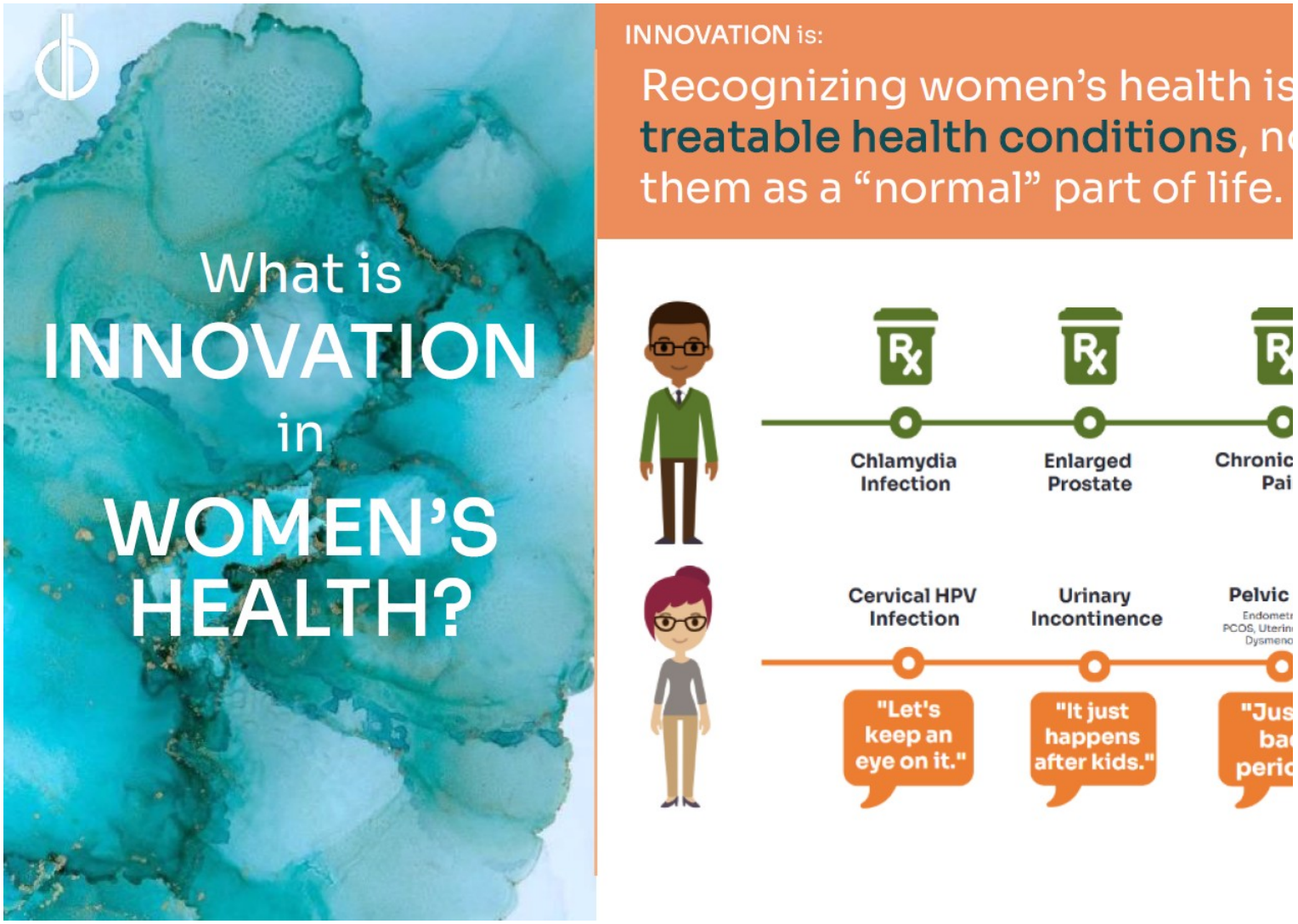
- **Strategic collaborations** can enhance our capabilities and expand our impact, helping to bring new solutions to market.

INNOVATION is:

Listening to doctors and v when they talk about what

The Status Quo	What
• Research into women's sexual health has been largely **overlooked for decades**.	• Since 20 onboard women's have rep **arousal.**
• The last published large cross-sectional surveys on female sexual dysfunction in the U.S., estimating prevalence of ~40-50%, were conducted **10-20 years ago**.[1]	• Sexual h highly m solution patients

1. Giraldi, et al. Female sexual arousal disorders. J Sex Med 2013;10(1):58-73. Shifren, et al States women: prevalence and correlates. Obstet Gynecol 2008;112(5):970-8. Addis, et a aged and older women. Obstet Gynecol 2006;107(4):755-64. Lindau, et al. A study of sex the United States. N Engl J Med 2007; 357(8):762-74.
2. Analysis provided by Rosy Wellness, March 2025


What is
INNOVATION
in
WOMEN'S
HEALTH?
INNOVATION is:
Recognizing women's health is
treatable health conditions, n
them as a "normal" part of life.
Chlamydia Infection
Enlarged Prostate
Chronic
Pai
Cervical HPV Infection
Urinary Incontinence
Pelvic
"Let's keep an eye on it."
"It just happens after kids."
"Jus
ba
perio

INNOVATION is:

Leveraging the learnings from therapeutics to accelerate our market.

We deploy established active pharmaceutical ingredi
first-in-category candidates.

API	Original FDA Approval		Daré
Sildenafil	Erectile dysfunction (oral)	→	Topical t arc
Tamoxifen	Breast cancer (oral)	→	Hormone sexua
Lopinavir	HIV (oral)	→	Vaginal HP

Our Track Record: 8 clinical trials with six assets in the including a Phase 3 trial that led to

Ovaprene PCT Study	Sild. Cream, 3.6%, Ph1	DARE-BVFREE, Ph3 XACIATO™	DARE-HRT1 Ph1	DARE-VVA1 Ph1/2	DA HI Ph
2019	2019	2020	2021	2022	20

We seek to challenge the status quo*

DARE TO PLAY: The First Sildenafil for Female Arousal

Despite significant advances in men's sexual health, there are no FDA-approved options for women v
Our **innovative proprietary cream** with the same active ingredient as an erectile dysfunction drug fo
long-overdue solution to bring equity and attention to an overlooked aspect of women's health.

