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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): September 30, 2021

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 8.01 Other Events

Included as Exhibit 99.1 to this report is a presentation about Daré Bioscience, Inc. ("Daré") and its product candidates, dated September 30, 2021, which is incorporated herein by reference. Daré intends to use the presentation and its contents in various meetings with investors, securities analysts and others, commencing on September 30, 2021.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate presentation, dated September 30, 2021

SIGNATURES

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

DARÉ BIOSCIENCE, INC.

Dated: September 30, 2021

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

Exhibit 99.1

Daré Bioscience

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

Forward-Looking Statements; Disclaimers

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

All statements in this presentation, other than statements of historical fact, are forward-looking statements within the meaning of federal securities laws. In some cases, you can identify forward-looking statements by terms such as "may," "will," "expect," "plan," "anticipate," "strategy," "designed," "could," "intend," "believe," "estimate," "target," or "potential," or the negative of these terms and other similar expressions. Such statements include, but are not limited to, statements relating to the clinical and market potential of Daré's product candidates, clinical trial advancement, timing and data, regulatory approval and commercialization, potential collaborations, benefits of a collaboration, pipeline expansion, and potential funding and financing transactions. As used in this presentation, "first-in-category" and "first-line" are forward-looking statements relating to market potential of a product candidate if it were to receive regulatory approval for the indication(s) for which it is being developed. None of the product candidates presented herein are approved for use outside of clinical trials. The timing of clinical trials, clinical trial data, FDA review and approval, collaborations and other milestones and events relating to development and commercialization of Daré's product candidates, other than those having occurred prior to the date of this presentation, are forward-looking statements. Forward-looking statements reflect management's estimates and expectations based on current information and involve risks, uncertainties and assumptions that may cause Daré's actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements, including, without limitation, as a result of risks and uncertainties inherent in Daré's business and those described 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 under the heading "Risk Factors." All forward-looking statements are current only as of the date of this presentation. Daré does not undertake any obligation to update any forward-looking statement in this presentation to reflect new information, future developments or otherwise, except as required by law.

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

Women's Health is Our Sole Focus

Daré Bioscience is a clinical-stage biopharmaceutical company committed to addressing the lack of innovation in women's health primarily in the areas of contraception, vaginal health, sexual health, and fertility.

We work to accelerate innovative product options in women's health that…

Expand treatment options,

Enhance outcomes, and

Improve ease of use for women.

We partner to…

Drive **innovation** and develop new solutions,

Accelerate novel products to **address persistent unmet needs** in a **time and capital efficient** manner, and

Become a **pipeline resource** for large and emerging commercial companies.

We look for differentiated investigational products with…

Attractive market opportunities + unmet medical needs,

Prior human **proof-of-concept** and/or ability to leverage a **505(b)(2)** regulatory pathway,

First-in-category or first-line potential, and

Opportunity to **personalize for women** with novel, convenient routes of administration.

Daré Bioscience: A Compelling Opportunity

Company Highlights

1. **Diverse pipeline with independent outcomes**
   Several programs, including an NDA stage and four clinical development stage or Phase 1-ready candidates utilizing different APIs and targeting different indications
2. **Multiple novel delivery platforms**
   Persistent unmet needs require creative new approaches designed for her
3. **Compelling market potential**
   First-line or first-in-category product opportunities across the portfolio
4. **505(b)(2) FDA pathway planned for most candidates**
   Use of well-characterized APIs expected to mitigate development risk, time, and cost
5. **Commercial value in women's health** evidenced by recent transformational pharma transactions

Program Milestones

2021

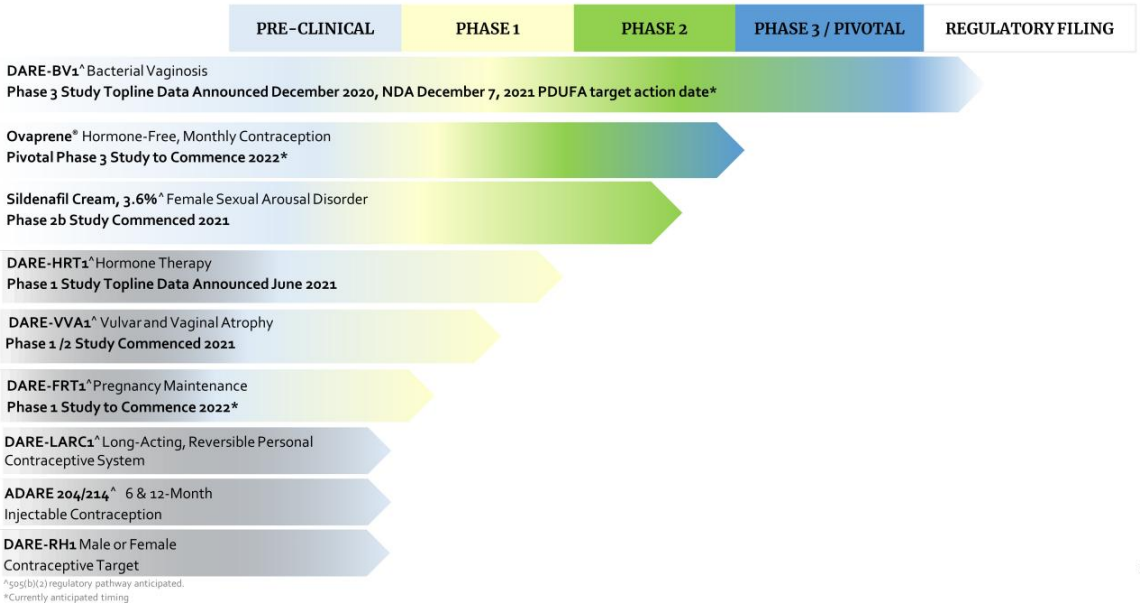
- ✓ Sildenafil Cream, 3.6% Phase 2b study commence (female sexual arousal disorder)
- ✓ DARE-BV1 NDA submission to FDA (bacterial vaginosis)
- ✓ DARE-HRT1 Phase 1 study topline data (hormone therapy)
- ✓ DARE-VVA1 Phase 1/2 study commence (vaginal atrophy treatment for women with breast cancer)
- • DARE-BV1 NDA PDUFA target *

2022

- • DARE-BV1 U.S. commercial launch
- • Ovaprene® pivotal Phase 3 study commence (hormone-free monthly contraception)
- • DARE-VVA1 Phase 1/2 study topline data
- • DARE-FRT1 Phase study commence (preterm birth and IVF luteal phase support)

• = currently anticipated timing
* Priority review designation granted by the FDA, PDUFA target action date is December 7, 2021

Advancing Products Women Want – The Portfolio Snapshot



^505(b)(2) regulatory pathway anticipated.
*Currently anticipated timing

Advancing Products Women Want – Late Stage Programs

PARTNERS	Product Candidate	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	REGULATORY FILING

DARE-BV1^ Bacterial Vaginosis
Phase 3 Topline Data Announced December 2020, NDA submitted 2Q2021, PDUFA target Dec. 7, 2021

1. Investigational thermosetting bioadhesive hydrogel.
2. Single-administration vaginal treatment for bacterial vaginosis, the most common vaginal infection in women of reproductive age.
3. In the DARE-BVFREE Phase 3 study, DARE-BV1 demonstrated the potential for improved clinical cure rates versus current branded FDA-approved products for the treatment of bacterial vaginosis.

