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): March 2, 2026

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.

On March 2, 2026, Daré Bioscience, Inc. ("Daré" or the "Company") made available an updated corporate presentation in the "Investors" section of its website (https://ir.darebioscience.com). A copy of the presentation, dated March 2, 2026, is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

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.

Information contained in, or that can be accessed through, the Company's website or any other website referenced in its corporate presentation is not incorporated by reference into this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Daré Bioscience corporate presentation, dated March 2, 2026
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.

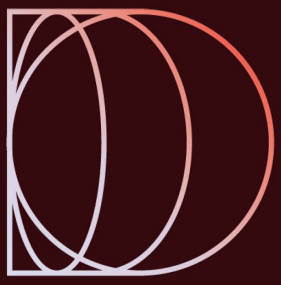
Dated: March 2, 2026

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

Exhibit 99.1

CORPORATE DECK

MARCH 2, 2026



DARÉ BIOSCIENCE

DAREBIOSCIENCE.COM | NASDAQ: DARE

Forward-Looking Statements & Disclaimers

This presentation is for informational purposes only and is not an offer to sell or a solicitation of an offer to buy any securities of Daré Bioscience, Inc. ("Daré" or the "Company"). This presentation 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 outside of clinical or preclinical studies, 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) does not approve. The FDA does not evaluate compounded drugs or cosmetic products for safety, effectiveness, or quality. None of the investigational products, compounded drugs or consumer health products discussed herein have been approved for marketing by the FDA or any other regulatory agency, and no 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 some cases, you can identify forward-looking statements by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "upcoming," "design," "intend," "expect," "could," "plan," "potential," "positioned," "pursue," "seek," "should," "would,", "project," "target," "objective," "near-term", "on track," or the negative of these terms and other similar expressions. Such statements include, but are not limited to, statements 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 drugs via Section 503B of the Federal Food, 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, including trial design, timelines, costs, milestones, and results, targeted indications, 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. Forward-looking statements reflect management's estimates and expectations based on current information and involve risks, uncertainties and assumptions that may cause Daré's actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements, including, without limitation, risks and uncertainties related to: Daré's ability to raise additional capital when and as needed to fund operations and execute its business strategy; Daré's dependence on grants and other financial awards from governmental entities and a private foundation; limitations on Daré's ability to raise additional capital through sales of its common stock or 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 of infrastructure for commercializing products; Daré's reliance on 503B-registered outsourcing facilities, dispensing pharmacies, telehealth providers, and other third parties to bring proprietary solutions to market as compounded drugs or as consumer health products and 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 outsourcing facilities to compound 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 Daré brings to market; developments by competitors that make Daré's products less competitive or obsolete; shifts in consumer spending or behavior; Daré's reliance on third parties to manufacture and conduct clinical trials and preclinical studies of its product candidates and commercialize XACIATO® (clindamycin phosphate) vaginal gel 2% and future FDA-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 communicated timelines; failure or delay 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 regulatory pathway known as the 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 rights to develop and commercialize a product or product candidate; Daré's and its licensors' ability to obtain and maintain sufficient intellectual property protection; the coverage, pricing and reimbursement that XACIATO and any future product obtains from third-party payors; product recalls; governmental investigations, actions or proceedings; litigation and legal proceedings, including product liability or intellectual property claims and actions; cybersecurity incidents or similar events that compromise Daré's technology systems and/or significantly disrupt Daré's business or those of third parties on which it relies; changes in laws and regulations that impact the pharmaceutical and health care industries, or changes in enforcement policies; the effects of macroeconomic conditions, geopolitical events, and major changes and disruptions in U.S. government policies and operations; Daré's ability to maintain compliance with Nasdaq's continued listing requirements and 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 most recent annual report on Form 10-K and quarterly report on Form 10-Q filed with the Securities and Exchange Commission. All forward-looking statements are current only as of the date of this presentation. Daré does not undertake any obligation to update any forward-looking statement in this presentation to reflect new information, future developments or otherwise, except as required by law.