DARE TO PLAN: The First Monthly Hormone-Free Vaginal Contraceptive

The most common non-hormonal option used by women today is the copper IUD, which can cause s
periods. **Daré's investigational contraceptive Ovaprene®** seeks to offers a hormone-free, self-contr
to insert and remove, **empowering women** without the pain and side effects.

DARE TO THRIVE: Products to Shift the Menopause Treatment Landscape

Gaps in solutions for menopause symptoms have given rise to an explosion of untested supplement
believe that developing new **FDA-approved** therapies that meet the needs of women and their docto
rigorously studied, safe and effective hormonal and non-hormonal treatment options.

DARE TO FIGHT: A Revolutionary HPV Treatment

Persistent HPV infections can progress to cervical precancers, often requiring surgery that increases
birth. **Daré's investigational antiviral vaginal capsules** could offer a proactive solution by treating H
surgery, stopping the spread, and transforming care for this critical health issue.

DARE TO SUPPORT: Relief for Women Undergoing IVF

A progesterone intravaginal ring, replaced every 3-7 days, could reduce or eliminate the need for pai
during IVF—**a potential game-changer for women** enduring this grueling process.

*This presentation references investigational products that have not been approved by the FDA or any comparable foreign regulatory agency for us
No representation is made as to the safety or effectiveness of these investigational products for the respective uses for which they are being studie

When fighting stigma becomes a multi-billion dolla

Before Viagra® (sildenafil citrate tablets), **erectile dysfunction (ED)** was 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 pe
billion in 2012
widely recogn
physiological

1998

Los A

BUSINESS

Number of V
Sets La

April 21, 1998 12 AM PT

1. https://qz.com/quartzy/1238783/its

However, there are still no FDA-approved treatments for female sex disorder (FSAD).

Sildenafil Cream, 3.6% is an investigational topical formulation of the ingredient in a common ED drug for the treatment of FSAD.

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

Fighting the Stigma Around 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]

1. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC. 2. Based on US Census projections for 2016.
3. Feldman, et al. J. Urol.1994 Jan, 151(1):54-61. Available at: https://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/endocrinology/erectile-dysfunction/. The study also found that the combined prevalence of minimal, moderate, and complete impotence was 52%.

The prevalence of FSAD and ED are similar.

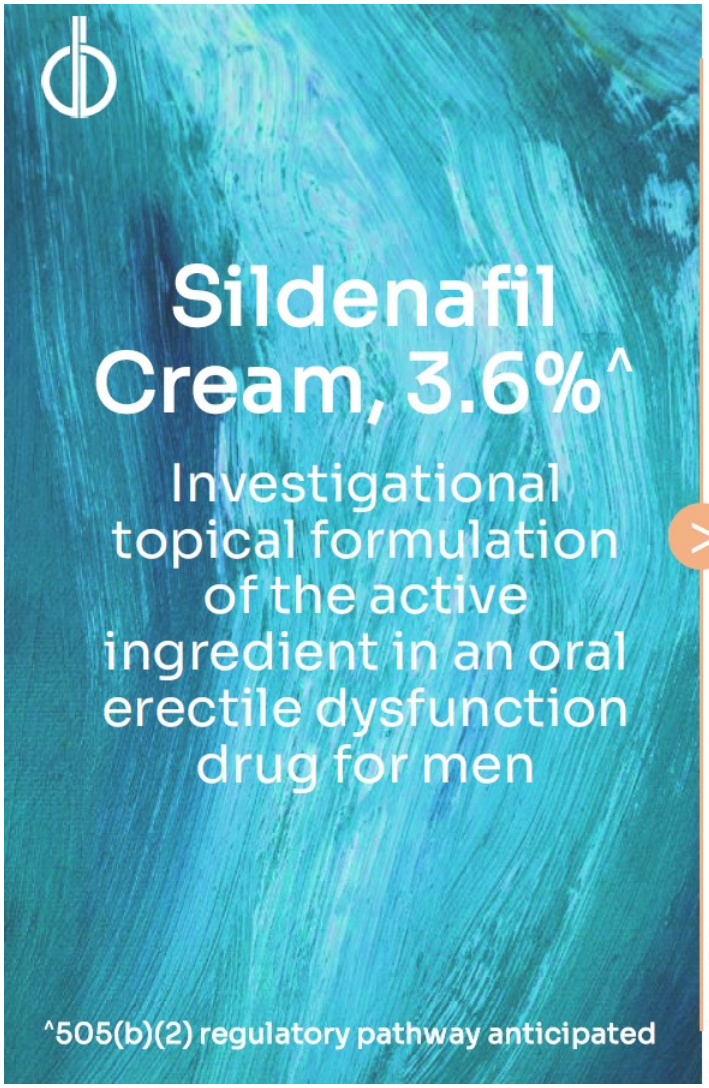
Sildenafil Cream

Targeting availability of our proprietary formulation in the 4th quarter 2025

- We believe women should not have to wait for needed medical treatment solutions. We are taking a **availability** of this proprietary formulation for healthcare providers and women by making it availabl fulfillment through a 503B-registered outsourcing facility partner.
- In parallel, we will continue to pursue FDA approval as a treatment for FSAD.
- There are no FDA-approved treatments for FSAD. Daré is breaking new ground and defining the clini new indication takes time. Our **dual path approach** will enable women to access a solution that is ba

Scientific & Regulatory Standards	
Toxicology studies	*Animal studies to evaluate product exposure and safety, including on reproductive organs and potential exposure routes (e.g. oral, vaginal, anal)*
Pharmacokinetic (PK) studies	*Blood levels of the drug in men and women*
Pharmacodynamic (PD) studies	*Evaluation of the product impact on genital blood flow and temperature to determine time to effect*
Placebo-controlled clinical study in women	*Randomized, placebo-controlled study designed with FDA input to ensure assessment of the product's effect; real science, not just marketing**
Good Manufacturing Practices (GMP)	*Produced in an 503B-registered facility that follows GMP standards for pharmaceutical products and is subject to FDA inspection*
Developed by a women's health pharmaceutical company	*Not a marketing brand*
>$20 million invested into research	*On this specific formulation to date*

* See slides 27-30 for information about the placebo-controlled clinical study of Sildenafil Cream.



