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Drug, and Cosmetic Act (503B) and for launching branded consumer health products; expected timing of revenue from sales of those products; market opportunity for those products and their ability to gain market acceptance; plans and expectations with respect to Daré's product candidates, including intent to continue to pursue an FDA approval pathway for those product candidates it brings to market as compounded drugs under 503B, clinical development plans, trial design, timelines, costs, milestones, targeted indications, clinical trials and results, regulatory strategy, and FDA communications, submissions and review of applications; the clinical potential of and market opportunities for Daré's product candidates; potential strategic partnerships and third-party collaborations; expectations regarding existing collaborations, including potential payments; potential pipeline expansion; the amount and timing of Daré's receipt of funds under grant agreements and other funding awards; 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 for which it is being developed because Daré believes it would address a need in women's health that is not being met by existing FDA-approved products. 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### 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's health1

Yet 27% of all blockbuster drug products are women's health drugs<sup>2</sup>

Women control 80% of U.S. healthcare purchasing decisions.<sup>3</sup>

<sup>1.</sup> GlobalData Drugs Database and McKinsey & Company

<sup>2.</sup> IQVIA Monthly Global MIDAS \$ Const-Exchng (MNF) 2013 – 2022

<sup>3.</sup> McKinsey & Company, February 14, 2022, Unlocking Opportunities in Women's Healthcare



### **Near-Term Commercial Path**

#### **ASSET / TARGET AVAILABILITY UNMET NEED MARKET INSIGHT** Q4 2025 A 2024 analyst report on HIMS estimated There are no FDA-approved treatments the erectile dysfunction market Designed for her Sildenafil for a problem likely as common as sexual opportunity to be Cream (Rx<sup>^</sup>) erectile dysfunction - except that it's in experience women.1 \$11 billion<sup>2</sup> Post DARE to PLAY Feminine care companies such as The Vaginal health awareness is growing -Designed to Vaginal Honey Pot Company and Bonafide Health mentions of the microbiome increased by probiotic maintain a have capitalized on this trend and achieved 54% in Reddit women's health suppositories healthy vaginal successful exits in 2024 and 2023 (non-Rx) microbiome communities from 1H 2023 to 1H 2024.3 respectively.4,5 Late 2026 An analysis conducted by TXMD in 2020 Monthly Designed to Gaps in solutions for menopause estimated the U.S. compounded estradio1+ support her symptoms have given rise to an explosion progesterone hormone therapy market to be through vaginal ring of untested supplements and therapies. menopause \$2.5-4.5 billion<sup>6</sup> $(Rx^{\prime})$

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) consumer health & sexual wellness portfolio includes anti-itch/soothing creams, suppositories, lubricants, & other intimacy products, & represented 8% of gross sales in FY2024. THPC's net sales for FY2024 were ~\$115.3M. CODI purchased a controlling interest THPC in Jan 2024 for ~\$380 million. 5. Bonafide's portfolio includes Clairvee® vaginal probiotic dietary supplements. Pharmavite LLC announced its acquisition of Bonafide Health for \$425M in Nov 2023.

6. TD Cowen Therapeutic Categories Outlook, February 2024. Women's Health.

<sup>^</sup>Proprietary formulations expected to be made available for prescription fulfillment via a 503B-registered outsourcing facility partner.



### 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.<sup>1, 2</sup>
- 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<sup>3</sup>



<sup>\*</sup>DARE to PLAY is a compounded drug. It is not FDA approved.

Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.

Based on US Census projections for 2016.

<sup>3.</sup> See slides 25-32.



### Key Data: DARE to PLAY™ Sildenafil Cream

PK study demonstrated minimal systemic exposure: (1–2% C<sub>max</sub> of oral sildenafil). <sup>1</sup>

Phase 2b study demonstrated **statistically significant arousal improvement in the target Phase 3 population** (post-hoc analysis).<sup>2</sup>

Sildenafil Cream was **well tolerated by exposed users and their sexual partners** in the Phase 2b study. There were no differences in the number of treatment-related TEAEs among Sildenafil Cream versus placebo cream users (p>0.99). <sup>2</sup>



### 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. <sup>2,3</sup>



<sup>2. &</sup>lt;a href="https://ir.darebioscience.com/news-releases/ne



### Menopause Franchise

The global market for menopausal products is expected to reach >\$24 billion by 2030.1