This presentation includes market size and growth data and estimates and other industry information published by independent third parties or based on management's review of such information, management's knowledge of the industry and good faith estimates of management. This market and industry data and information involves a number of assumptions and limitations, and you are 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 guarantee the accuracy or completeness of this information and has not independently verified this information. Projections, assumptions and estimates of the future performance of the industry in which Daré operates and market size and opportunities for product candidates Daré develops and products Daré brings to market are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results to differ materially from those expressed in the data and estimates made by the independent parties and by Daré.

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

CAPITAL-EFFICIENT MODEL

Significant non-dilutive funding

Why Invest in Women

<2% of the global healthcare pipeline addresses non-oncologic women's health[1]

Yet **27% of all blockbuster drug products** are women's health drugs[2]

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 conditions in women

Near-Term Commercial Path

ASSET / TARGET AVAILABILITY			UNMET NEED	MARKET INSIGHT
Now accepting Rx's nationwide **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 report on HIMS estimated the **erectile dysfunction market opportunity** to be **$11 billion**[2]
Q1 2026 **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 companies such as **The Honey Pot Company** and **Bonafide Health** have capitalized on this trend and achieved successful exits in 2024 and 2023 respectively.[4,5]
EARLY 2027 **DARE to RECLAIM™**	**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 conducted by TXMD in 2020 estimated the U.S. **compounded hormone therapy market** to be **$2.5-4.5 billion**[6]

^Proprietary formulations made or expected to be made available for prescription fulfillment via a 503B-registered outsourcing facility partner and a licensed dispensing pharmacy with an online platform.
1. See Slide 17 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.

DARE to PLAY™
Sildenafil Cream*

PRODUCT INFO

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).**

DUAL PATH APPROACH

Now accepting prescriptions nationwide in the U.S. as a compounded drug through a 503B-registered outsourcing facility partner in the pre-fulfillment phase

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

VISIT DARETOPLAYBIO.COM FOR MORE INFORMATION

*This is a compounded drug. It is not FDA approved. DARE to PLAY Sildenafil Cream will be manufactured in a 503B outsourcing facility under pharmaceutical Good Manufacturing Practice (GMP). The FDA does not evaluate compounded drug products for safety, efficacy, or quality.

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 19-23.

DARE to PLAY™
Sildenafil Cream

KEY DATA

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

Phase 2b study demonstrated **statistically significant arousal improvement in the target Phase 3 population** (post-hoc analysis). [2]

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). [2]

1. See slide 22.
2. See slides 21 and 23.

OVAPRENE®

Investigational Hormone-Free Monthly Intravaginal Contraceptive

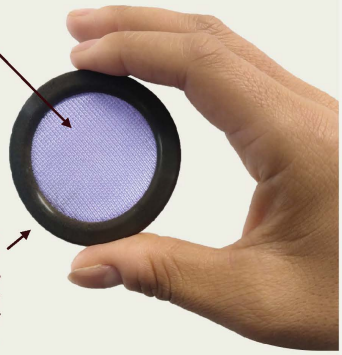
PRODUCT INFO

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.

Design Features of Ovaprene® [2,4]

Physical Barrier [2]
*3D, knitted polymer barrier to **physically block** the passage of sperm*



Spermiostatic Environment [2]
*A silicone ring releasing hormone-free ferrous gluconate to chemically **impede sperm motility**.*

- 86% - 91% expected typical use effectiveness[2,3]
- 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**

1. See Slide 25
2. Mauck, et al. Contraception, Vol. 132, April 2024
3. Mauck C., Vincent K. Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437–444
4. Del Priore, et al. Journal of Reproductive Medicine 2009; 54: 685-690

Menopause Franchise

The global market for menopausal products is expected to reach >$24 billion by 2030.[1]