Daré's Potential First-in-Category Treatme Sexual Arousal Disorder (FSAD)

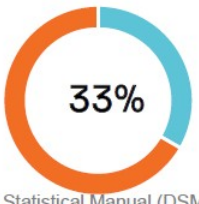
Female Sexual Arousal Disorder

FSAD is characterized primarily by inability t sufficient genital arousal during sexual activ

FSAD should be distinguished from other se characterized in the DSM, such as orgasmic and hypoactive sexual desire disorder (HSD characterized as lack or absence of sexual fa sexual activity for some period of time.[2,3]

FSAD Market Analysis

Meta-analysis of 95 studies from 2000-2014 inc female sexual dysfunction in premenopausal wo and difficulty with arousal alone is 23%.[4]



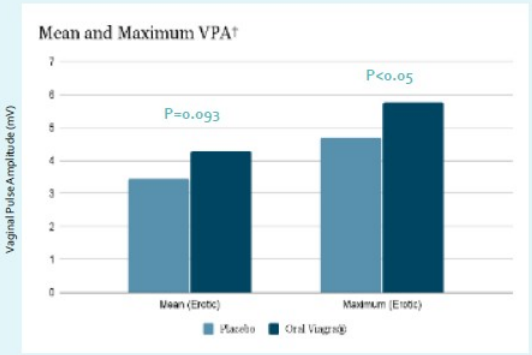
of U.S. women aged 21 to 60 (~**20 million women**), experience symptoms of low or no sexual arousal.[5,6]

1. Diagnostic and Statistical Manual (DSM) 4th Edition Text Revision (DSM IV TR) defines FSAD or to maintain until completion of the sexual activity, an adequate lubrication-swelling response of also state that the inability causes marked distress or interpersonal difficulty, is not better account another sexual dysfunction) and is not due exclusively to the direct physiological effects of a subs a general medical condition. 2. https://labs.la.utexas.edu/mestonlab/female-sexual-interestarousa 3. https://my.clevelandclinic.org/health/diseases/24640-anorgasmia, accessed 6 May 2024 4. M 197-212. DOI: 10.1016/j.sxmr.2016.03.002 5. Ad Hoc Market Research: FSAD Prevalence Repo 6. Based on US Census projections for 2016.

Oral Sildenafil provided a compelling proof of conc

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

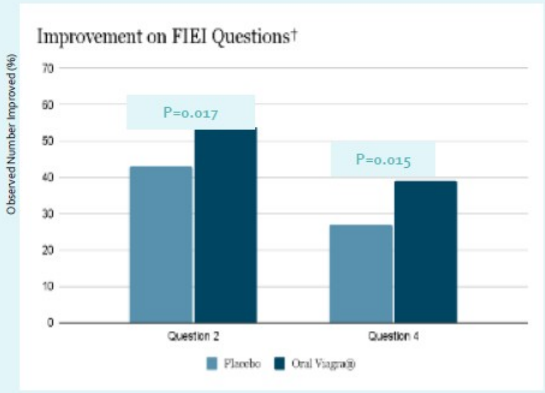
***Pfizer** VPA Clinical Lab Study – Oral Viagra*



† Twelve healthy premenopausal women were studied.

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

***Pfizer** Clinical Field Study – Oral Viagra*



† Question #2 – "After
sensation/feeling in my
area during intercours
seemed to be: (a) mor
before, or (c) unchanged

Question #4 – "After t
intercourse and/or for
satisfying; better thar
medication, (b) unpleas
study medication, (c) un
pleasant; but still not lik
to be."

202 postmenopausal w
protocol specified estr
concentrations, and/or
and/or androgen replace

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 inclu 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
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, Decem

Path Forward for Sildenafil Cream for Treatment of FSA

Exploratory Phase 2b Clinical Study [1]

- 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.
- Among the ITT population, which included women with only FSAD as well as those with FSAD and concomitant sexual dysfunction diagnoses or genital pain, though the Sildenafil Cream group demonstrated greater improvement in the Sexual Function Questionnaire (SFQ28) Arousal Sensation (AS) Domain scores, there were no statistically significant differences between Sildenafil Cream and placebo cream users in the co-primary and secondary efficacy endpoints.
- 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.

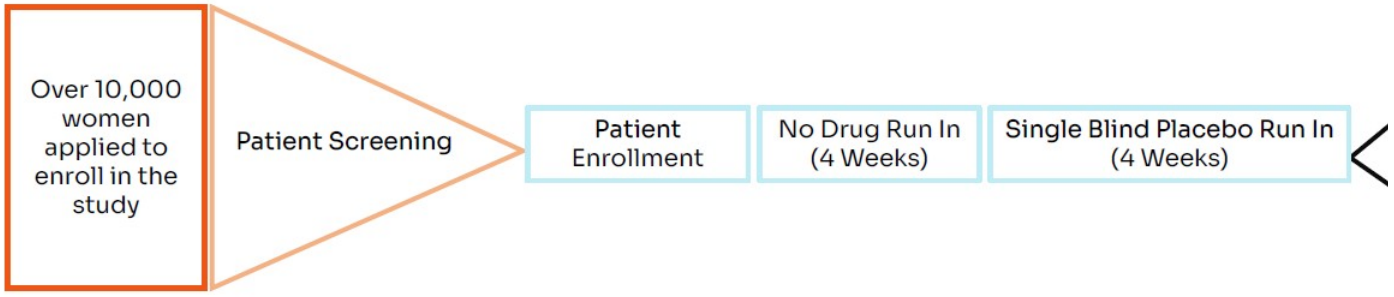
Clinical Developme

- Sildenafil Cream has potential to be **a first-in- significant commercial opportunity** as there approved treatments for FSAD.
- Daré intends to leverage existing safety data f FDA's 505(b)(2) pathway to obtain marketing Cream in the U.S.
- **Phase 3 Development Plans**
  - Two successful Phase 3 trials will be requir Application (NDA) submission for the trea
  - Phase 3 study protocol and statistical anal FDA pending review of additional feedbac
    - *Patients with FSAD with or without con*
    - *12-week double-blind treatment perio Cream compared to placebo cream*
    - *Co-primary efficacy endpoints and sec endpoints evaluated in the Phase 2b RE*
- Discussions with FDA regarding Phase 3 endp ongoing. We cannot at this time reasonably p commence.