Potential first-line option for bacterial vaginosis
Bioadhesive gel, clindamycin 2%

Ovaprene® Hormone-Free, Monthly Contraception
Pivotal Phase 3 Study to Commence 2022

1. Investigational hormone-free monthly intravaginal contraceptive.
2. Designed to be an easy-to-use monthly option with effectiveness approaching hormonal methods. There are currently no FDA-approved monthly hormone-free contraceptives.
3. Commercial partnership agreement with Bayer.

Potential first-in-category hormone-free contraception
Self-administered intravaginal drug/device

Sildenafil Cream, 3.6%^ Female Sexual Arousal Disorder
Phase 2b Study Commenced 2021

1. Investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical administration to treat FSAD.
2. FSAD is a physiological condition characterized by the inability to attain or maintain sufficient genital arousal during sexual activity, for which there are no FDA-approved treatments.
3. Of the various types of female sexual dysfunction disorders, FSAD is most analogous to erectile dysfunction in men.

Potential first-in-category treatment for female sexual arousal disorder (FSAD)
Topical cream, same active ingredient as Viagra®

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

Advancing Products Women Want – Phase 1 and Preclinical

PRODUCT CANDIDATE	PRE-CLINICAL	PHASE 1
DARE-HRT1^Hormone Therapy - **Phase 1 Study Completed**		1. First-in-category combination hormone delivery for treatment of vasomotor and vaginal symptoms of menopause. 2. Intravaginal ring (IVR) designed to release bio-identical estradiol and bio-identical progesterone over 28 days. 3. Potential to be the first convenient monthly format product with both hormones.
DARE-FRT1^Pregnancy Maintenance - **Phase 1 Study Preparation**		1. First-in-category progesterone delivery for pregnancy maintenance including the prevention of preterm birth and for luteal phase support as part of an IVF regimen. 2. IVR designed to release bio-identical progesterone over 14 days. 3. Alternative to daily IM injections or vaginal gel
DARE-VVA1^ Vulvar and Vaginal Atrophy – **Phase 1/2 Study Commenced**		1. First-in-category hormone-free vaginal treatment for vulvar and vaginal atrophy (VVA) in a hormone-receptor positive (HR+) breast cancer patient population. 2. Proprietary formulation of tamoxifen for vaginal administration. 3. Potential to be the first therapeutic specifically approved for treatment of VVA in patients with HR+ breast cancer.
DARE-LARC1^ Long-Acting, Reversible Personal Contraceptive System		Levonorgestrel-releasing, long-acting contraceptive implant that a woman can turn on and off herself, according to her own needs. Grant of up to $48.95 M to advance technology through non-clinical proof of principle to enable IND submission, and an NIH grant to explore device insertion/removal in non-clinical studies.
ADARE 204/214^ 6 & 12-Month Injectable Contraception		Novel 6 & 12-month injectable formulations of etonogestrel being developed as a longer-acting, reversible method of contraception with a more predictable return to fertility.
DARE-RH1 Male or Female Contraceptive Target		A potential new rapidly reversible, non-hormonal contraceptive solution with application for women and men.

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

Near Term Catalysts to Drive Value

Milestones

DARE-BV1
1. NDA submitted during 2Q2021
2. PDUFA target December 7, 2021

Sildenafil Cream, 3.6%
1. Phase 2b commenced 1Q2021
2. Topline Phase 2b data target date pending interim analysis for study sizing

Ovaprene
1. IDE submission planned for 4Q2021
2. Pivotal study commence anticipated 2022

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

Daré: Advancing Products Women Want

Innovative women's health pipeline with multiple clinical, regulatory and commercial milestones anticipated in 2021-2022.

Every program, if approved, represents a potential first-line or first-in-class product opportunity.

Experienced Board of Directors and Management Team with demonstrated success in clinical and product development, regulatory affairs, corporate strategy and financial operations.

Women's health generating more interest as evidenced by transformational transactions.[1-6]

Pharmaceutical companies will continue to seek new and differentiated products to supplement their branded women's health offerings

BAYER

License agreement for Daré's investigational Ovaprene®. Deal includes up to $310 million in potential commercial milestone payments, plus double-digit, tiered royalties on net sales.

KaNDY acquisition for upfront consideration of $425 million.

Pfizer

Myovant to receive up to $4.2 B in collaboration to develop and commercialize relugolix in oncology and women's health including up to $200m in regulatory milestones for the women's health product candidate.

CooperCompanies

Acquired global rights to PARAGARD® Intrauterine Device (IUD) from Teva in a $1.1 billion cash transaction.

astellas

Acquisition of Ogeda for €500 million upfront and the potential for up to another €300 million in milestone payments.

ORGANON

Merck spinoff, a new firm focused on women's health (including Nexplanon® and NuvaRing®) and other drugs with projected annual revenue of >$6.5 billion.

1. https://www.businesswire.com/Dare Bioscience
2. https://www.businesswire.com/KaNDy-Therapeutics-Ltd
3. https://www.pfizer.com/news/press-release/press-release-detail/myovant-sciences-and-pfizer-announce-collaboration-develop
4. https://www.globenewswire.com/The-Cooper-Companies-Announces-Definitive-Agreement-to-Acquire-PARAGARD-IUD-From Teva..
5. https://www.biopharmadive.com/news/astellas-ogeda-womens-health-deal
6. https://www.organon.com/news/organon-launches-as-new-global-womens-health-company/

Experienced Management & Board of Directors

Management Team

Sabrina Martucci Johnson MSc, MIM
President & CEO

John Fair
Chief Strategy Officer

Lisa Walters-Hoffert
Chief Financial Officer

David Friend, PhD
Chief Scientific Officer

Mary Jarosz, RPh, RAC, FTOPRA
Global Head of Regulatory Affairs

Mark Walters
Vice President of Operations

Christine Mauck, MD, MPH
Medical Director

Board of Directors

William Rastetter, PhD
Chairman

Cheryl Blanchard, PhD

Jessica Grossman, MD

Susan Kelley, MD

Greg Matz, CPA

Sophia N. Ononye-Onyia, PhD, MPH, MBA

Robin Steele, JD, LLM

Sabrina Martucci Johnson MSc, MIM
President & CEO

We are delivering **innovation** by **daring to be different®**

DARE-BV1 Clindamycin 2% Gel for Bacterial Vaginosis

Best-in-class curative potential for the most common[1] vaginal infection in women of reproductive age, designed for convenient, one-time administration

NDA PDUFA target December 7, 2021

1.https://www.cdc.gov/std/bv/stats.htm

Bacterial Vaginosis - What is the clinical issue?