DARE-VVA1*	DARE-HRT1*
Hormone-free tamoxifen inserts for painful intercourse associated with menopause	**Monthly estradiol + progesterone intravaginal ring**
Investigational New Drug (IND) application cleared for Phase 2 start	WE ARE PURSUING A DUAL PATH APPROACH **Targeting prescription launch in early 2027 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-VVA1 and DARE-HRT1 are investigational products. They are not FDA approved. See slide 28.
1. https://www.washingtonpost.com/opinions/2022/04/28/menopause-hormone-therapy-nih-went-wrong/

DARE-HPV^

Investigational Antiviral Vaginal Insert For Persistent High-Risk HPV Infection

PRODUCT INFO

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; $6.5 million received to date.
- **IND cleared in February 2026** allowing initiation of planned Phase 2 clinical study to evaluate DARE-HPV as a potential treatment for persistent high-risk HPV infection.

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

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. 2016 Jan 29.

FDA APPROVED PRODUCT: XACIATO™
(Clindamycin Phosphate) Vaginal Gel 2%

PRODUCT INFO

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

- **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 27

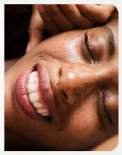
†100% of royalties and commercial milestone payments based on XACIATO net sales are subject to a royalty purchase agreement with XOMA (April 2024) and a royalty interest financing agreement (Dec 2023). Upon achieving a pre-specified return threshold, XOMA will make upside-sharing milestone payments to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

Pipeline Overview

Diverse, strategically balanced portfolio of late-, mid-, and early-stage assets targeting non-oncologic conditions across women's health; Large addressable U.S. and global markets.

DARE to PLAY™ — Designed for her sexual experience

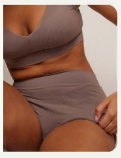
DARE to PLAN™ — Designed for her contraception needs



DARE to RECLAIM™ — 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

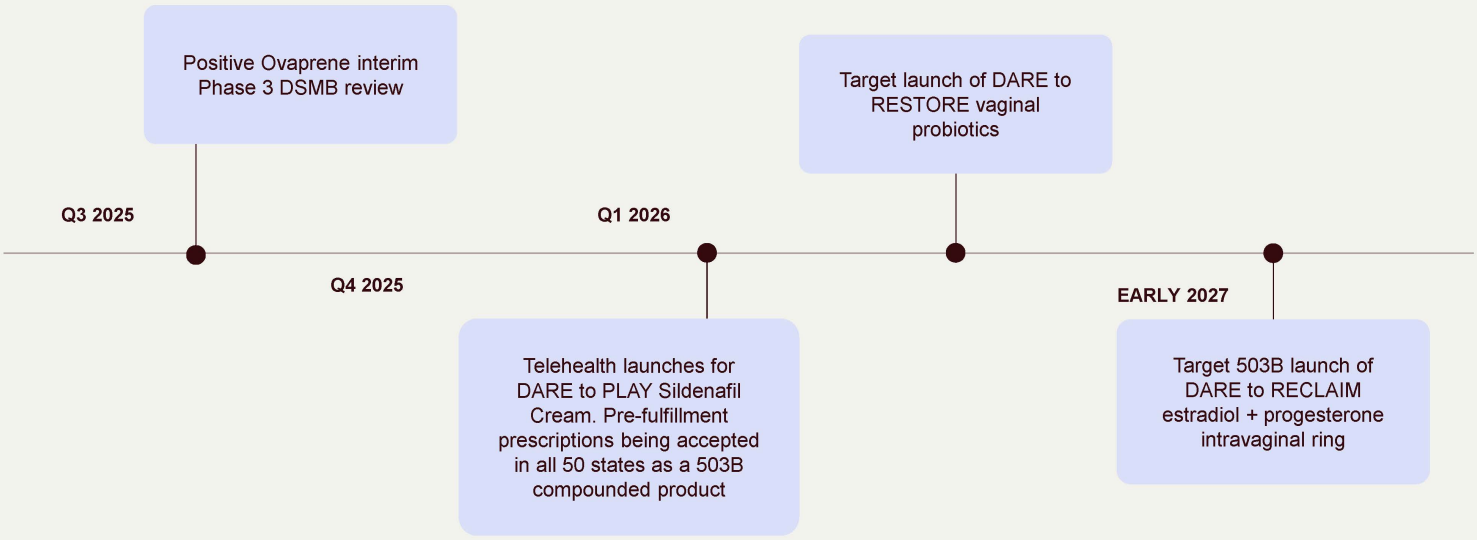
Strategic Collaborations & Non-Dilutive Funding