1. The preliminary efficacy and safety results of the Phase 2b study were published in 2024 in Obstetrics & Gynecology and The Journal of Sexual Medicine. See slide 32

Overview of Phase 2b Study evaluating Sildenafil Cream i

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



Co-Primary Endpoints: Change from baseline (BL) in Sexual Function Questionnaire (SFQ28) Arousal Sensation (AS) Doma 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 S AS domain, FSDS-DAO Question 14, Patient Benefit Evaluation (PBE), and what constitutes meaningful improvement on the Patie (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 correlati period and the 4-week recall period was evaluated for all patients who completed both the Arousal Diary, the FSDS-DAO, and the same intervals, a subset of patients selected randomly via interactive response technology, who completed the FSDS-DAO and t the Arousal Diary, were evaluated to investigate whether completion of the diary questions influences how the patient answers F SFQ28 AS domain scores. These patients completed the entire study but did not complete the Arousal Diary throughout the stud 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 evaluated.

Sildenafil Cream Phase 2b in FSAD – Exploratory Post-Hoc

- 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**
- 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 FSAD with or without concomitant decrea

Endpoint	Sildenafil Cream 3.6% (N=33)	Pl Cr (N
	LS change (SE) from BL to Week 12	*LS fro BL*
SFQ28 Arousal Sensation Domain*	2.03 (0.62)	0.0
SFQ28 Desire Domain	1.27 (0.76)	-0.
SFQ28 Orgasm Domain	1.12 (0.49)	0.1
FSDS-DAO – Item 3 Guilt	-0.73 (0.16)	-0.
FSDS-DAO – Item 5 Stressed	-0.50 (0.16)	-0.
FSDS-DAO – Item 10 Embarrassed	-0.51 (0.17)	0.0
FSDS-DAO – Item 14 Concerned*‡	-0.27 (0.18)	-0.

LS, least squares; SE, standard error
*Co-primary endpoint.
‡Previously reported as -0.21 (0.16) / -0.22 (0.16) / 0.95. New calculations w data on file. New analysis excludes from the calculation a pre-planned Eva group of patients who provided patient reported outcomes via the 1-mont provide data via the 24-hour recall eDiary. This ERS is excluded from the p AS and FSDS-DAO #14).

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

Sildenafil Cream Phase 2b in FSAD – Summary of Safety R

Sildenafil Cream was well tolerated by exposed users and their sexual p

- During the 12-week double-blind dosing period, there were 78 TEAEs reported by 29 of the 9 Cream-assigned participants and 65 TEAEs reported by 28 of the 94 placebo cream-assigne (p=0.76). **All TEAEs were mild or moderate in severity.**
- The most common treatment-related TEAE among these participants was application site di
- There were **no differences in the number of treatment-related TEAEs among Sildenafil Crea placebo cream users** (p>0.99).
- Four Sildenafil Cream participants and three placebo cream participants discontinued the st TEAEs involving application site discomfort (p>0.99).
- There were 9 TEAEs reported by 7 of 91 sexual partners exposed to Sildenafil Cream versus 4 by 4 of 84 sexual partners exposed to placebo cream (p=0.54).
- For the full data on adverse events, please see the publication:

Thurman, et al. Safety of topical sildenafil cream, 3.6% in a randomized, placebo-controlled treatment of female sexual arousal disorder. J Sex Med. 2024 Sep 3;21(9):793-79

Sildenafil Cream, 3.6% Pharmacokinetic and Pharmacody Studies

Phase 1 and Phase 2a Study Results

Phase 1 Study of SST-6007 (Sildenafil Cream, 3.6%)[1]

Normal healthy postmenopausal women (n=20) 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 well tolerated at clinically relevant doses (1-2g):

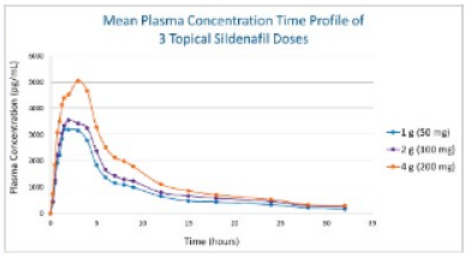
- Favorable product characteristics as self-reported by subjects
- Easy to use
- Readily absorbed

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

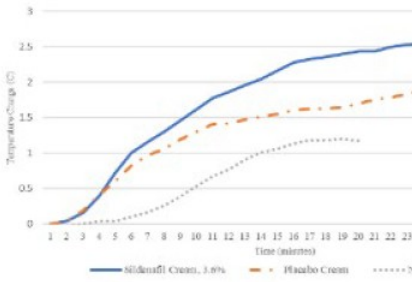


Thermography Study

- Demonstrated **time to effect (11-15 mi**
- Positive cognitive arousal responses v
- Significantly **greater increases in geni** application of Sildenafil Cream compa
- Significantly **greater self-reported arc** Sildenafil Cream visits compared to pl

Statistically significant greater linear slo sexually explicit stimuli as compared to t vestibule.

Figure 1. Clitoral temperature change during the sexually exp



Thermography Study Design & Methodology (M

Phase 1, single-dose, double-blind, placebo-c study evaluating the feasibility of using therm pharmacodynamics of Sildenafil Cream, 3.6% i study required 3 visits and a follow up contact (double-blind dosing) and a phone call (safety

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 surrogat

Notable Publications for Daré's Sildenafil Cream, 3.6

Publication	Author(s)	Title
Sexual Medicine, Volume 12, Issue 5, October 2024	Johnson, et al.	*Impact of age, race, and medication use on efficacy endpoi controlled trial of topical sildenafil cream for the treatment disorder*
Obstetrics & Gynecology. 144(2):p 144-152, August 2024.	Johnson, et al.	*Preliminary Efficacy of Topical Sildenafil Cream for the Trea Arousal Disorder*
The Journal of Sexual Medicine. 2024 Sep 3;21(9):793-799.	Thurman, et al.	*Safety of topical sildenafil cream, 3.6% in a randomized, pla treatment of female sexual arousal disorder*
The Journal of Sexual Medicine. 2024 Jul 26; 21(9): 787-792.	Johnson, et al.	*Comparisons and correlations of 1-month recall vs 24-hou outcomes of an exploratory, phase 2b, randomized, double clinical trial of sildenafil cream, 3.6% for the treatment of fe*
The Journal of Sexual Medicine. 2023 Feb 27; 20(3):277-286	Symonds, et al.	*Symptoms and associated impact in pre- and postmenopa arousal disorder: a concept elicitation study*
The Journal of Sexual Medicine. 2020 Jan; 17(Suppl 1):S69.	Goldstein, et al.	*A Double-blind, Placebo-controlled, 2-Way Crossover Stu Assess the Pharmacodynamics of Sildenafil Cream, 3.6% in*

Huge Gaps Remain in the Contraceptive Landscape

We believe that millions of women have not found the contraceptive option that r

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

18 million[1,2] U.S. women use hormonal contraception

27 million[1,2]

2.5% of all U.S. contraceptive use

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®[3-5]

- 86% - 91% expected typical use **effectiveness**[3]
- 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
*3D, knitted polyme barrier to **physicall block** the passage o sperm*

Spermiostati Environment
*A silicone ring releasin hormone-free ferrou gluconate to chemicall **impede sperm motilit***

Market Data Sources: Harris, E. (2024). JAMA, 332(1), 8. doi:10.1001/jama.2024.10333; Merck & Co, Form 10-K for the year ended December 31, 2019.