Recurring infection, difficult to treat effectively

➤Most common vaginal infection in women ages 15-44, affecting ~**21 million women** in the US[1]

➤Current Rx suboptimal: clinical cure rates of 37-68%[2]

Bacterial Vaginosis increases health risk[3]

➤Preterm birth – bacterial vaginosis is linked to premature deliveries, low birth weight babies

➤Sexually transmitted infections – bacterial vaginosis increases susceptibility to HIV, herpes simplex virus, chlamydia, gonorrhea

➤Post-surgical infection – bacterial vaginosis may increase risk of infection after gynecologic procedures

➤Pelvic inflammatory disease – bacterial vaginosis may cause PID, an infection that affects women's reproductive organs and can increase the risk of infertility

1.https://www.cdc.gov/std/bv/stats.htm
2.Bacterial vaginosis product data: http://www.clindesse.com/pdf/PI.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf
3.https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-20352279

DARE-BV1- Phase 3 Study Design & Demographics[1]

DARE-BV1 is a thermosetting vaginal gel formulated with clindamycin phosphate 2%, a well-known and well-characterized antibiotic designed for prolonged, localized release.

➤DARE-BVFREE randomized 307 women at 32 centers across the US in a 2:1 ratio to receive a single vaginal dose of DARE-BV1 (N=204) or a single vaginal dose of placebo gel (N=103).

➤The intent to treat (ITT) population[2] comprised primarily patients aged 15 to 59 years, with a mean age of 34.8 (6=8.8) and median age of 35. Over 53% of the ITT population qualified as obese (BMI ≥30.0), with a mean BMI of 31.50 (6=8.5).

➤In the ITT population, 56.0% of women identified as Black or African American, 41% identified as white and 25.5% identified as of Hispanic or Latino origin (compared to 74.5% as not of Hispanic or Latino origin).

➤In addition, more than 75% of women in the ITT population reported one or more episodes of bacterial vaginosis in the 12 months before they were randomized into the study (77.4% in the DARE-BV1 group and 73.8% in the placebo group).

➤The mITT study population[3] also required a Nugent score of 7 or greater at time of randomization per the new 2019 FDA bacterial vaginosis guidance.

Definitions:

Primary Endpoint: Clinical Cure (Day 21-30 visit)[4]: Resolution of the abnormal vaginal discharge associated with BV; Negative 10% KOH "whiff test"; Clue cells < 20% of the total epithelial cells in the saline wet mount.

Secondary endpoints: Proportion of subjects with Clinical Cure, Bacteriological Cure and Therapeutic Cure at Day 7-14 Visit[5]

Bacteriological Cure: a Nugent score < 4.

Therapeutic Cure: both a Clinical Cure and Bacteriological Cure.

The DARE-BVFREE study's two treatment arms were well balanced in terms of age, race, ethnicity, bacterial vaginosis history, and body mass index (BMI).

N=307 subjects enrolled (age 15 and above)
Duration ~30 days per subject
Diagnosis - Bacterial vaginosis

1. Data on file.
2. ITT population N=307
3. Modified ITT (mITT) population N=180. In accordance with FDA guidance, the mITT population excludes subjects from the ITT population who subsequently demonstrated a positive test result for other concomitant vaginal or cervical infections at baseline.
4. Visit occurred 21 to 30 days after study drug administration.
5. Visit occurred 7 to 14 days after study drug administration.

DARE-BV1: Potential for Improved Clinical Cure Rates vs. Current Branded Rx

Product	Frequency, Dose, and Route of Administration	Study Descriptions			Clinical Cure Rates
DARE-BV1 (Investigational) (clindamycin phosphate vaginal gel, 2%)	1 time, 5g applicator, applied vaginally	**Randomized Placebo-Controlled Phase 3 Trial [1] Topline data**	**DARE-BVFREE (Day 21-30)** *Modified-Intent-to-Treat Population at 21-30 Days* **DARE-BVFREE (Day 7-14)** *Modified- Intent-to-Treat Population at 7-14 Days* **DARE-BVFREE (Day 21-30)** *Per Protocol Population at 21-30 Days* **DARE-BVFREE (Day 7-14)** *Per Protocol Population at 7-14 Days*	**DARE-BV1 (N=121)** Placebo (N=59) **DARE-BV1 (N=121)** Placebo (N=59) **DARE-BV1 (N=101)** Placebo (N=47) **DARE-BV1 (N=101)** Placebo (N=47)	70.5% 35.6% 76.2% 23.7% 77.5% 42.6% 81.4% 29.8%
Solosec® (secnidazole 2g oral granules)	1 time, 2g dose, taken orally	**Two Randomized, Placebo-Controlled Phase 3 Studies [2]**	Study 1 (Day 21-30) *Modified-Intent-to-Treat Population at 21-30 Days* Study 2 (Day 21-30) *Modified-Intent-to-Treat Population at 21-30 Days* Study 2 (Day 7-14) *Modified- Intent-to-Treat Population at 7-14 Days*	SOLOSEC (N=62) Placebo (N=62) SOLOSEC (N=107) Placebo (N=57) SOLOSEC (N=107) Placebo (N=57)	**67.7%** 17.7% **53.3%** 19.3% **57.9%** 24.6%
Clindesse® (clindamycin phosphate vaginal cream, 2%)	1 time, 5g applicator, applied vaginally	**Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study [3]** **Randomized, Investigator-Blind, Active-Controlled Comparative Study**	Study 1 (Day 21-30) *Modified-Intent-to-Treat Population at 21-30 Days* Study 2 (Day 21-30) *Modified-Intent-to-Treat Population at 21-30 Days* Study 2 (Day 21-30) *Per Protocol Population at 21-30 Days*	Clindesse (N=78) Placebo (N=66) Clindesse Single Dose (N=221) Clindamycin Vaginal Cream, 7 doses (N=211) Clindesse Single Dose (N=126) Clindamycin Vaginal Cream, 7 doses (N=125)	**41.0%** 19.7% **53.4%** 54.0% **64.3%** 63.2%
Nuvessa™ (metronidazole vaginal gel 1.3%)	1 time, 5g applicator, applied vaginally	**Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study [4]**	Study 1 (Day 21-30) Study 1 (Day 7)	NUVESSA (N=292) Vehicle Gel (N=285) NUVESSA (N=292) Vehicle Gel (N=285)	**37.0%** 26.7% **41.1%** 20.0%

