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): February 16, 2021

DARÉ BIOSCIENCE, INC. (Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-36395 (Commission File Number)

20-4139823 (I.R.S. Employer

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

	(total name of former address, it changed since tast reports)							
Che	ck 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))							
Sec	urities 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 and its product candidates, dated February 16, 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 February 16, 2021.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 <u>Corporate presentation, dated February 16, 2021</u>

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: February 16, 2021

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



NASDAQ: DARE www.darebioscience.com

Daré Bioscience

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

©2021 Daré Bioscience | All rights reserved

Corporate Presentation: February 16, 2021

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 "MAX," "WILL," "EXPECT," "PLAN," "ANTICIPATE," "STRATEGY," "DESIGNED," "COULD," "INTEND," "BELIEVE," "ESTIMATE," TARGET," OR "POTENTIAL" AND OTHER SIMILAR EXPRESSIONS, OR THE NEGATIVE OF THESE TERMS. AS USED IN THIS PRESENTATION, "FIRST-IN-CATEGORY" IS A FORWARD-LOOKING STATEMENT REGARDING MARKET POTENTIAL OF A PRODUCT CANDIDATE. FORWARD-LOOKING STATEMENTS 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 RELATING TO: THE OUTCOME OR SUCCESS OF CLINICAL TRIALS; DARÉ'S ABILITY TO RAISE ADDITIONAL CAPITAL AS NEEDED; DARÉ'S ABILITY TO OBTAIN AND MAINTAIN INTELLECTUAL PROPERTY PROTECTION FOR ITS PRODUCT CANDIDATES; DARÉ'S ABILITY TO DEVELOP AND OBTAIN REGULATORY APPROVAL OF PRODUCT CANDIDATES ON THE TIMELINES SET FORTH HEREIN; INCLUDING DUE TO THE EFFECT, IF ANY, THAT COVID-19 MAY HAVE THEREON; AND OTHER RISK FACTORS DESCRIBED IN DARÉ'S MOST RECENT ANNUAL REPORT ON FORM 10-K AND QUARTERLY REPORT ON FORM 10-Q FILED WITH THE

ALL FORWARD-LOOKING STATEMENTS IN THIS PRESENTATION ARE CURRENT ONLY AS OF THE DATE HEREOF AND DARÉ DOES NOT UNDERTAKE ANY OBLIGATION TO UPDATE ANY FORWARD-LOOKING STATEMENT 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.



Daré Bioscience - A Compelling Opportunity



Daré Bioscience is a clinical-stage biopharmaceutical company committed to advancing innovative products for women's health. The company's mission is to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Company Highlights

- ✓ June 2019 Positive findings of Sildenafil Cream, 3.6% thermography clinical study
- ✓ Nov. 2019 Positive topline data for Ovaprene® postcoital test clinical study
- ✓ Jan. 2020 Exclusive licensing agreement with Bayer for Ovaprene
- ✓ May/Sept 2020 Strategic partnerships with Health Decisions / Avomeen
- ✓ Sept. 2020 Bill & Melinda Gates Foundation grant funding for DARE-LARC1 reaches \$20.5 million
- ✓ Dec. 2020 Positive topline data for DARE-BV1 Phase 3 study

Anticipated Clinical & Regulatory Milestones*

2021 □ NDA submission to FDA for DARE-BV1
□ Topline data for DARE-HRT1 Phase 1 study
□ PDUFA date for DARE-BV1^
□ Topline data for Sildenafil Cream, 3.6% for FSAD Phase 2b study
2022 □ U.S. commercial launch of DARE-BV1
□ Data from Ovaprene pivotal Phase 3 study

Timeline reflects management's current estimates and constitutes a forward-looking statement subject to qualifications noted elsewhere in this presentation.



Women's Health Is Our Sole Focus



Working to accelerate innovative product options in women's health by...

- Identifying and advancing new therapies that provide additional choices
- · Enhancing outcomes
- · Improving ease of use

We look for...

- Differentiated investigational products with attractive market opportunities + unmet medical needs
- Proof-of-concept and/or ability to leverage a 505(b)(2) regulatory pathway
- First-in-category or first-line opportunities
- Personalized for women with novel, convenient routes of administration.



Partnering to Accelerate Innovation



We partner to...

Accelerate exciting new products

Develop new solutions to address persistent unmet needs

Become a pipeline resource for large and emerging commercial companies

Drive innovation

We partner with...