Ovaprene Data Sources: 1. Contraceptive Use in the United States by Method, May 2021 Fact Sheet, Guttmacher Institut Contraceptive and Intrauterine Device Use among Reproductive-aged Women in the US from 1999-2017. Cancer Cause 3. See Slide 35 for more details. 4. Del Priore, et al. Journal of Reproductive Medicine 2009; 54: 685-690 5. Mauck, et al

Daré's Potential First-in-Category C Product

- Designed to be an **easy-to-use monthly op effectiveness approaching hormonal meth**
- There are currently no FDA-approved mont contraceptives.

Pivotal Study Collaborator

NIH

- 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.

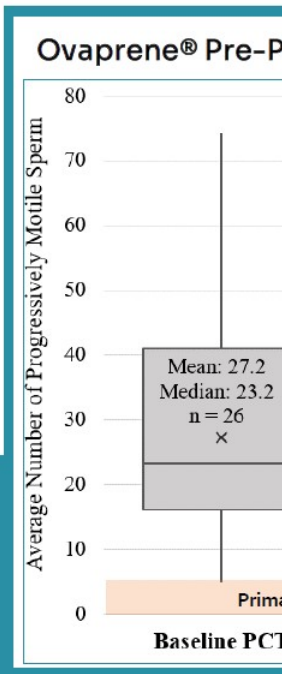
Comme Collabo

- Bayer rece exclusive U commercia **following clinical tri** discretion,
- Daré may r **in commer plus doubl** on net sale

† Minority interest in $20 million payment and royalties on Ovaprene net sales subject to syntheti

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 c PCT assessments later demonstrated "typical use" contraceptive effectiveness of 86-91% in pivot 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 registration study will be sufficient to support a premarket approval** application subm

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 R lead review division.

Pivotal study ongoing

- **Enrollment is ongoing across the five study sites initiated** funding received in November 2024.
- In Q3 2025, the study's DSMB conducted a planned interim analysis and recommended the study continue without **modification. No new safety or** tolerability concerns and no serious safety concerns were **identified. Interim pregnancy** rate of women treated in the study was consistent with our expectations based on the **PCT study of Ovaprene.[3]**

1. Anticipated regulatory pathway and timelines. 2. Clinicaltrials.gov ID: NCT06127199 3. The results of the PCT study and the interim results of the Phase 3 stud necessarily predictive of final results of the Phase 3 study. There is no guarantee of a successful outcome in the Phase 3 study.

Ovaprene® – Commercial License Agreement with

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.*

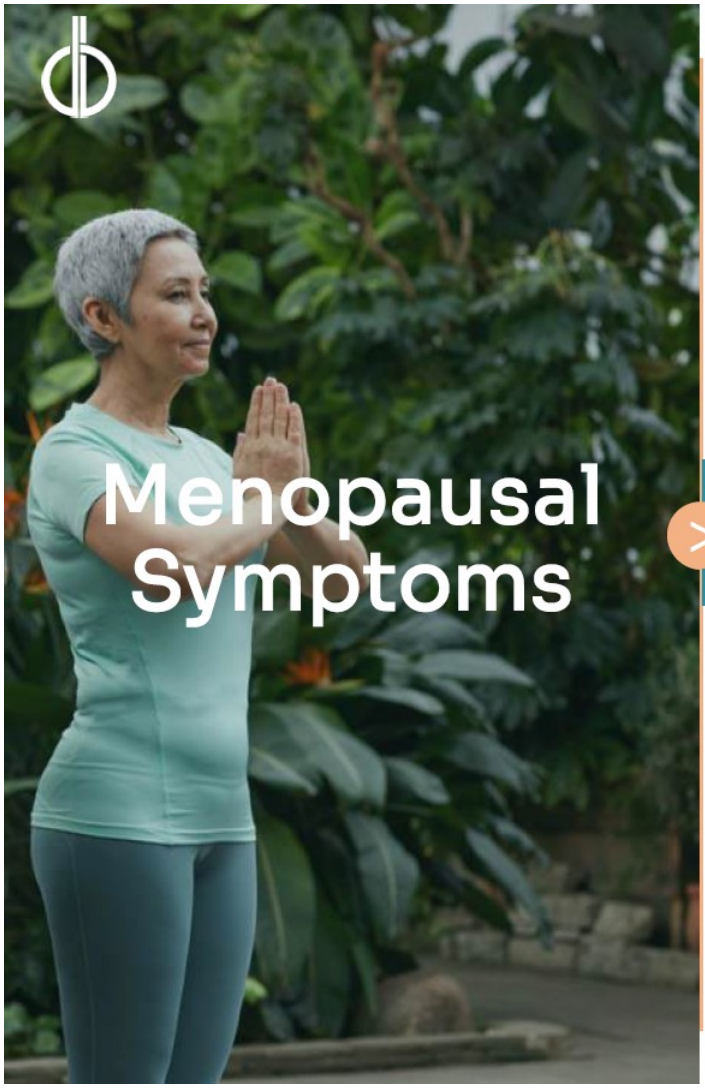
Bayer received the rig
US rights to commerc
following compl
pivotal clinical tr
discretion, pays Daré

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.