1. Data on file
2. SOLOSEC PRESCRIBING INFORMATION https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5512e435-f709-4d6e-8029-026f8a8932ff&type=display
3. Clindesse PRESCRIBING INFORMATION https://www.clindesse.com/pdf/PI.pdf
4. Nuvessa PRESCRIBING INFORMATION https://www.nuvessa.com/nuvessa_files/Nuvessa%20PI%202018-08.pdf

DARE-BV1: Looking Forward

DARE-BV1 delivered **better clinical cure rate values than currently marketed FDA-approved products** for treatment of bacterial vaginosis.[1] DARE-BVFREE Study:

➤71% at Day 21-30 (primary endpoint) and 76% at Day 7-14 in the mITT population, and **rates of 78% at Day 21-30 and 81% at Day 7-14 in the per protocol population**. [2]

➤Demonstrated that DARE-BV1 is significantly effective in what we believe was a representative patient population, including a large proportion of patients who reported one or more episodes of bacterial vaginosis in the 12 months before they were randomized into the study (75% of the ITT population).

➤**Consistent clinical cure rates even in the subset of women who reported having 3 or more prior bacterial vaginosis episodes in the last year.**[3]

FDA set a **PDUFA goal date of December 7, 2021** for completion of its NDA review and communication of its decision**, potentially permitting a 2022 commercial launch in the U.S.**

DARE-BV1 Qualified Infectious Disease Product (QIDP) and Fast Track Designations

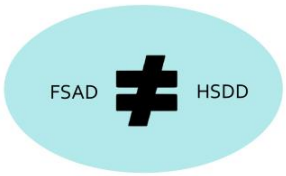
Priority Review Granted

1. Based on topline data from the Phase 3 DARE-BVFREE study and the prescribing information for currently marketed products.
2. For more detail regarding topline study results see our December 7, 2020 announcement available at: https://ir.darebioscience.com/news-releases/news-release-details/dare-bioscience-announces-positive-topline-results-dare-bvfree; the per protocol population (N=148) includes subjects from the mITT population who have no major protocol violations that impact the primary or secondary endpoints or who received any other bacterial vaginosis therapy for any reason.
3. Prior episodes were self reported


Sildenafil
Cream, 3.6%
Potential First-In-Category treatment for Female Sexual Arousal Disorder (FSAD), which has no FDA-approved therapies
Novel cream formulation of sildenafil to treat FSAD, utilizing active ingredient in Viagra®
16

FSAD – The Clinical Issue

Female Sexual Arousal Disorder (FSAD) is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity and, of female sexual function disorders, is most analogous to **erectile dysfunction (ED)** in men.*



The condition should be distinguished from a general loss of interest in sexual activity and from other sexual dysfunctions, 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.[1,2]

*Diagnostic and Statistical Manual 4th Edition Text Revision (DSM IV TR), defines female sexual arousal disorder 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.

1.https://drgeo.com/womens-sexual-health-overview/;
2.https://health.usnews.com/conditions/sexual-disorder-dysfunction

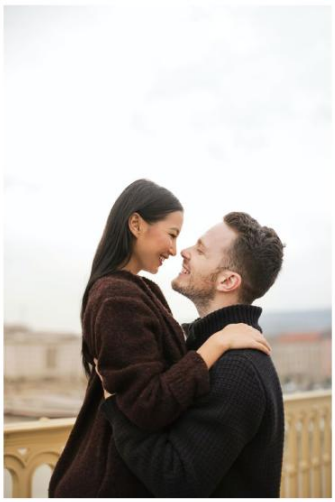
FSAD – What is the incidence?

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%.**[1]

Market research estimates:

➤33% of US women aged 21 to 60 (~ **20 million women**), experience symptoms of low or no sexual arousal.[2,3]

➤**10 million women** are considered distressed and actively seeking treatment.[2]



1.McCool et al. Sex Med Rev 2016;4:197-212.
2.Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.
3.Based on US Census projections for 2016.

Sildenafil Cream, 3.6% - Product Profile

Topically administered investigational Sildenafil Cream[1] is…

➤A PDE5 inhibitor utilized in ED medications for men – ED product Viagra® peaked at $2.05 billion in sales in 2012.[2]

➤Designed to increase local blood flow to provide improvement in genital arousal response.

➤**Applied topically,** avoiding hepatic first-pass metabolism response, resulting in lower systemic exposure potentially resulting in reduced side effects vs. oral sildenafil, including Viagra®

➤Given **similarities between ED and FSAD**, sildenafil - the active ingredient in Viagra® - may improve genital arousal response and overall sexual experience for women as it does in men.

There are no FDA-approved treatments for FSAD

1. Sildenafil Cream, 3.6%, (formerly SST-6007)
2. https://qz.com/quartzy/1238783/its-the-20th-anniversary-of-viagra-heres-how-its-changed-the-world/#:~:text=Annual%20sales%20of%20Viagra%20peaked,Viagra%20is%20set%20to%20expire .

Sildenafil Cream, 3.6% - Phase 2b

Ongoing Phase 2b clinical study aims to evaluate Sildenafil Cream vs. placebo over 12 weeks of dosing following both a non-drug and placebo run-in period.

➤Compares Sildenafil Cream vs. placebo used in patients' home setting.

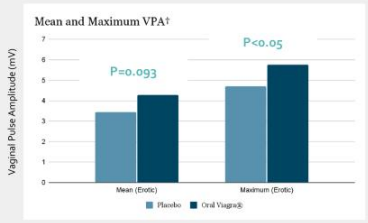
➤Primary endpoint: patient reported outcome (PRO) instruments to measure improvement in localized genital sensations of arousal and reduction in FSAD related distress.

➤Several exploratory efficacy endpoints will be measured and could become additional measurements of efficacy in a future Phase 3 program.

Oral Sildenafil provided a compelling proof of concept for FSAD

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

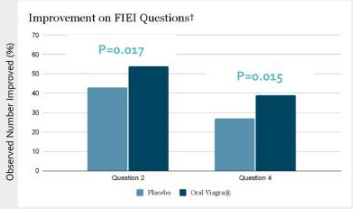
Pfizer *VPA Clinical Lab Study – Oral Viagra*



† Twelve healthy premenopausal women were studied.

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

Pfizer *Clinical Field Study – Oral Viagra*



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

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

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

Key Takeaways of Viagra® studies:

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

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

Sildenafil Cream, 3.6% - Phase 1 and Phase 2a Study Results

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

Normal healthy postmenopausal women were dosed with escalating doses of Sildenafil Cream, 3.6%, using a cross-over study design.