XACIATO™
commercialization
via Organon

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

>$75 million awarded since 2018

Recent & Upcoming Catalysts



Why Daré, Why Now

DARE to PLAY Sildenafil Cream nationwide availability anticipated in early 2026

Three additional revenue catalysts on the horizon

Capital-efficient, partnership-driven model

Appendix

DARÊ BIOSCIENCE

FSAD is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity[1] and is clinically analogous to erectile dysfunction in men.

33%

of U.S. women aged 21 to 60 **(~20 million women)**, experience symptoms of low or no sexual arousal.[2,3]

16%

of women in the U.S. aged 21 to 60 **(~10 million women)** are distressed from experiencing no or low sexual arousal, according to market research, **and are actively seeking treatment**. [2,3]

5 -15%

5% of men **experience complete ED** at age 40, increasing to 15% at age 70.[4]

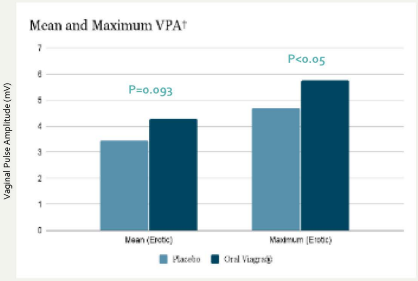
1. Diagnostic and Statistical Manual (DSM) 4th Edition Text Revision (DSM IV TR) defines FSAD as a persistent or recurrent inability to attain or to maintain until completion of the sexual activity, an adequate lubrication-swelling response of sexual excitement. The diagnostic criteria also state that the inability causes marked distress or interpersonal difficulty, is not better accounted for by another Axis I disorder (except another sexual dysfunction) and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.
2. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC. 3. Based on US Census projections for 2016.
4. 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%.

DARÊ BIOSCIENCE

Oral Sildenafil provided a compelling proof of concept for FSAD

STATISTICALLY SIGNIFICANT INCREASES IN VAGINAL PULSE AMPLITUBE (VPA)[1]

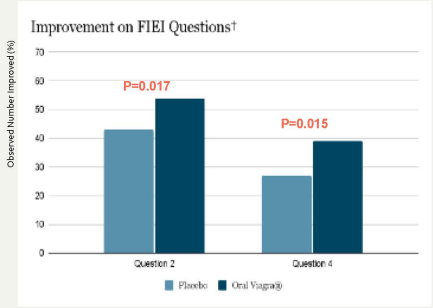
Pfizer VPA Clinical Lab Study – Oral Viagra



† Twelve healthy premenopausal women were studied.

STATISTICALLY SIGNIFICANT IMPROVEMENT IN GENITAL STIMULATION (FIEI)[2]

Pfizer Clinical Field Study – Oral Viagra



† Question #2 – "After taking study medication, the sensation/feeling in my genital (vaginal, labia, clitoris) area during intercourse or stimulation (foreplay) seemed to be: (a) more than before, (b) less than before, or (c) unchanged."

Question #4 – "After taking the study medication, intercourse and/or foreplay was: (a) pleasant and satisfying; better than before taking the study medication, (b) unpleasant; worse than before taking study medication, (c) unchanged; no difference, or (d) pleasant; but still not like it used to be or I would like it to be."

202 postmenopausal women with FSAD who had protocol specified estradiol and free testosterone concentrations, and/or were receiving estrogen and/or androgen replacement therapy were studied.

Key Takeaways of Viagra® studies:

- Increased blood flow and clinical efficacy observed with oral sildenafil (Viagra®) in women.
- The side effect profile of the oral formulation was not optimal for women - leading to the exploration of alternative delivery options including a topical route of administration.