Daré may receive up t
commercial mile
plus double-digi
on net sales.[2]

Bayer supports the de
regulatory process by
full-time equivalents (
advisory capacity, whi
their global manufactu
medical and commerc

* 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)



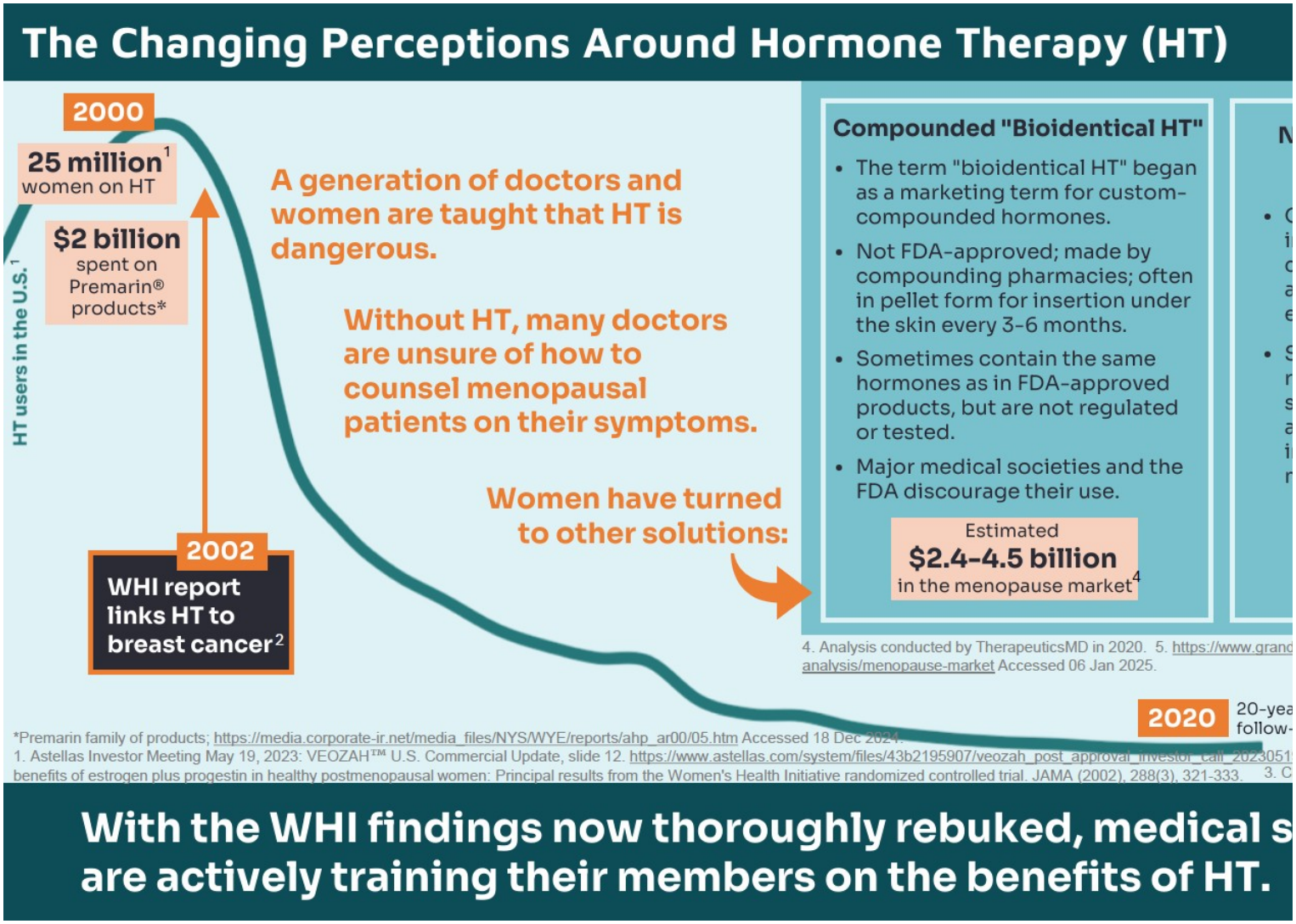
Menopause is Having a Mome

- The menopause market is a large and growing n
  than 1 billion people worldwide expected to be
  2025[1]. Approximately **51% of menopausal wom**
  moderate to severe vasomotor symptoms (VM
- The global market for menopausal products is g
  rate of more than 5%, rising from its 2021 level c
  to reach **$24.4 billion by 2030.**[1]

With the rise of digital support platforn
clinics, **menopausal women are looki**

However, in a landscape with **limited F**
treatment options, they are turni
burgeoning industry of compounde
supplements, and natural remedies – r
are evaluated by the FDA for safety a

1. https://www.washingtonpost.com/opinions/2022/04/28/menopause-hormone-ther
2. Astellas Investor Meeting Dec 14, 2017, slide 21. https://www.astellas.com/system/file

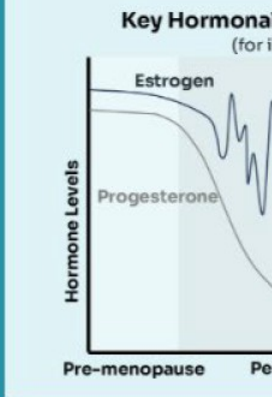

The Changing Perceptions Around Hormone Therapy (HT)
2000
25 million[1] women on HT
$2 billion spent on Premarin® products*
HT users in the U.S.[1]
A generation of doctors and women are taught that HT is dangerous.
Without HT, many doctors are unsure of how to counsel menopausal patients on their symptoms.
Women have turned to other solutions:
2002
WHI report links HT to breast cancer[2]
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]
4. Analysis conducted by TherapeuticsMD in 2020. 5. https://www.grand
analysis/menopause-market Accessed 06 Jan 2025.
2020
20-yea
follow-
*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_2023051
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. C
With the WHI findings now thoroughly rebuked, medical s
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 o hormones, there is interest in nc especially with **breast cancer s**

Tamoxifen is commonly prescribed treatment of hormone receptor positive blocks estrogen activity in breast tissue shown an inverse effect in vaginal tissue **estrogen-like effects on vag** could counter the physiological change genitourinary syndrome of menopause

3. Cleveland Clinic: Tamoxifen. https://my.clevelandclinic.o
4. Thurman, et al. Climacteric Volume 26, 2023 - Issue 5

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.