#### 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 intravaginal ring

We are pursuing a dual path approach:

Targeting prescription launch in late 2026 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 the vasomotor symptoms of menopause (VMS)



### **DARE-HPV**

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

- A proprietary fixed-dose formulation of lopinavir and ritonavir 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.<sup>2</sup>
- Up to \$10 million non-dilutive funding award to support U.S. IND filing and enable progression to Phase 2 clinical development

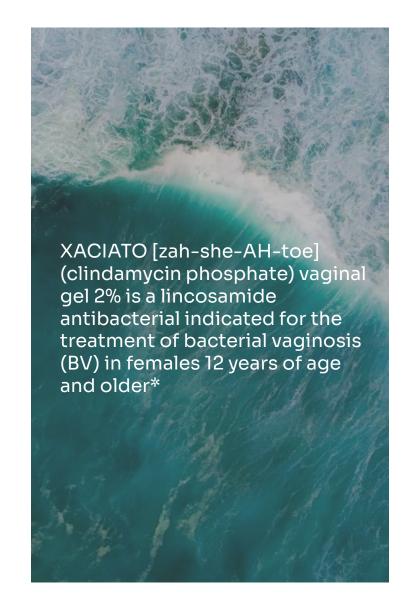




### FDA Approved Product: XACIATO™

(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<sup>†</sup>
- Demonstrates validation of partnership-driven commercialization strategy where appropriate



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



### Pipeline Overview

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

Large addressable U.S. and global markets



Designed for her sexual experience





Designed for her contraception needs





Designed to help her keep living her best life





Designed to treat vaginal infections





Designed to maintain a healthy vaginal microbiome





Designed to support her pregnancy





### Strategic Collaborations & Non-Dilutive Funding

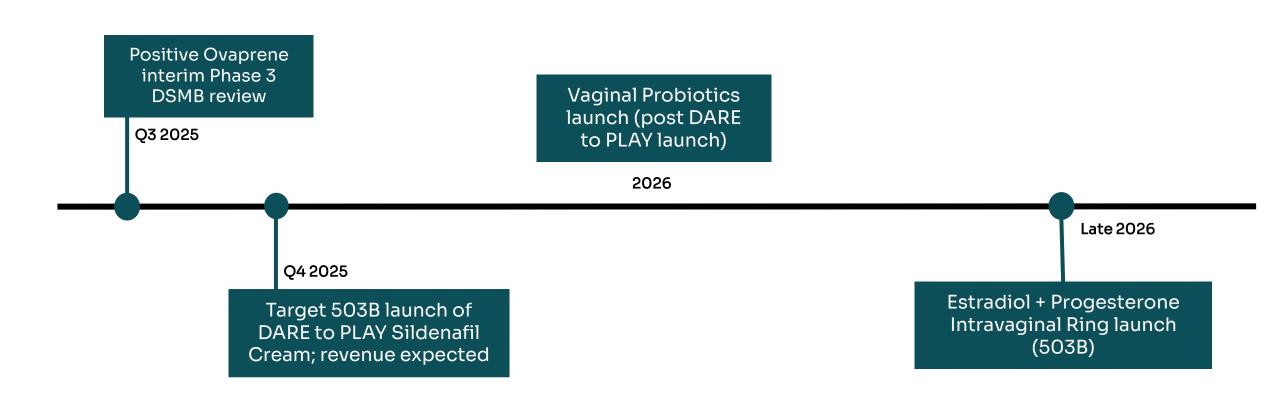
Organon - XACIATO™ commercialization

Bayer - Ovaprene™ commercialization

NIH, ARPA-H, Foundation grants and other awards across several portfolio programs >\$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-efficient, partnership-driven model





### Cutting through the noise

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

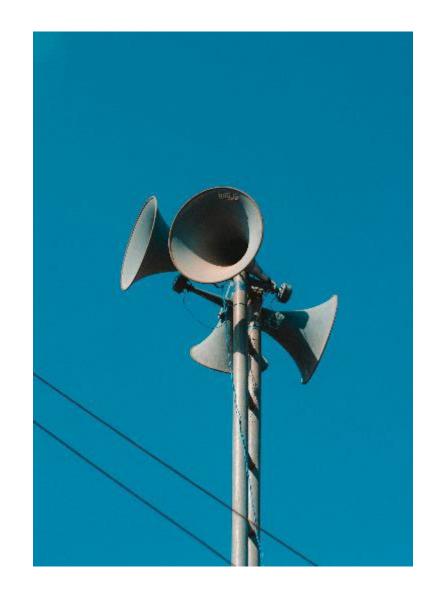
• We believe innovation does not have to start from scratch. Our core strategy is to **start with the unmet needs**, then identify and acquire the rights to differentiated evidence-based solutions in those areas of need.