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

Path Forward for Sildenafil Cream for Treatment of FSAD

EXPLORATORY PHASE 2B CLINICAL STUDY[1]

- The **Phase 2b Clinical Study** (ID# NCT04948151) 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[2], 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[3].

CLNICAL 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.

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 23.
2. "ITT" means intention-to-treat population. N=200 randomized participants (101 to Sildenafil Cream, 99 to placebo cream). Sildenafil Cream-assigned women and 94 placebo cream-assigned women who received at least one dose made up the ITT population.
3. This subset of participants was made up of 33 Sildenafil Cream-assigned women and 32 placebo cream-assigned women.

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 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 Phase 3 population: FSAD with or without concomitant decreased desire

Endpoint	Sildenafil Cream 3.6% (N=33)	Placebo Cream (N=32)	P value
	LS change (SE) from BL to Week 12	*LS change (SE) from BL to Week 12*	
SFQ28 Arousal Sensation Domain*	2.03 (0.62)	0.08 (0.71)	0.04
SFQ28 Desire Domain	1.27 (0.76)	-0.89 (0.86)	0.06
SFQ28 Orgasm Domain	1.12 (0.49)	0.18 (0.52)	0.19
FSDS-DAO – Item 3 Guilt	-0.73 (0.16)	-0.23 (0.17)	0.04
FSDS-DAO – Item 5 Stressed	-0.50 (0.16)	-0.02 (0.16)	0.04
FSDS-DAO – Item 10 Embarrassed	-0.51 (0.17)	0.00 (0.17)	0.04
FSDS-DAO – Item 14 Concerned*‡	-0.27 (0.18)	-0.12 (0.20)	0.58

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

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

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. Safety of topical sildenafil cream, 3.6% in a randomized, placebo-controlled trial for the treatment of female sexual arousal disorder. J Sex Med. 2024 Sep 3;21(9):793-799.

Sildenafil Cream, 3.6% Pharmacokinetic and Pharmacodynamic Studies

PHASE 1 & 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[2]:

- AUC – 3-6%
- Cmax – 1-2%

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

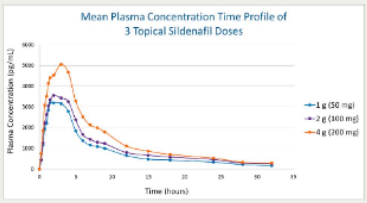
- Favorable product characteristics as self-reported by subjects
- Easy to use
- Readily absorbed

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		
	1g cream (36mg sildenafil), n=20	2g cream (71mg sildenafil), n=20	4g cream (142mg sildenafil) , n=19
Cmax (ng/mL)	3.61	4.10	5.65
AUC0-t (h*ng/mL)	27.45	33.32	45.33
Tmax (hr)	2.56	2.60	2.42



1. Data on file. Sildenafil Cream, 3.6% was previously known as SST-6007.
2. Nichols, et al. Br J Clin Pharmacol. 2002;53(Suppl 1):5S-12S.
3. Data on file.

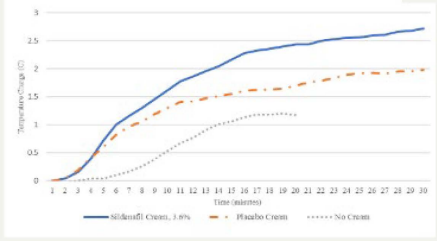
* Thermography utilizes sensitive cameras capable of detecting and recording temperature variations over time. Genital temperature changes are a surrogate for genital blood flow.

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)[3]

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).