Hormone-Free Product Ca

DARE-VVA1 Vaginal Inserts Intercourse Associated v

Phase 1 / 2 study completed; Activities to support Phase 2 st

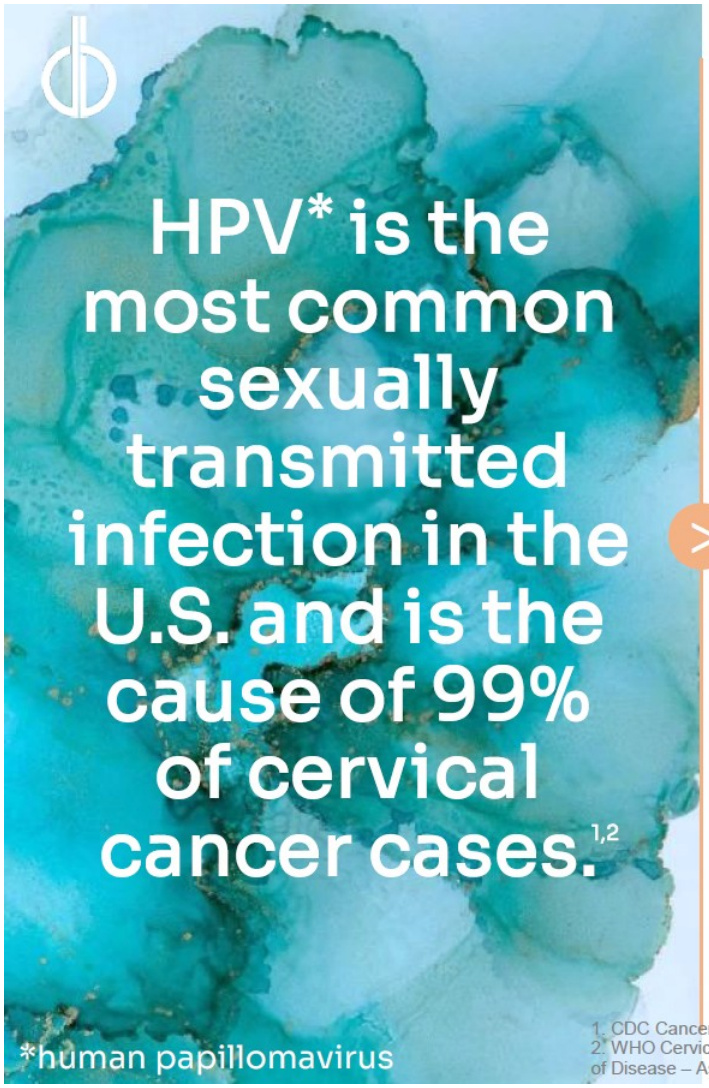
For women who cannot or choose not t there is interest in non-hormonal prod targeting to the **breast cancer populat**

Bayer and Astellas are pursuing appro hormonal VMS products specifically in populations.

Tamoxifen is commonly prescribed by treatment of hormone receptor positiv cancer, as it blocks estrogen activity in However, studies have shown an invers tissue where it **has demonstrated estr vaginal epithelium which could count changes that lead to GSM.**

- The Ph1/2 study demonstrated tole as well as improvement in vaginal c bothersome vaginal symptoms ass

1. Thurman, et al. Menopause 30(8):p 817-823, August 2023.
2. Cleveland Clinic: Tamoxifen. https://my.clevelandclinic.org/
3. 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 vaccinat
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Today, HPV infections are not treated upon diagnosis.

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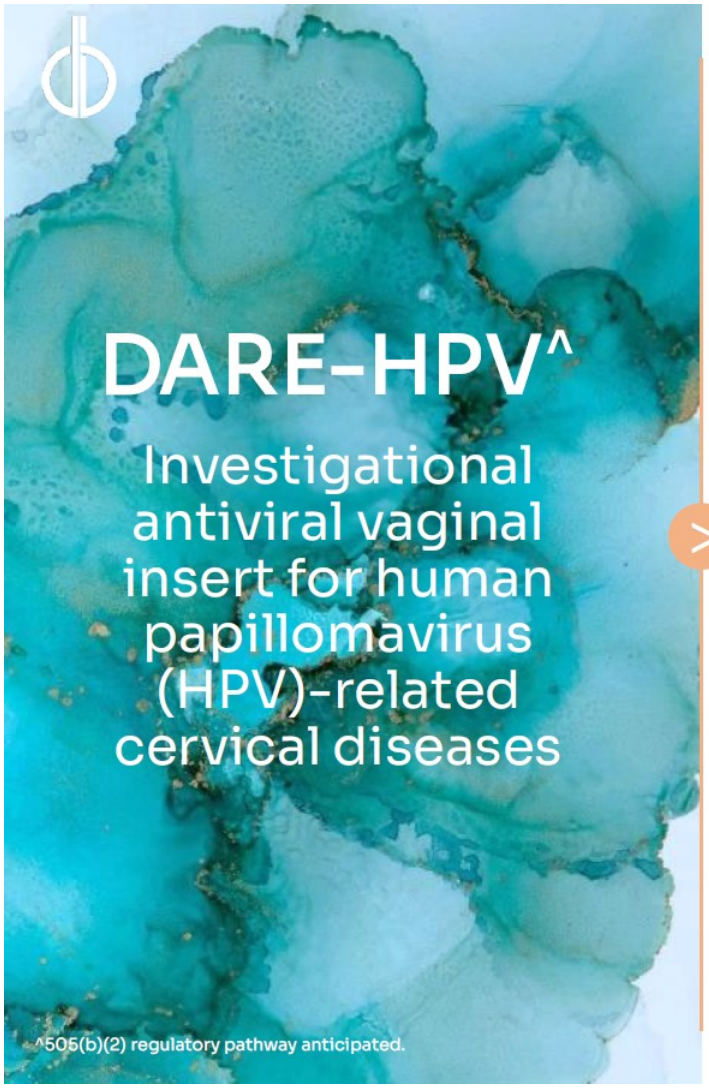
This surgery is associated with an **increased risk of preterm birth** and sexual dysfunction and therefore is **not recommended for patients with fertility concerns.**

1. CDC Cancer Statistics: Cancers Associated with Human Papillomavirus. https://www.cdc.gov/vaccine-safety/vacci
2. WHO Cervical Cancer. https://www.who.int/health-topics/cervical-cancer. Accessed 18 Dec 2024. 3. Lewis, et al
of Disease – Associated Human Papillomavirus Types Among 15-59-Year-Olds in the United States. Sex Trans Dis.