# 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.





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

### The Status Quo



### What We've Heard

- Research into women's sexual health has been largely overlooked for decades.
- 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.<sup>1</sup>
- Since 2022, 64% of women onboarding with the women's health app Rosy have reported low sexual arousal.
- Sexual health clinicians highly motivated to find a solution to offer their patients that they can trust.



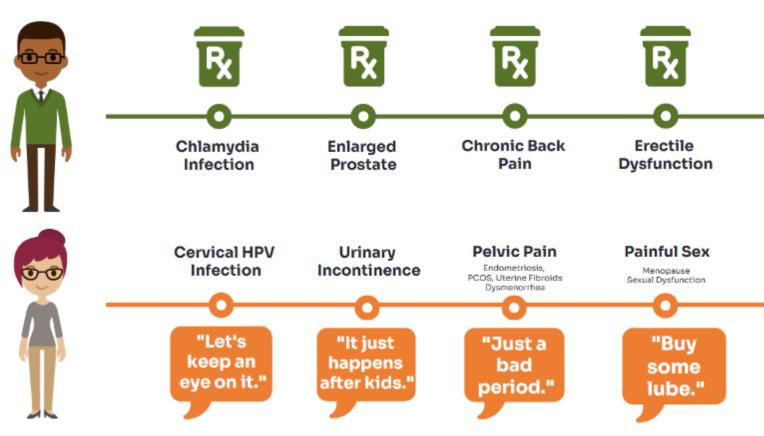
1. Giraldi, et al. Female sexual arousal disorders. J Sex Med 2013;10(1):58-73. Shifren, et al. Sexual problems and distress in United States women: prevalence and correlates. Obstet Gynecol 2008;112(5):970-8. Addis, et al. Sexual activity and function in middle-aged and older women. Obstet Gynecol 2006;107(4):755-64. Lindau, et al. A study of sexuality and health among older adults in the United States. N Engl J Med 2007; 357(8):762-74.

2. Analysis provided by Rosy Wellness, March 2025



**INNOVATION** is:

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





#### **INNOVATION** is:

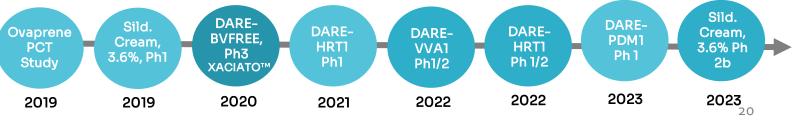
Leveraging the learnings from existing therapeutics to accelerate our path to market.

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

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

Our Track Record:

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





### 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 with sexual arousal issues. Our **innovative proprietary cream** with the same active ingredient as an erectile dysfunction drug for men seeks to provide a 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 severe cramping and heavy periods. **Daré's investigational contraceptive Ovaprene®** seeks to offers a hormone-free, self-controlled alternative that's easy 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 supplements and therapies. We believe that developing new **FDA-approved** therapies that meet the needs of women and their doctors can shift the focus to **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 the risk of preterm birth. **Daré's investigational antiviral vaginal capsules** could offer a proactive solution by treating HPV early, preventing 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 painful daily injections during IVF—a potential game-changer for women enduring this grueling process.

### When fighting stigma becomes a multi-billion dollar industry

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 peaked at \$2.05 billion in 2012<sup>1</sup> and ED is now widely recognized as a physiological medical condition.



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

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

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

### 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%** 

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



5%

**15%** at age 70<sup>3</sup>

of men experience complete ED at age 40, increasing to

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/erectiledysfunction/. The study also found that the combined prevalence of minimal, moderate, and complete impotence was 52%.



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



### Sildenafil Cream

### Targeting availability of our proprietary formulation in the 4<sup>th</sup> quarter 2025

- We believe women should not have to wait for needed medical treatment solutions. We are taking action to accelerate
   availability of this proprietary formulation for healthcare providers and women by making it available for prescription
   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 clinical requirements for a new indication takes time. Our **dual path approach** will enable women to access a solution that is backed by science.