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.	*A Double-blind, Placebo-controlled, 2-Way Crossover Study Using Thermography to Assess the Pharmacodynamics of Sildenafil Cream, 3.6% in Healthy Women*

OVAPRENE®

Investigational Hormone-Free Monthly Intravaginal Contraceptive

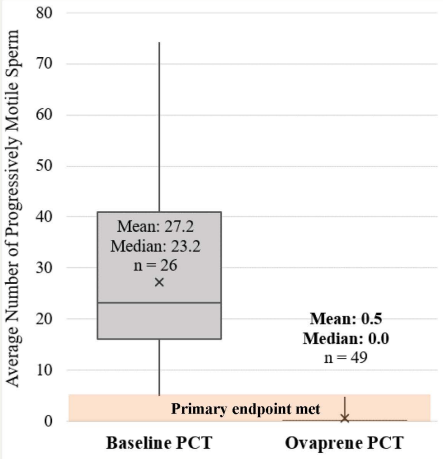
OVAPRENE® PRE-PIVOTAL STUDY

The Ovaprene® Pre-Pivotal Postcoital Test (PCT) study met its primary endpoint.

- In **100% of women and cycles**, Ovaprene prevented the requisite number of sperm from reaching the cervix.
- A successful cycle was defined as an average of less than five (< 5) progressively motile sperm (PMS) per high-powered field (HPF) being present in the midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place.[1]
- Using a surrogate marker for contraceptive effectiveness, the PCT study showed **similar results to products that later demonstrated "typical use" contraceptive effectiveness of 86-91%***

*In PCT studies of similar size, products (diaphragms) that demonstrated no motile sperm in the cervical mucus during PCT assessments later demonstrated "typical use" contraceptive effectiveness of 86-91% in pivotal contraceptive studies evaluating pregnancy rates over six-month periods.[2]

OVAPRENE® PRE-PIVOTAL STUDY RESULTS



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
3. Del Priore, et al. Journal of Reproductive Medicine 2009; 54: 685-690

OVAPRENE®

Investigational Hormone-Free Monthly Intravaginal Contraceptive

U.S. REGULATORY STRATEGY[1]

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

Pivotal study design[2]

- This is a non-comparative study meaning all women will use Ovaprene – **there is no placebo**
- Target approximately 250 subjects to complete ~12 months (13 menstrual cycles) of use

Primary objective

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

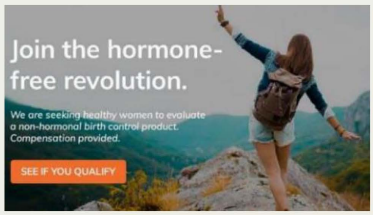
Secondary objectives

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

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

Pivotal study ongoing

- Enrollment is ongoing; recruiting at five study sites supported by grant funding received in November 2024; currently anticipate enrollment will be completed in 2026.
- 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]