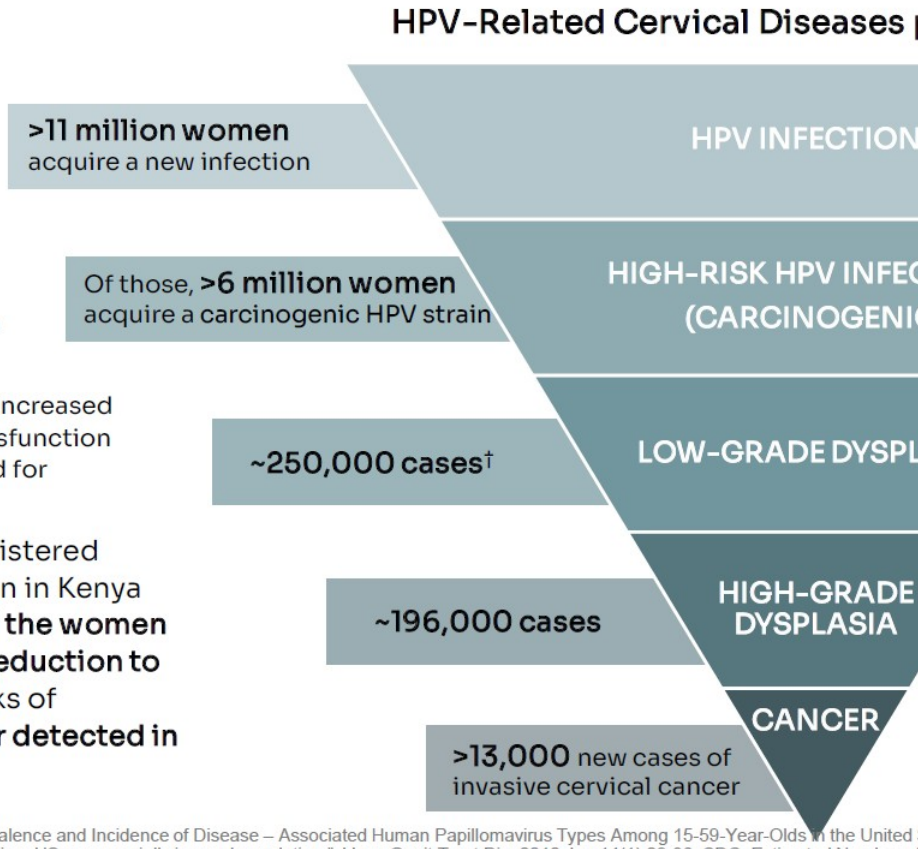
- There are currently **no FDA-approved surgical pharmaceutical interventio HPV-related cervical dysplasia.**
- There are **no FDA-approved treatme infection.**

- DARE-HPV is a proprietary fixed-dos formulation of lopinavir and ritonavi soft gel vaginal insert.
- Phase 1 and proof-of-concept studie have been completed.
- Activities to support U.S. IND filing t enable progression to Phase 2 clinic development underway supported b two-year **non-dilutive funding awar**

1. Lopinavir and ritonavir are the active pharmac FDA-approved drug Kaletra® for the treatmer

Safe and Effective HPV Treatments Remain an Unm

- 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]



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
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
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
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-Re
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

Daré's first product: FDA-approved in from in-license

In **less than five years**, Daré:

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

Commercialization Collaborator

- **$12.8 million in payments received through 20 license agreement**
- License agreement provides for **tiered double** potential milestone payments from Organon o **million.**†
- **$27 million raised in royalty financings**; eligibl sharing milestone payments from XOMA†

*See Full Prescribing Information for the safe and effective use of XACIATO. See XACIAT

†100% of royalties and commercial milestone payments based on XACIATO net sales are with XOMA (April 2024) and a royalty interest financing agreement (Dec 2023). Upon ach XOMA will make upside-sharing milestone payments to Daré representing 50% of the fu payable to XOMA.

XACIATO Selected Safety Information

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

Our Therapeutics Portfolio*

Our investigational products seeking FDA approval are some of the most pote
therapeutic candidates for women in decades, targeting unmet needs with inr

ASSET		ADDRESSABLE MARKET (millions of U.S. women)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL
Ovaprene®	Monthly **hormone-free contraceptive**	27				Pivotal Phase
Sildenafil Cream, 3.6% ^	Topical cream for **female sexual arousal disorder**	20				Phase 3 study prepara
DARE-HRT1^	Monthly hormone therapy for **menopause symptoms**[1]	45				U.S. IND and Phase 3 stu
DARE-VVA1^	Hormone-free treatment for **sexual pain associated with menopause**	25			U.S. IND cleared; Phase 2 study prepara	
DARE-HPV^ *$10M non-dilutive funding award*	HPV therapy to **prevent cervical cancer**	6† (annually)			Phase 1 and proof of concept studies c	

^505(b)(2) regulatory pathway anticipated.
* We are developing these assets with the intent to seek marketing approval from the FDA.
† Addressable market reflects potential treatment of all cases of high-risk HPV infections in the U.S. See slide 44 for more details.

Timelines represent anticipated tim
1. Target indication is the treatment
menopause in women with intact ut

Earlier stage programs with grant funding enhance the pipel

ASSET			ADDRESSABLE MARKET	PRE-CLINICAL	PHASE 1
Australia R&D Cash Rebate	DARE-PDM1^	Vaginal diclofenac once-daily thermosetting hydrogel for pelvic pain	50% menstruating women experience dysmenorrhea		Ph U.S
Theramex	Casea S^	18-24 month biodegradable contraceptive implant	12 million women		Phase 1 Stu
NIH National Institutes of Health	DARE-FRT1/PTB1^	Bio-identical progesterone in an intravaginal ring for preterm birth (DARE-PTB1) and for luteal phase support as part of an IVF regimen (DARE-FRT1)	1 in 10 births		U.S. IND and Phase 1
NIH National Institutes of Health	DARE 204/214^	6 & 12-month injectable etonogestrel contraceptive	12 million women		Phase 1 Study Prepa
NIH National Institutes of Health *Foundation grant up to ~$49M*	DARE-LARC1^	Long-acting, reversible personal contraceptive system	17 million women		Pre-IND Activities
UNIVERSITY OF COPENHAGEN	DARE-RH1	Male or female contraceptive target	27 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.
* We are developing these assets with the intent to seek marketing approval from the FDA.

† The Phase 1 study is being conducted by FHI 360 with support fror currently developing this asset, but may exercise rights to do so in t development and license agreement with Theramex.

darébio