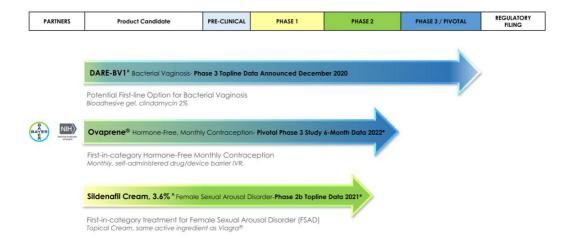






Advancing Products Women Want



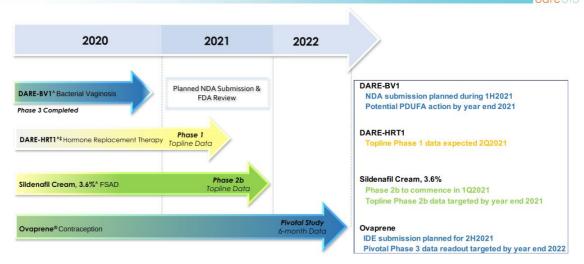


Triville reflects ranagement's current estimates and constitutes a forward fooling statement solder to qualifications noted determine in the presentation. Actual development timelines may be substantially longer, and Dark in under no obligation to update or review these estimates. "First-interactive control and the present control and the p



Near Term Catalysts to Drive Value





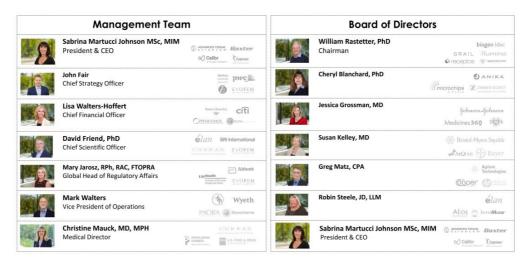
DARE-BV1 NDA filing and two top-line data readouts expected during 2021

reline reflects management's current estimates and constitutes a forward-fooding statement subject to qualifications noted elsewhere in this generation. Actual development timelines may be substantially longer, and Due is under no obligation to applies or review these estimates. "Exit-invegent's statements are forward-fooding statements relation to annualize outside to administration statement relations to mainter constituted in the product conditions to produce the production statement relations to mainter constituted in forward statements relation to mainter constituted in forward statements. Text-invegent statements relation to mainter constituted in forward statements relation to mainter constituted in forward statements. Text-invegent statements relation to mainter constitute of the production of the produ



Experienced Management & Board of Directors





We are delivering innovation by daring to be different®







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

Expect pre-NDA meeting with FDA early 2021, planned **NDA submission 1H 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 US¹
- Current Rx suboptimal: clinical cure rates of 37-68%



Bacterial Vaginosis increases health risk³

- 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



Bacterial vaginosis product data: http://www.clndesse.com/pdf/Pi.pdf: http://www.accessdata.fda.gov/drupsatfda_docs/label/2014/205223s000lbi.pdf; http://www.accessdata.fda.gov/drupsatfda_docs/label/2014/20523s000lbi.pdf; http://www.accessdata.gov