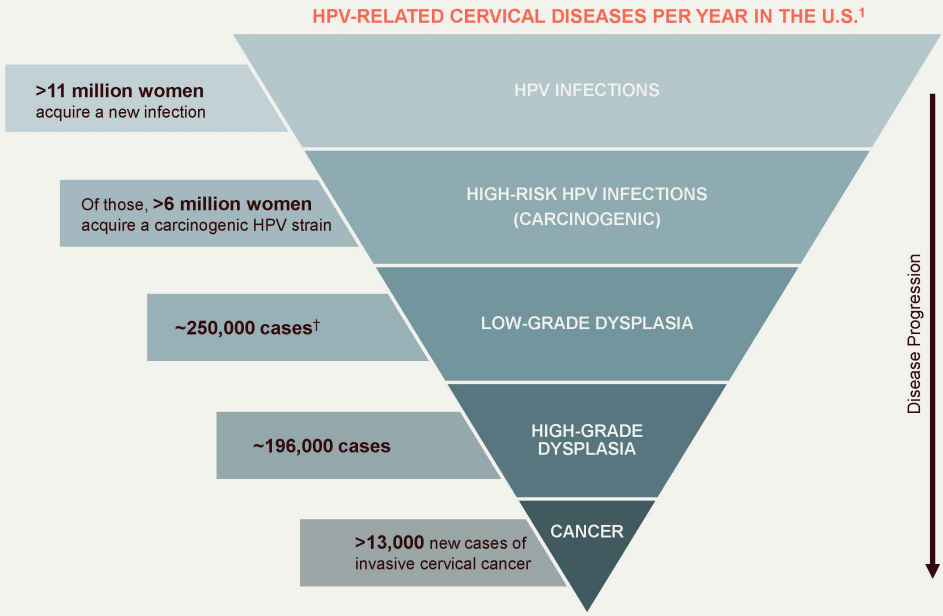


ovaprenestudy.com

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 study of Ovaprene are not necessarily predictive of final results of the Phase 3 study. There is no guarantee of a successful outcome in the Phase 3 study.

Safe and Effective HPV Treatments Remain an Unmet Need

- HPV is the most common sexually transmitted infection in the United States and is the cause of 99% of cervical cancer cases.
- 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 States. Sex Trans Dis. 2021 Apr 1; 48(4):273-277. Henk, et al. "Incidence and costs of cervical intraepithelial neoplasia in a US commercially insured population." J Low Genit Tract Dis. 2010 Jan;14(1):29-36. CDC: Estimated Number of Cases of High-Grade Cervical Lesions Diagnosed Among Women — United States, 2008 and 2016 https://www.cdc.gov/mmwr/volumes/68/wr/mm6815a1.htm Accessed 16 Oct 2024. American Cancer Society: Key Statistics on Cervical Cancer. https://www.cancer.org/cancer/ types/cervical-cancer/about/key-statistics.html Accessed 16 Oct 2024. 2. Hampson, et al. "A Single-Arm, Proof-of-Concept Trial of Lopimune (Lopinavir/Ritonavir) as a Treatment for HPV-Related Pre-Invasive Cervical Disease." PLoS One. 2016 Jan 29. †Estimate calculated from CIN1 and CIN2/3 annual incidence of 1.6 and 1.2 per 1,000 women, respectively (Henk, 2010) and CIN2 cases per year (CDC). 196,000 / 1.2 * 1.6 = 261,333 cases of CIN1 per year.

XACIATO™
(Clindamycin Phosphate) Vaginal Gel 2%

SELECTED SAFETY INFORMATION

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

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.

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

^505(b)(2) regulatory pathway anticipated.
* We are developing these assets with the intent to seek marketing approval from the FDA. We assembled our pipeline primarily through acquisitions, in-license agreements, and other collaborations, and have royalty, milestone and other payment obligations to third-parties relating to product development and/or commercialization.
† Addressable market reflects potential treatment of all cases of high-risk HPV infections in the U.S. See slide 27 for more details.

1. Target indication is the treatment of moderate-to-severe VMS due to menopause in women with intact uteri
2. Total of $6.5 million received to date

Earlier stage programs with grant funding enhance the pipeline*

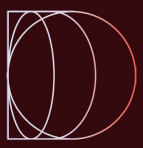
ASSET			ESTIMATED ADDRESSABLE MARKET	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL
Australia R&D Cash Rebate	DARE-PDM1^	Vaginal diclofenac once-daily thermosetting hydrogel for pelvic pain	50% menstruating women experience dysmenorrhea			**Phase 1 study completed 2023 U.S. IND preparations**	
Theramex	Casea S^	18-24 month biodegradable contraceptive implant	12 million women			**Phase 1 study ongoing †**	
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 study preparation**		
NIH National Institutes of Health	DARE 204/214^	6 & 12-month injectable etonogestrel contraceptive	12 million women		**Phase 1 study preparation**		
NIH National Institutes of Health *Foundation grant up to ~$49M*[1]	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. We assembled our pipeline primarily through acquisitions, in-license agreements, and other collaborations, and have royalty, milestone and other payment obligations to third-parties relating to product development and/or commercialization.

† The Phase 1 study is being conducted by FHI 360 with support from a foundation grant (ID# NCT05174884). We are not currently developing this asset but may exercise rights to do so in the U.S. under our co-development and license agreement with Theramex.

1. Total of $41.8 million received to date.



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