Scier	DARE Sildenafil Cream	
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	Ø
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	Ø
>\$20 million invested into research	On this specific formulation to date	



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

Investigational topical formulation of the active ingredient in an oral erectile dysfunction drug for men

# 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.<sup>1</sup>

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.<sup>2,3</sup>

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%.<sup>4</sup>



6. Based on US Census projections for 2016.

of U.S. women aged 21 to 60 (~ **20 million Women**), experience symptoms of low or no sexual arousal.<sup>5,6</sup>

10 million

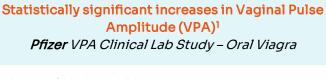
women are considered distressed and actively seeking treatment.<sup>5</sup>

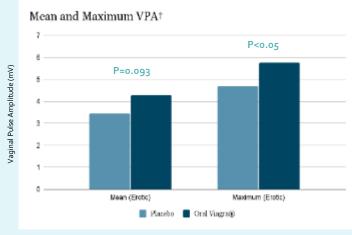
^505(b)(2) regulatory pathway anticipated

<sup>1.</sup> 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: 25 197-212. DOI: 10.1016/i.sxmr.2016.03.002 5. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.



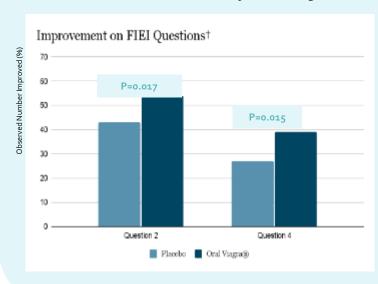
### Oral Sildenafil provided a compelling proof of concept for FSAD





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

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:

† Twelve healthy premenopausal women were studied.

- 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.



### Path Forward for Sildenafil Cream for Treatment of FSAD

#### 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 Development Plan

- 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.
- Phase 3 Development Plans
  - 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 to the FDA pending review of additional feedback from FDA:
    - 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 and secondary endpoints utilizing endpoints evaluated in the Phase 2b RESPOND study
- Discussions with FDA regarding Phase 3 endpoint assessments are ongoing. We cannot at this time reasonably predict when the study will commence.



### Overview of Phase 2b Study evaluating Sildenafil Cream in FSAD

Phase 2b, Exploratory, Randomized, Placebo-Controlled, Trial of Sildenafil Cream 3.6% for the Treatment of Female Sexual Arousal Disorder in Healthy Premenopausal Women (#NCTO4948151) – 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): Els 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 evaluated.



### Sildenafil Cream Phase 2b in FSAD – 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 subpopulations 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 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

<sup>\*</sup>Co-primary endpoint.

<sup>‡</sup>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 Phase 2b in FSAD – Summary of Safety Results

### Sildenafil Cream was well tolerated by exposed users and their sexual partners.

- During the 12-week double-blind dosing period, there were 78 TEAEs reported by 29 of the 99 Sildenafil Cream-assigned participants and 65 TEAEs reported by 28 of the 94 placebo cream-assigned participants (p=0.76). All TEAEs were mild or moderate in severity.
- The most common treatment-related TEAE among these participants was application site discomfort.
- There were no differences in the number of treatment-related TEAEs among Sildenafil Cream versus placebo cream users (p>0.99).
- Four Sildenafil Cream participants and three placebo cream participants discontinued the study due to 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 TEAEs reported 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. <u>Safety of topical sildenafil cream, 3.6% in a randomized, placebo-controlled trial for the</u> <u>treatment of female sexual arousal disorder</u>. J Sex Med. 2024 Sep 3;21(9):793-799.



# Sildenafil Cream, 3.6% Pharmacokinetic and Pharmacodynamic 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):

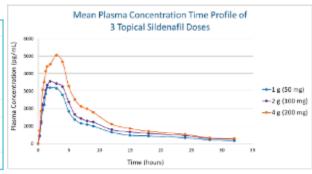
- Favorable product characteristics as self-reported by subjects
- Easy to use
- · Readily absorbed

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

 Demonstrated increased blood flow in the genital tissue compared to placebo (mean change in VPA analysis) in 31 women (pre and postmenopausal) ~30 minutes post dosing

#### Phase 1 Study

rilase i study				
	Treatment Level			
Parameter	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	

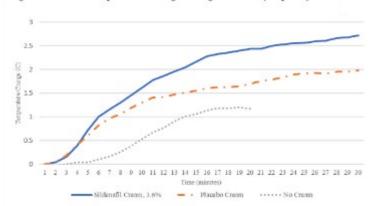


### Thermography Study Results\*

- 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.
- Data on file.