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



	Product	Frequency, Dose, and Route of Administration	Study Descriptions		Clinical Cure Rates	
			Randomized Placebo-Controlled Phase 3 Trial ¹			
1				Topline data		
	DARE-BV1 (Investigational)	1 time, 5g applicator, applied vaginally	DARE-BVFREE (Day 21-30)	DARE-BV1 (N=121)	70.2%	
rébic	(clindamycin phosphate vaginal gel, 2%)		Modified-Intent-to-Treat Population at 21-30 Days	Placebo (N=59)	35.6%	
COIL			DARE-BVFREE (Day 7-14)	DARE-BV1 (N=121)	76.0%	
			Modified- Intent-to-Treat Population at 7-14 Days	Placebo (N=59)	23.7%	
			DARE-BVFREE (Day 21-30)	DARE-BV1 (N=101)	77.2%	
			Per Protocol Population at 21-30 Days	Placebo (N=47)	42.6%	
			DARE-BVFREE (Day 7-14)	DARE-BV1 (N=101)	81.2%	
			Per Protocol Population at 7-14 Days	Placebo (N=47)	29.8%	
*1	Two Randomized, Placebo-Controlled Phase 3 Studies ²					
i.	Solosec®	1 time, 2g dose, taken orally	Study 1 (Day 21-30)	SOLOSEC (N=62)	67.7%	
UPIN	(secnidazole 2g oral granules)		Modified-Intent-to-Treat Population at 21-30 Days	Placebo (N=62)	17.7%	
			Study 2 (Day 21-30)	SOLOSEC (N=107)	53.3%	
			Modified-Intent-to-Treat Population at 21-30 Days	Placebo (N=57)	19.3%	
			Study 2 (Day 7-14)	SOLOSEC (N=107)	57.9%	
			Modified- Intent-to-Treat Population at 7-14 Days	Placebo (N=57)	24.6%	
			Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study ³			
rrigo	Clindesse*	1 time, 5g applicator, applied vaginally	Study 1 (Day 21-30)	Clindesse (N=78)	41.0%	
	(clindamycin phosphate vaginal cream, 2%)		Modified-Intent-to-Treat Population at 21-30 Days	Placebo (N=66)	19.7%	
			Randomized, Investigator-Blind, Active-Controlled Comparative Study			
			Study 2 (Day 21-30)	Clindesse Single Dose (N=221)	53.4%	
			Modified-Intent-to-Treat Population at 21-30 Days	Clindamycin Vaginal Cream, 7 doses (N=211)	54.0%	
			Study 2 (Day 21-30)	Clindesse Single Dose (N=126)	64.3%	
			Per Protocol Population at 21-30 Days	Clindamycin Vaginal Cream, 7 doses (N=125)	63.2%	
eltis	Nuvessa™	1 time, 5g applicator, applied vaginally	Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study 4			
	(metronidazole vaginal gel 1.3%)		Study 1 (Day 21-30)	NUVESSA (N=292)	37.0%	
				Vehicle Gel (N=285)	26.7%	
			Study 1 (Day 7)	NUVESSA (N=292)	41.1%	
				Vehicle Gel (N=285)	20.0%	

^{1.} Data on file



[.] Nuvessa PRESCRIBING INFORMATION https://www.nuvessa.com/nuvessa-files/Nuvessa%20P1%202018-08.pd

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:

- 70% at Day 21-30 (primary endpoint) and 76% at Day 7-14 in the mITT population, and rates of 77% 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
 diagnosed in the 12 months before they were randomized into the study
 (75% of the ITT population).³
- We expect pre-NDA meeting with FDA early 2021 and NDA submission 1H 2021
- NDA may qualify for priority review and, if granted, receive a 2021 PDUFA date, permitting potential 2022 commercial launch in the U.S.



QIDP and Fast Track designations support request for Priority Review



Based on topline data from the Phase 3 DARE-BYFREE study and the prescribing information for currently marketed product

per protocol population (N=148) includes subjects from the miTT population who have no major protocol violations that impact the primary or secondary endoports or who received any other bacclear degrees the resource of the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary or secondary endoports or who received any other bacclear degrees the primary of the primary or secondary endoports or who received any other bacclear degrees the primary of the primary or secondary endoports or who received any other bacclear degrees the primary of the primary or secondary endoports or who received any other bacclear degrees the primary of the primary of the primary of the primary of the primary or secondary endoports or who received any other bacclear degrees the primary of the primary of



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®



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 N/TR), defines female sexual arousal disorder as a pensistent or recurrent inability to attain or to maintain until completion of the sexual activity, an adequate lubrication-swelling respon 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 continue.

https://drgeo.com/womens-sexual-health-overview/;
 https://health.usnews.com/conditions/sexual-disorder-dysfunctions/sexual-dysfunc



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%.

Market research estimates:

- 33% of US women aged 21 to 60 (~ 20 million women), experience symptoms of low or no sexual arousal.²³
- 10 million women are considered distressed and actively seeking treatment.²





McCool et al. Sex Med Rev 2016;4:197-212.
 Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.

Sildenafil Cream, 3.6% - Product Profile



Topically administered investigational Sildenafil Cream¹ 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



Sildenafil Cream, 3.6% - Phase 2b



The planned 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 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.









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





Ovaprene® - Commercial License Agreement with Bayer¹





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 doubledigit, 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.