- Sildenafil Cream had significantly lower systemic exposure compared to a 50 mg oral sildenafil dose
- AUC – 3-6%
- C_{max} – 1-2%
- Sildenafil Cream was safe and well tolerated at clinically relevant doses (1-2g)
- Favorable product characteristics as self-reported by subjects
- Easy to use
- Readily absorbed

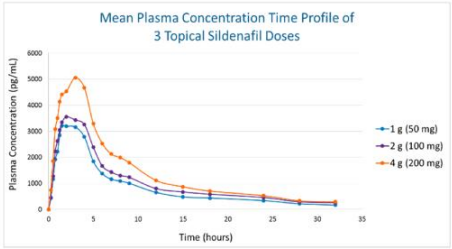
Phase 2a Study of SST-6007(Sildenafil Cream, 3.6%)[1]

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

Phase 1 Study

Treatment	N=59	Sildenafil Single Dose	C_{max} (ng/ml)	T_{max} (hr)	AUC_{last} (h*ng/ml)
Topical Sildenafil 1 g of cream	20	35 mg	3.4	2.37	25.6
Topical Sildenafil 2 g of cream	20	71 mg	3.8	2.27	30.8
Topical Sildenafil 4 g of cream	19	142 mg	5.3	2.22	42.5

Phase 1 Study



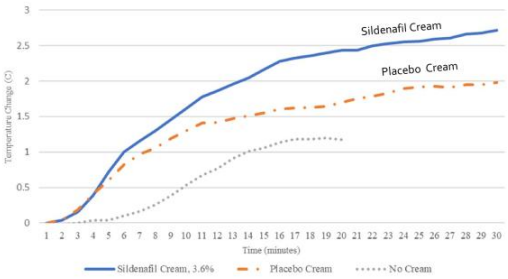
1. Data on file. Sildenafil Cream, 3.6% was previously known as SST-6007.

Sildenafil Cream, 3.6% - Thermography Study Results

Demonstrated time to effect (See Figure 1)

- 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.

Figure 1. Clitoral temperature change during the sexually explicit film



Statistically significant greater linear slope during minutes 11-15 of the sexually explicit stimuli as compared to the placebo cream for the vestibule.

Thermography Study Design & Methodology (N=6)[1]

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.

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

Ovaprene®

Investigational potential first-in-category, hormone-free, monthly birth control

Partnered With BAYER

Ovaprene® - Commercial License Agreement with Bayer[1]

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.

Mirena® is the **#1 prescribed IUD** in the U.S.*

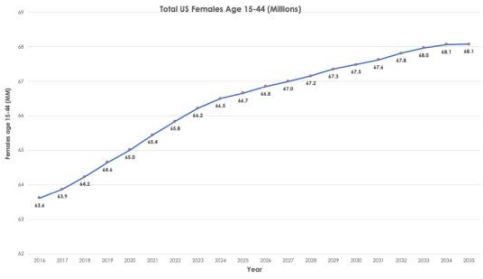
- Bayer received the right to obtain exclusive US rights to commercialize the product, following completion of the pivotal clinical trial if Bayer, in its sole discretion, pays Daré $20 million.
- Daré may receive up to $310 million in commercial milestone payments, plus double-digit, tiered royalties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

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.

* https://www.mirena-us.com/; supported by 2014-2016 SHS data.
1.https://ir.darebioscience.com/news-releases/news-release-details/bayer-and-dare-bioscience-announce-exclusive-licensing-agreement

Contraception: Large Market Opportunity

Women in the Reproductive Health & Contraception Market Segment (over 60 million women)



Source: US Census Bureau, 2017 National Dataset (2016 is base population estimate for projection) https://www.census.gov/programs surveys/popproj.html

Successful Contraceptive Brands Peak Sales:

Mirena® Hormone IUD

(levonorgestrel-releasing intrauterine system) 52mg
Physician inserted, long-acting. low/locally delivered hormone IUS
2019 worldwide sales: €1.2 billion (Bayer)[1]

Lo Loestrin®

(norethindrone acetate and ethinyl estradiol, ethinyl estradiol tablets)
Lowest amount of daily estrogen (10 micrograms) available in pill form
2019 US sales: $588 million (Allergan)[2]

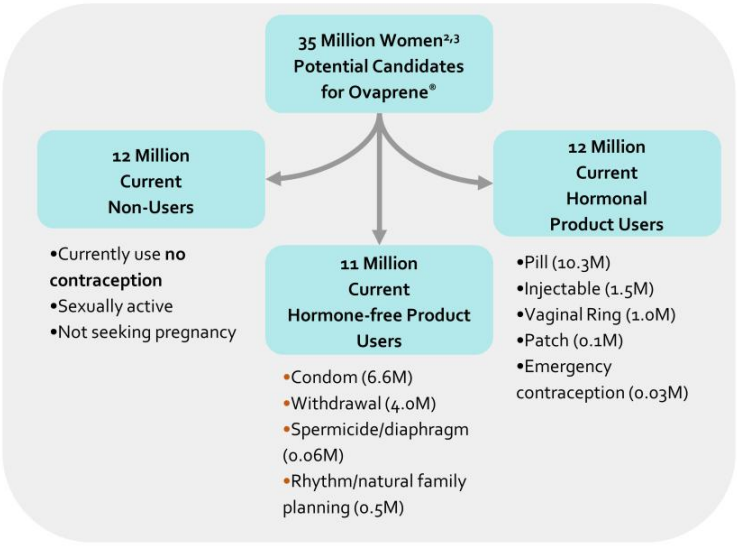
NuvaRing®

(etonogestrel/ethinyl estradiol vaginal ring)
Monthly vaginal ring
2019 worldwide sales: $879 million (Merck)[3]

1. https://www.bayer.com/en/bayer-ag-annual-report-2019.pdfx. Includes sales for Mirena®, Kyleena® and Jaydess® / Skyla®
2. https://www.prnewswire.com/news-releases/allergan-reports-fourth-quarter-and-full-year-2019-financial-results-301002646.html
3. https://s21.q4cdn.com/488056881/files/doc_financials/2019/q4/2019-Form-10-K-Final.pdf

Ovaprene® - Potential Market Opportunity

There are approximately 65 million women in the US Aged 15-44[1]



1.Source: CDC National Survey for Family Growth,2013-2015 dataset, cdc.gov.
2.Market research study conducted in 2019 for Daré Bioscience
3.Contraceptive use data applied to 2019 population data from US Census

Contraception: What's Missing from Current Hormone-Free Options?