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



# 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 endpoints in a randomized controlled trial of topical sildenafil cream for the treatment of female sexual arousal disorder
Obstetrics & Gynecology. 144(2):p 144-152, August 2024.	Johnson, et al.	Preliminary Efficacy of Topical Sildenafil Cream for the Treatment of Female Sexual 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, placebo-controlled trial for the 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-hour recall in patient-reported outcomes of an exploratory, phase 2b, randomized, double-blind, placebo-controlled clinical trial of sildenafil cream, 3.6% for the treatment of female sexual arousal disorder
The Journal of Sexual Medicine. 2023 Feb 27; 20(3):277–286	Symonds, et al.	Symptoms and associated impact in pre- and postmenopausal women with sexual arousal disorder: a concept elicitation study
The Journal of Sexual Medicine. 2020 Jan; 17(Suppl 1):S69.	Goldstein, et al.	<u>A Double-blind, Placebo-controlled, 2-Way Crossover Study Using Thermography to</u> <u>Assess the Pharmacodynamics of Sildenafil Cream, 3.6% in Healthy Women</u>



### 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
18 million 1.2 U.S. women use hormonal contraception

No method Withdrawal Pills
Condoms 27 million 2.2 U.S. women are potential candidates for Ovaprene®

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



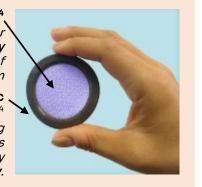
#### Design Features of Ovaprene®3-5

- 86% 91% expected typical use effectiveness<sup>3</sup>
- 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 4
3D, knitted polymer
barrier to physically
block the passage of
sperm

Spermiostatic Environment <sup>4</sup> A silicone ring releasing hormone-free ferrous

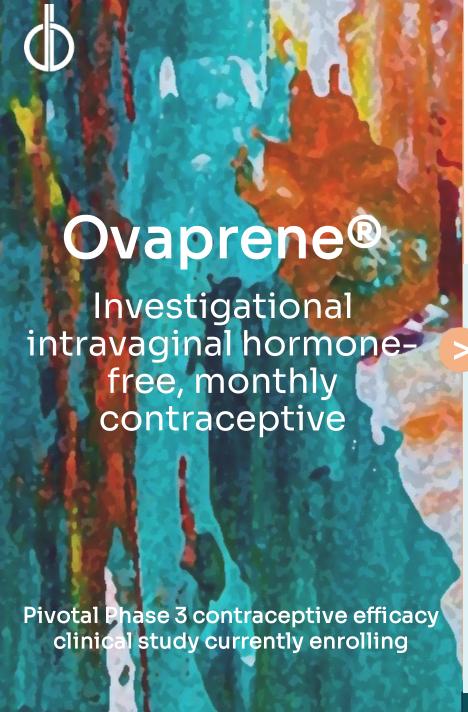
hormone-free ferrous gluconate to chemically impede sperm motility.



Market Data Sources: Harris, E. (2024). JAMA, 332(1), 8. doi:10.1001/jama.2024.10333; 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 Institute. 2. King, et al. Trends in Oral Contraceptive and Intrauterine Device Use among Reproductive-aged Women in the US from 1999-2017. Cancer Causes Control. 2021 Mar 10;32(6):587–595.