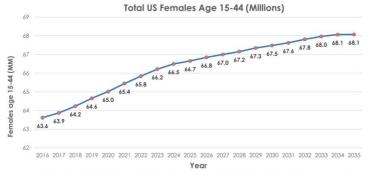
https://www.mirena-us.com/; supported by 2014-2016 SHS data.
https://ir.darebioscience.com/news-releases/news-release-details/baver-and-dare-bioscience-announce-exclusive-licensing-agreemen



Contraception: Large Market Opportunity



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



Successful Contraceptive Brands



Mirena® Hormone IUD (levonorgestrel-releasing intrauterine system) 52mg Physician inserted, long-acting. Iow/locally delivered hormone IUS 2019 worldwide sales: €1.2 billion (Bayer)



rone 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



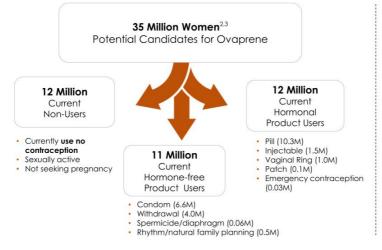
(etonogestrel/ethinyl estradiol vaginal ring)
Monthly vaginal ring
2019 worldwide sales: \$879 million (Merck)³



Ovaprene® - Potential Market Opportunity



There are approximately 65 million women in the US Aged 15-441



30 Million Women^{2.3}
Not candidates for
Ovaprene

Sterilization (10.5M)
Pregnant/postpartum/
seeking pregnancy (5.6M)
Never had intercourse
(8.2M)
Current LARC (IUD or implant) user (5.4M)



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





^{1.} U.S. Food and Drug Administration. Birth Control Guide dated 2/11/2020: https://www.fda.gov/consumers/free-publications-women/birth-control-chart

Programs, raises tell you the number of programsies expected per 1,00 women during the first year of bypical use. Typical uses shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or represent). For more priormation on the chapter of metrils to represent white insurance, in conduct, release of the first perfect and in the chapter of metrils to the IT states. II. 2013/1.17.07.04.04.



U.S. Food and Drug Administration Drug Data Prescribing information for a recently approved vaginal get, Phiexin^{III} provides that in a multicenter, open-label, single-arm clinical trial in the U.S. (AMPOXI2: NCT03243305), the 7-cycle cumulative pregnancy rate was 73.7% (69% Ct. 12.0%, 17.5%), exclusing cycles with back-up contraception, cycles <2 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% Ct. 22.4 33.5%), https://www.accessdata.fda.gov/drugsatified.gov/carbales/02/02/03825/20000BL.pdf

Ovaprene® Investigational Hormone-Free, Monthly Contraceptive



Desired Features of Birth Control Products:1-4	Design Features of Ovaprene:5-7	Phy:
+ Efficacy	86% - 91% Expected Typical Use Effectiveness Approaching Hormone Contraception	barrie
+ Hormone Free	No Hormones in the API Unique dual action MOA (spermiostatic & barrier)	
+ Convenience	Monthly Ring Form Women choose monthly rings 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	Spe
+ Easily Manage Fertility	No Systemic/Long-term Activity Inserted and removed without a provider allowing for immediate return to fertility	Cont relea Ferro

Barrier 6 ensional, knitted polymer



static Environment ptive-loaded silicone ring non-hormonal active uconate





Early-Stage Portfolio

Innovative prescription drug delivery programs

DARE-HRT1

DARE-FRT1

DARE-VVA1

DARE-LARC1

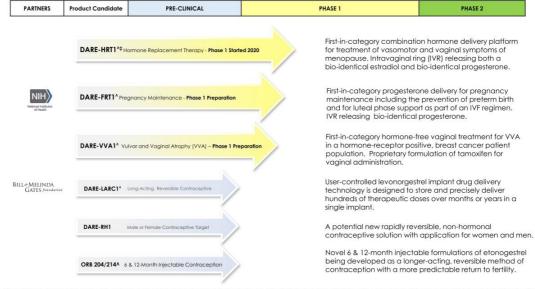
DARE-RH1

ORB 204 & 214



Advancing Products Women Want





reliner reflects management's current estimates and constitutes a forward-looking statement subject to qualification noted elsewhere in this presentation. Actual development timelines may be substantially longer, and Daré is under no obligation to update or review these estimates. "First-in-category" tements are forward-looking statements reliefung to marker operated in Care's posted concretely available. (First-port operations) part of the presentation of the p



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: 1-7



Licensed Ovaprene from Daré Bioscience. 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.



AbbVie \$63 billion acquisition of Allergan plc (creates women's health franchise - Lo Loestrin, Liletta and Elagolix).

astellas

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



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



Spinoff Organon, a new firm focused on women's health (including NuvaRing) and other drugs with projected revenues of \$6-\$6.5 billion (expected completion in 2021).