Hormone-free Options	Pregnancies Expected (per 100 women) [1,*]
Spermicides & Vaginal Gels [2]	>27
Condoms (male)	18
Diaphragms (with a spermicide)	12
Easy-to-use monthly option	**Effectiveness approaching hormonal methods**
Copper IUD	<1

Least Effective

Most Effective

1.U.S. Food and Drug Administration Birth Control Guide dated 6/14/2021: https://www.fda.gov/consumers/free-publications-women/birth-control-chart

2.U.S. Food and Drug Administration Drug Data Prescribing information for a vaginal gel approved in 2020, Phexxi™ provides that in a multicenter, open-label, single-arm clinical trial in the U.S. (AMP002; NCT03243305), the 7-cycle cumulative pregnancy rate was 13.7% (95% CI: 10.0%, 17.5%), excluding cycles with back-up contraception, cycles <21 or > 35 days in length and cycles in which no intercourse was reported. The estimated Pearl Index, calculated based on data from the 7-cycle study, was 27.5 (95% CI: 22.4%, 33.5%). https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208352s000lbl.pdf

* Pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). For more information on the chance of getting pregnant while using a method or on the risks of a specific product, please check the product label or Trussell, J. (2011)."Contraceptive failure in the United States." Contraception 83(5):397-404.

Ovaprene® Investigational Hormone-Free, Monthly Contraceptive

Physical Barrier[6]

Three-dimensional, knitted polymer barrier

Spermiostatic Environment[6]

Contraceptive-loaded silicone ring releasing non-hormonal active Ferrous gluconate

Desired Features of Birth Control Products:[1-4]	**Design Features of Ovaprene:**[5-7]
+Efficacy	86% - 91% Expected Typical Use Effectiveness Approaching Hormone Contraception
+Hormone Free	No Hormones in the API Unique dual action MOA (spermiostatic & barrier)
+Convenience	Monthly Ring Form Women choose monthly intravaginal products for the convenience of a non-daily option
+Favorable Side Effect Profile	Safety Profile Similar to a Diaphragm No significant changes in vaginal flora and no serious adverse effects observed in studies to date
+Easily Manage Fertility	No Systemic/Long-term Activity Inserted and removed without a provider allowing for immediate return to fertility

1. https://www.urban.org/urban-wire/women-want-effective-birth-control
2. Lessard, L, Perspectives on Sexual and Reproductive Health, Volume 44, Number 3, 9-2012
3. Hooper, DJ, Clin Drug Investig. 2010;30(11):749-63
4. Ersek, J, Matern Child Health J (2011) 15:497–506
5. In PCT studies of similar size, products (diaphragms) that demonstrated no motile sperm in the cervical mucus during PCT assessments later demonstrated "typical use" contraceptive effectiveness of 86-91% in pivotal contraceptive studies evaluating pregnancy rates over six-month periods. Mauck C, Vincent K. Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437–444
6. Journal of Reproductive Medicine 2009; 54: 685-690
7. Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.

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

Premarket approval (PMA) strategy –
The Center for Devices and Radiological Health (CDRH) as lead review division

Step 1 (Completed)
•Postcoital Test (PCT) Clinical Study - Completed 4Q 2019

Step 2 (Ongoing)

1 - File investigational device exemption (IDE) 4Q2021 to support 2022 pivotal study start.

2 - Conduct pivotal study

- ~250 completers up to 12 months of use
- Primary endpoints: safety and efficacy (pregnancy probability)
- Secondary endpoints: acceptability, product fit/ease of use and assessments of vaginal health

The PCT Clinical Study Met its Primary Endpoint

Ovaprene prevented the requisite number of sperm from reaching the cervix across all women and all cycles evaluated.

•Specifically, in 100% of women and cycles, an average of less than five (< 5) progressively motile sperm (PMS) per high-powered field (HPF) were present in the midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place.

•Women enrolled in the study who completed at least one Ovaprene PCT (N=26) had a mean of 27.21 PMS/HPF in their baseline cycle (without any contraceptive device), a mean of 0.22 PMS/HPF in their diaphragm cycle (in the presence of an FDA-cleared diaphragm with spermicide), and a mean of 0.48 PMS/HPF in their Ovaprene PCT cycles (in the presence of the Ovaprene device), with a median of zero PMS.

	Mean *Progressively Motile Sperm*	Median *Progressively Motile Sperm*	Standard Deviation	Interquartile Range
Baseline PCT's	27.21	23.20	17.88	24.80
Ovaprene PCT's	0.48	0.00	1.18	0.10

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

1.Anticipated regulatory pathway and timelines.
2.Mauck C, Vincent K. Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437–444

Ovaprene® - Collaborative Research Agreement with NIH[1]

July 2021 – Daré announced that funding and clinical operations support for the Phase 3 will be provided by the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Under the CRADA

Cooperative Research and Development Agreement (CRADA) for the Pivotal Phase 3 Study

- The pivotal Phase 3 study will be supported by the NICHD's Contraceptive Development Program which oversees the Contraceptive Clinical Trial Network (CCTN) established in 1996 to conduct studies of investigational contraceptives. The Phase 3 study will be conducted within the CCTN with the NICHD contractor Health Decisions Inc.
- Daré will be responsible for providing clinical supplies of Ovaprene® and coordinating interactions with and preparing and submitting supportive regulatory documentation to the FDA.
- Under the CRADA, Daré has also agreed to contribute $5.5 million toward the total estimated cost to conduct the pivotal Phase 3 study, payable in four payments.

"This collaboration between Daré and NICHD marks an important milestone in Women's Healthcare Innovation. Women are at the center of everything we do and we are so pleased to continue to partner with Daré in support of our mission We're For Her to provide women with education and access to contraceptive options," said John Berrios, Bayer's Head of Women's Healthcare.

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

Milestones and Catalysts

Daré – Working to Accelerate Innovation in Women's Health

2019 and 2020

- ✓ Positive findings of Sildenafil Cream, 3.6% thermography clinical study
- ✓ Positive topline data for Ovaprene® postcoital test clinical study
- ✓ Exclusive licensing agreement with Bayer for Ovaprene
- ✓ Strategic partnerships with Health Decisions / Avomeen
- ✓ Grant funding for DARE-LARC1 reaches $20.5 million
- ✓ Positive topline data for DARE-BV1 Phase 3 study

2021

- ✓ Sildenafil Cream, 3.6% Phase 2b study commence
- ✓ DARE-HRT1 Phase 1 study positive topline data
- ✓ DARE-LARC1 grant of up to $48.95 M awarded, $11.45 M of which received
- ✓ Ovaprene – CRADA with NICHD for Phase 3 Study providing non-dilutive cost-sharing and operational collaboration
- ✓ DARE-BV1 NDA accepted for priority review by the FDA
- ✓ DARE-VVA1 Phase 1/2 study commence
- ✓ DARE-LARC1 – NIH grant for $309,000 awarded

Anticipated Milestones*

2021

- •DARE-BV1 NDA PDUFA target December 7, 2021
- •DARE-BV1 commercialization strategy
- •Ovaprene IDE submission