3. See Slide 35 for more details. 4. Del Priore, et al. Journal of Reproductive Medicine 2009; 54: 685-690 5. Mauck, et al. Contraception, Vol. 132, April 2024



# 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



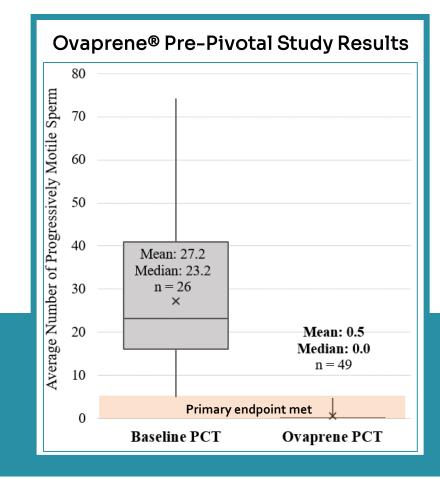
- Bayer received the right to obtain exclusive US rights to commercialize the product, following completion of the pivotal clinical trial if Bayer, in its sole discretion, pays Daré \$20 million<sup>†</sup>
- Daré may receive up to \$310 million in commercial milestone payments, plus double-digit, tiered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



### 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.<sup>1</sup>

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.<sup>2</sup>



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

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<sup>2</sup>

- 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 ongoing

- Enrollment is ongoing across the five study sites initiated in Q1 2025 with grant 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.<sup>3</sup>



ovaprenestudy.com



## 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<sup>1</sup>.



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.

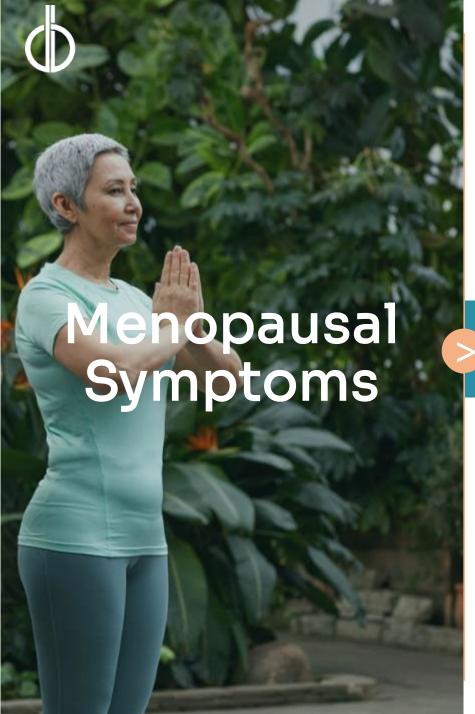
Bayer received the right to obtain exclusive US rights to commercialize the product, following completion of the pivotal clinical trial if Bayer, in its sole discretion, pays Daré \$20 million.<sup>2</sup>

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

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.

<sup>\*</sup> https://www.mirena-us.com/; supported by 2014-2016 SHS data.

<sup>1. &</sup>lt;a href="https://ir.darebioscience.com/news-releases/news-release-details/bayer-and-dare-bioscience-announce-exclusive-licensing-agreement">https://ir.darebioscience.com/news-releases/news-release-details/bayer-and-dare-bioscience-announce-exclusive-licensing-agreement</a>



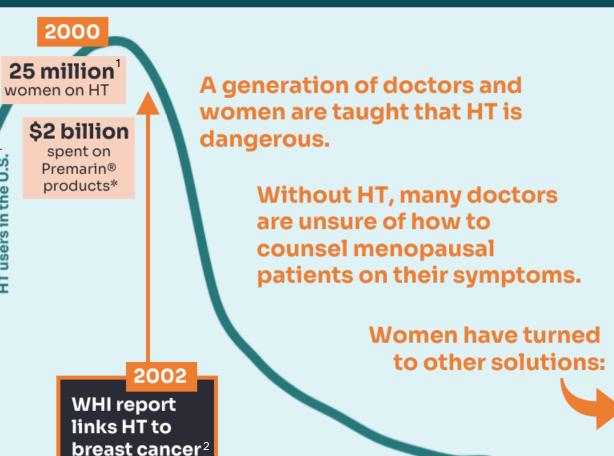
## Menopause is Having a Moment

- The menopause market is a large and growing market, with more than I billion people worldwide expected to be in menopause by 2025<sup>1</sup>. Approximately 51% of menopausal women experience moderate to severe vasomotor symptoms (VMS) or hot flashes.<sup>2</sup>
- 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.

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.

## The Changing Perceptions Around Hormone Therapy (HT)



### Compounded "Bioidentical HT"

- The term "bioidentical HT" began as a marketing term for customcompounded 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

### Non-HT Supplements for Menopause Symptoms

- Often contain herbal ingredients such as black cohosh, evening primrose oil, and ashwagandha root extract
- Supplements are not FDAregulated and can cause serious health problems such as liver toxicity and interactions with other medications.

\$16 billion globally in 2023 5

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

20-year WHI follow-up (JAMA)<sup>3</sup>

\*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<sup>TM</sup> U.S. Commercial Update, slide 12. <a href="https://www.astellas.com/system/files/43b2195907/veozah\_post\_approval\_investor\_caii\_20230519.pdf">https://www.astellas.com/system/files/43b2195907/veozah\_post\_approval\_investor\_caii\_20230519.pdf</a> 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.

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.<sup>1</sup>

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.<sup>2</sup>

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

# Key Hormonal Changes During Menopause (for illustrative purposes only) Estrogen Progesterone Pre-menopause Perimenopause Post-menopause

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. 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



## 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

- 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.<sup>1</sup>
- 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.<sup>1</sup>

#### 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 approvals for 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.<sup>2</sup> 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 tolerability of DARE-VVA1, as well as improvement in vaginal cytology & the bothersome vaginal symptoms associated with GSM.<sup>3</sup>

<sup>^</sup> 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-HRTI and the selected listed estradiol and progesterone drugs.

<sup>1.</sup> Thurman, et al. Menopause 30(8):p 817-823, August 2023.

<sup>2.</sup> Cleveland Clinic: Tamoxifen. https://my.clevelandclinic.org/health/treatments/9785-tamoxifen.41

<sup>3.</sup> Thurman, et al. Climacteric Volume 26, 2023 - Issue 5

# HPV\* is the most common sexually transmitted infection in the U.S. and is the cause of 99% of cervical cancer cases.1,2

## >6 million women

are diagnosed each year with high-risk HPV infections that could lead to cervical cancer.<sup>3</sup>

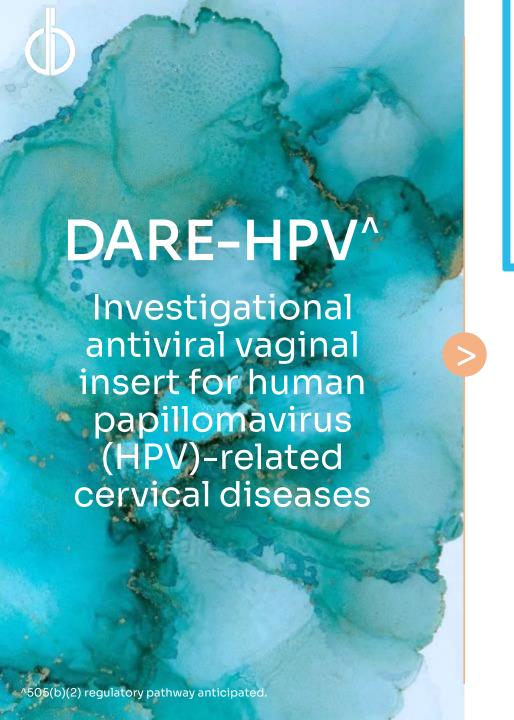
While vaccinations and screenings are important tools, safe and effective HPV treatments remain an unmet need.

Today, HPV infections are not treated upon diagnosis.

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

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.



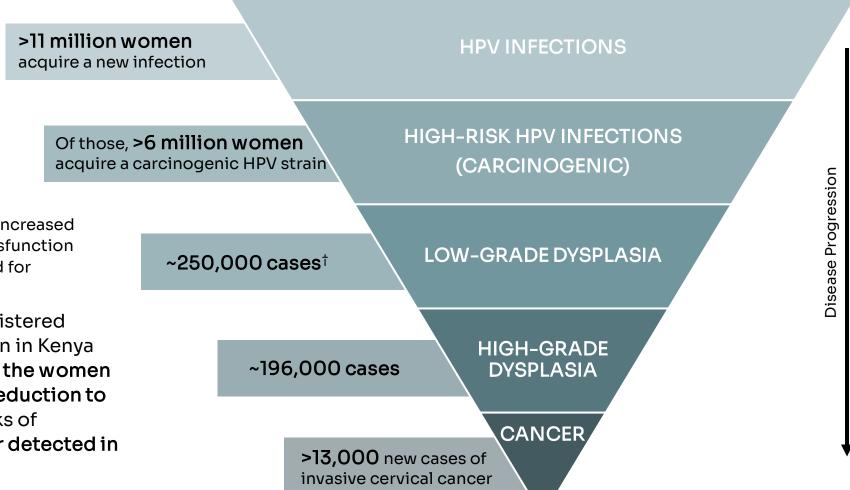
- There are currently no FDA-approved, nonsurgical pharmaceutical interventions to treat HPV-related cervical dysplasia.
- There are no FDA-approved treatments for HPV infection.
- DARE-HPV is a proprietary fixed-dose formulation of lopinavir and ritonavir<sup>1</sup> in a soft gel vaginal insert.
- Phase I and proof-of-concept studies have been completed.
- Activities to support U.S. IND filing to enable progression to Phase 2 clinical development underway supported by a two-year non-dilutive funding 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.<sup>2</sup>