2022

- •DARE-BV1 U.S. commercial launch
- •Ovaprene pivotal Phase 3 study commence
- •DARE-FRT1 Phase 1 study commence
- •DARE-VVA1 Phase 1/2 study topline data

*Currently anticipated timing

Phase 1 and Preclinical Programs

New investigational prescription drug delivery options for women

Advancing Products Women Want – Phase 1 and Preclinical

PRODUCT CANDIDATE	PRE-CLINICAL	PHASE 1
DARE-HRT1^Hormone Therapy - **Phase 1 Study Completed**		1. First-in-category combination hormone delivery for treatment of vasomotor and vaginal symptoms of menopause. 2. Intravaginal ring (IVR) designed to release bio-identical estradiol and bio-identical progesterone over 28 days. 3. Potential to be the first convenient monthly format product with both hormones.
DARE-FRT1^Pregnancy Maintenance - **Phase 1 Study Preparation**		1. First-in-category progesterone delivery for pregnancy maintenance including the prevention of preterm birth and for luteal phase support as part of an IVF regimen. 2. IVR designed to release bio-identical progesterone over 14 days. 3. Alternative to daily IM injections or vaginal gel
DARE-VVA1^ Vulvar and Vaginal Atrophy – **Phase 1/2 Study Commenced**		1. First-in-category hormone-free vaginal treatment for vulvar and vaginal atrophy (VVA) in a hormone-receptor positive (HR+) breast cancer patient population. 2. Proprietary formulation of tamoxifen for vaginal administration. 3. Potential to be the first therapeutic specifically approved for treatment of VVA in patients with HR+ breast cancer.
DARE-LARC1^ Long-Acting, Reversible Personal Contraceptive System		Levonorgestrel-releasing, long-acting contraceptive implant that a woman can turn on and off herself, according to her own needs. Grant of up to $48.95 M to advance technology through non-clinical proof of principle to enable IND submission, and an NIH grant to explore device insertion/removal in non-clinical studies.
ADARE 204/214^ 6 & 12-Month Injectable Contraception		Novel 6 & 12-month injectable formulations of etonogestrel being developed as a longer-acting, reversible method of contraception with a more predictable return to fertility.
DARE-RH1 Male or Female Contraceptive Target		A potential new rapidly reversible, non-hormonal contraceptive solution with application for women and men.

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

Intravaginal Ring (IVR) Technology Highlights

The Vaginal Route of Drug Administration[1]

➤Vaginal drug delivery offers many potential advantages due to large surface area, dense network of blood vessels and high elasticity due to presence of smooth muscle fibers.

➤Recognized advantages include comparable ease of administration and ability to bypass hepatic first-pass metabolism.

Our IVR Technology – Design Features:

➤**Sustained** drug delivery,

➤**Variable** dosing and duration,

➤Solid ethylene vinyl acetate (EVA) polymer matrix that can contain and release one or several active drugs,

➤No need for membrane or reservoir to contain active drug(s) or control the release.

1.Sonia, T.A. & Sharma, C.P., "Routes of administration of insulin – Vaginal route," Oral Delivery of Insulin, 2014, https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/vaginal-drug-delivery

DARE-HRT1

Combination bio-identical estradiol + bio-identical progesterone 28-day IVR for hormone therapy following menopause

45M women in U.S. approaching or in menopause[1]

Hormone Therapy (HT)

HT remains the most effective treatment for vasomotor symptoms (VMS) and genitourinary syndrome of menopause (GSM), and has been shown to prevent bone loss and fracture.[2]

•The 2017 Hormone Therapy Position Statement of The **North American Menopause Society** (NAMS), supports HT in peri-and post-menopausal women.[2]

NAMS observes: **non-oral routes may offer advantages** over oral routes of administration.[2]

Completed Phase 1 STUDY

A Phase 1, Open-Label, 3-arm Parallel Group Study to Evaluate the Pharmacokinetics and Safety of DARE-HRT1 (80 µg and 160 µg Estradiol/ 4 mg and 8 mg Progesterone Intravaginal Rings) in Healthy Post-Menopausal Women.

The topline data from the study support DARE-HRT1's potential to be the first FDA-approved product to offer **vaginal delivery** of combination bio-identical estradiol and bio-identical progesterone hormone therapy in a convenient **monthly format** to treat both VMS as well as vaginal symptoms of menopause.

505(b)(2) candidate[3]

1.U.S. Census Bureau, Population Division. Table 2. 2015 to 2060 (NP2012-T2). Released Dec. 2012.

2.The 2017 hormone therapy position statement of The North American Menopause Society; Menopause: The Journal of The North American Menopause Society Vol. 24, No. 7, pp. 728-753, https://www.menopause.org/docs/default-source/2017/nams-2017-hormone-therapy-position-statement.pdf

3.Anticipated regulatory pathway. Daré has not had any communications with the FDA regarding the specific marketing approval requirements for DARE-HRT1

DARE-FRT1

Bio-identical progesterone 14-day IVR for prevention of preterm birth and luteal phase support as part of an IVF treatment plan

Prevention of Preterm Birth (PTB)

After steadily declining from 2007 to 2014[2], the US premature birth rate rose for the fourth straight year in 2018 with ~10% of babies born preterm (<37 weeks).[3]

NIH Grant Funding for DARE-FRT1 PTB Program

Potential for up to $2.3 million in NIH grant funding to support DARE-FRT1 development

- Notice of award for initial $300,000 in grant funding announced Aug 2020.
  Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health Award Number R44 HD101169.

Assisted Reproductive Technologies (ART)/IVF

As women wait longer to have children, infertility risk increases

- ~12-15% of couples cannot conceive after 1-year of unprotected sex.[4]
- ~20% of US women have their first child after age 35; ~1/3 of couples in which the woman is older than 35 years have fertility problems.[5]

Current products for delivery of progesterone for prevention of preterm birth, as well as luteal phase support in ART, are limited to daily vaginal or intramuscular injectable dosage forms, which have limitations in patient comfort, convenience, and outcomes.

DARE-FRT1 is designed to deliver bio-identical progesterone continuously over a 14-day period and is being developed as a more convenient treatment option for the prevention of preterm birth and broader luteal phase support as part of an in vitro fertilization regimen.

505(b)(2) candidate[1]

1. Anticipated regulatory pathway. Daré has not had any communications with the FDA regarding the specific marketing approval requirements for DARE-FRT1
2. 2019 March of Dimes Report Card, https://www.marchofdimes.org/mission/reportcard.aspx
3. CDC's National Center for Health Statistics, National Vital Statistics Reports, Births: Final Data for 2018, Nov 27, 2019, https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13-508.pdf
4. https://www.nichd.nih.gov/health/topics/infertility/conditioninfo/common accessed January 8, 2021
5. https://www.cdc.gov/reproductivehealth/infertility/index.htm accessed January 8, 2021
6. Harris Williams & Co. Fertility market overview. May 2015.

DARE-VVA1

Proprietary tamoxifen formulation for vaginal administration for vulvar and vaginal atrophy (VVA), a chronic condition characterized by pain during intercourse, vaginal dryness and irritation

Potential to be the first therapeutic specifically approved for treatment of VVA in patients with hormone-receptor positive (HR+) breast cancer.

- Approximately 3.8 million US women have a history of breast cancer; HR+ is the most common type.[2]
- Localized estrogen therapy for VVA may be contraindicated for women diagnosed with, or at risk of recurrence of, ER-positive and PR-positive breast cancer.
- VVA prevalence in postmenopausal breast cancer survivors is estimated at **42 to 70%.**[3]

Daré is developing this novel local application of tamoxifen to mitigate the symptoms of VVA for HR+ breast cancer patients, including women currently on anti-cancer therapy.

505(b)(2) candidate[1]

1.Anticipated regulatory pathway. Daré has not had any communications with the FDA regarding the specific marketing approval requirements for DARE-VVA1.
2.American Cancer Society, Breast Cancer Facts & Figures 2019-2020, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf
3.Clinical Breast Cancer, Dec 2017: https://www.sciencedirect.com/science/article/pii/S1526820917300952

DARE-VVA1 - Proof of Concept

This exploratory study[1] in four postmenopausal women diagnosed with VVA demonstrated that a self-administered vaginal suppository containing tamoxifen (20mg) dosed daily for one week and twice weekly for three months **was effective in reducing vaginal pH and vaginal dryness.**

Vaginal Tamoxifen	Enrollment (Baseline)	On Treatment (Month 3)	Paired Difference (Baseline vs. Month 3)
Median Vaginal pH Normal vaginal pH is usually less than 4.5.[2]	7.1 range 6.5 to 7.5	5.0 range 5.0 to 5.2	**-2.0 median** **range -2.5 to -1.5** Lower pH value is a measure of symptom relief
Vaginal Dryness Rated using a visual analogue scale (VAS) that ranged from: 0 = Not bothered by dryness 10 = Extremely bothered by dryness	8.0 range of 7.5 to 9.0	3.0 range 2.0 to 3.0	**-5.5 median** **range -6.0 to -4.5** Decreased vaginal dryness is a measure of symptom relief

In addition, systemic absorption of tamoxifen was not significant:

- After 8 weeks of study treatment with vaginal tamoxifen, median plasma concentration of tamoxifen was 5.8 ng/ml, with a range of 1.0 to 10.0 ng/ml
- In comparison, after 3 months of administration of 20mg, once-daily oral tamoxifen citrate (Nolvadex),[3] the average steady state plasma concentration of tamoxifen is 122 ng/ml with a range of 71 to 183 ng/ml

1. Clin. Exp. Obstet. Gynecol. - ISSN: 0390-6663 XLVI, n. 2, 2019
2. https://www.medicalnewstoday.com/articles/322537.php
3. US Food and Drug Administration: "Drug Approval Package: Nolvadex (Tamoxifen Citrate) NDA# 21-109.2002". Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21109_Nolvadex.cfm

DARE-VVA1 – Phase 1/2 Study

Phase 1/2 study[1] is designed to evaluate the safety, pharmacokinetics and pharmacodynamics of DARE-VVA1 in postmenopausal participants with **moderate to severe VVA** and is being conducted by the Company's wholly owned subsidiary in Australia.

- The Phase 1/2 study will evaluate different doses of DARE-VVA1, a tamoxifen vaginal insert, in approximately 40 postmenopausal women with VVA, **including a cohort of women with a history of breast cancer**.
- The study is a randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging study that will evaluate the safety, tolerability, plasma pharmacokinetics (PK) and pharmacodynamics (PD) of DARE-VVA1.
- Eligible participants will be randomly allocated to one of five treatment groups (approximately 8 participants per group) that will evaluate four dose levels (1 mg, 5 mg, 10 mg, and 20 mg) and a placebo.
- Following a screening visit, DARE-VVA1 will be self-administered intravaginally once a day for the first two weeks, and then twice a week for the following six weeks for a total treatment period of 56 days.
- In each treatment group, participants will have serial blood sampling for PK analysis and undergo safety evaluations and preliminary assessments of effectiveness. Following the completion of the treatment period, participants will attend a safety follow-up visit.

The primary endpoints of the study will evaluate the **safety and tolerability** of DARE-VVA1 by vaginal administration and determine the plasma PK of DARE-VVA1 after intravaginal application.

Secondary endpoints will evaluate **preliminary efficacy** and PD of DARE-VVA1 in terms of most bothersome symptom and changes in vaginal cytology and pH.

1. https://ir.darebioscience.com/news-releases/news-release-details/dare-bioscience-initiates-phase-12-clinical-study-dare-vva1

DARE-LARC1

Long-Acting, Reversible Personal Contraceptive System – levonorgestrel-releasing implant drug delivery system designed to store and precisely deliver hundreds of therapeutic doses over years that a woman can turn on and off herself, according to her own needs, without further healthcare provider intervention.

Through June 2021

Define, develop, and evaluate the product concept

- Prototypes developed
- Market research conducted to evaluate the target product profile
- Demonstrated multiple drug releases *in vivo*

June 2021 – Nov. 2026

Grant of up to $48.95 M to advance technology through non-clinical proof of principle to enable IND submission

- Funding is intended to advance development of the technology
- Conduct preclinical activities and proof of principle studies
- IND enabling work to allow for IND submission

September 2021-2022

NIH grant of ~$300,000 to explore device insertion/removal in non-clinical studies

505(b)(2) candidate[1]

1. Anticipated regulatory pathway. Daré has not had any communications with the FDA regarding the specific marketing approval requirements for DARE-LARC1

Financial Summary

Daré Financial Summary

1H-2021 Financial Highlights:

- Cash provided from financing activities during 6 months ended 6/30/21: $24.6 million (net)
- Cash and equivalents at 6/30/2021: $9.1 million

July 1 - August 10, 2021 Update:

- Cash provided from financing activities: $25.4 million (net)
- DARE-LARC1 grant: Total award for up to $48.95 million; $11.45 million cash payment received in July
- Common shares o/s: 70.5 million shares
- Warrants o/s: 1.9 million

Funding sources:

- Since inception, we have raised cash through sale of equity securities, M&A transactions, warrant and option exercises, non-dilutive grants, and license fees
- We endeavor to be creative and opportunistic in seeking capital required to advance our candidates, and to be efficient in use of such capital

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