HPV-Related Cervical Diseases per year in the U.S.<sup>1</sup>



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 vertical 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." 44
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.



## Daré's first product: FDA-approved in 3 years from in-license

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

## 



- \$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 upsidesharing milestone payments from XOMA†

\*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 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.



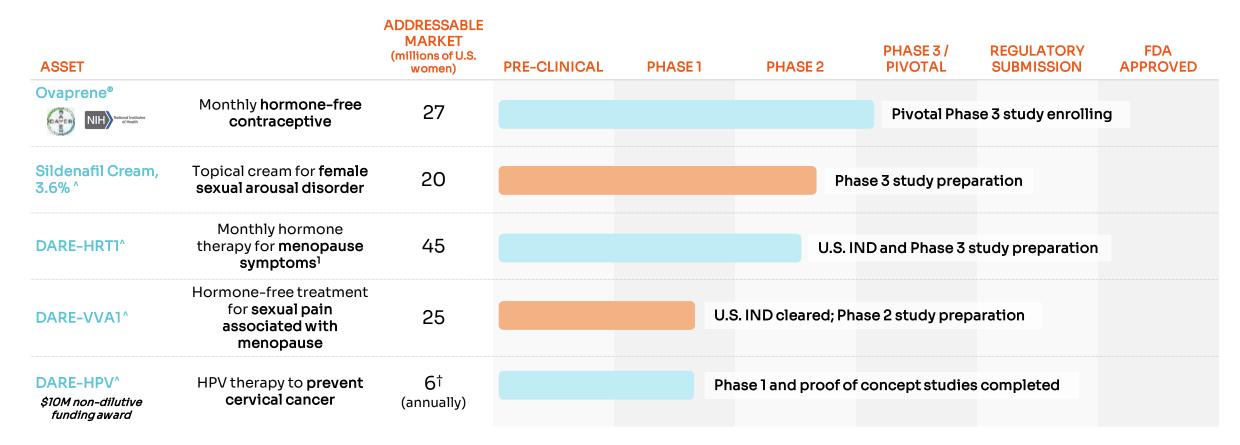
## **XACIATO Selected Safety Information**

- 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 <u>Prescribing Information</u>, <u>Patient Information</u>, and <u>Instructions for Use</u>.



## Our Therapeutics Portfolio\*

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





## Earlier stage programs with grant funding enhance the pipeline\*

ASSET			ADDRESSABLE MARKET	PRE- CLINICAL	PHASE1	PHASE 2	PHASE 3 / PIVOTAL
Australia R&D Cash Rebate	DARE-PDM1 <sup>^</sup>	Vaginal diclofenac once-daily thermosetting hydrogel for pelvic pain	50% menstruating women experience dysmenorrhea		Phase 1 Study Completed 2023 U.S. IND preparations		
Theramex	Casea S <sup>^</sup>	18-24 month biodegradable contraceptive implant	12 million women		Phase	e 1 Study ongoing <sup>1</sup>	
National Institutes of Health	DARE- FRT1/PTB1 <sup>^</sup>	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 Study Preparation			
NIH National Institutes of Health	DARE 204/214 <sup>^</sup>	6 & 12-month injectable etonogestrel contraceptive	12 million women	Phase 1 Study Preparation			
National Institutes of Health  Foundation grant up to ~\$49M	DARE- LARC1 <sup>^</sup>	Long-acting, reversible personal contraceptive system	17 million women		Pre-IND Activ	ities	
UNIVERSITY OF COPENHAGEN	DARE-RH1	Male or female contraceptive target	27 million women		Hit to lead sta	ge	
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 st	udies	

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