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

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



Appendix







DARING TO BE DIFFERENT® AND ADVANCING PRODUCTS WOMEN WANT

NASDAQ: DARE www.darebioscience.com





DARE-BV1- Phase 3 Study Design & Demographics¹



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)² population 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 \geq 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 diagnosed 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 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

oint: Clinical Cure (Day 21-30 visit): Resolution of the abnormal vaginal discharge associated with 8V; Negative 10% KOH "whilf test"; Clue cells < 20% of the total epithelial cells in the saline wet mount. adpoints: Proportion of subjects with Clinical Cure, Bacteriological Cure and Therapeutic Cure at Day 7-14 Visit ondary endpoints: Proportion of subjects with Clinical Cure, B eriological Cure: a Nugent score < 4. apeutic Cure: both a Clinical Cure and Bacteriological Cure.



DARE-BV1- Phase 3 Study Topline Results



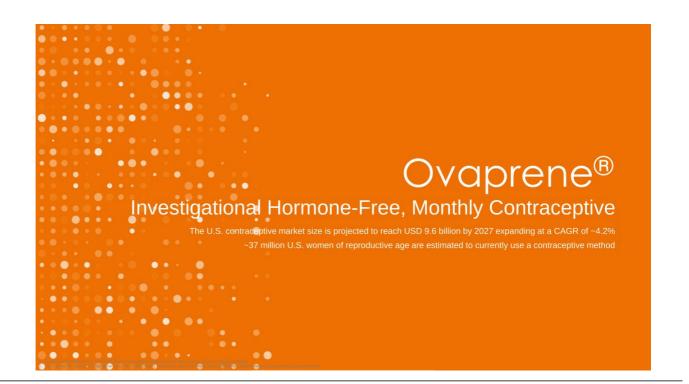
- The study's primary endpoint was clinical cure of bacterial vaginosis determined at Day 21-30 visit in the modified intent-to-treat (mITT) study population (N=180). $^{\rm 1}$
- The study met its primary endpoint, demonstrating single administration of DARE-BV1 proved statistically superior to placebo (p-value < 0.001) at Day 21-30 visit.
- DARE-BV1 also demonstrated statistically significant efficacy in all five pre-specified secondary efficacy assessments.
- Summary of clinical cure results (mITT population), p-value < 0.001:

DARE-BVFREE Phase 3 Study	DARE-BV1 (N = 121)	Placebo (N = 59)
Clinical Cure at Day 7-14 visit	76.0%	23.7%
Clinical Cure at Day 21-30 visit (primary endpoint)	70.2%	35.6%

DARE-BV1 was well tolerated in the study.







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) Study - Completed 4Q 2019

Step 2 (Ongoing)

- File investigational device exemption (IDE) to support 1Q2022 pivotal study start.
- Conduct pivotal study
 Six-month efficacy and safety data expected by yearend 2022
- ~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

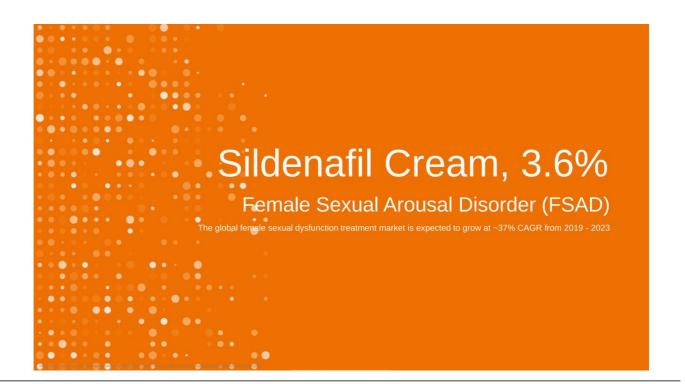
The PCT Clinical Study Met its Primary Endpoint 2

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 Progressives Alories 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



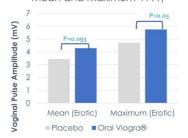


Oral Sildenafil provided a compelling proof of concept for FSAD



Statistically significant increases in Vaginal Pulse Amplitude (VPA)

Pfizer VPA Clinical Lab Study – Oral Viagra Mean and Maximum VPA†

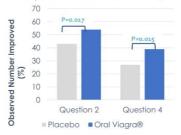


† Twelve healthy premenopausal women were studied.

Statistically significant improvement in genital stimulation (FIEI)²

Pfizer Clinical Field Study - Oral Viagra

Improvement on FIEI Questions†



Kev Takeaways of Viaara® 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 o alternative delivery options including a topical route of administration.

Female Intervention Efficacy Index (FIEI)

↑ Question #2 - "After toking study medication, the sensotion/feeling in my genital (vaginal, labia, cliticis) area during infercourse or stimulation (foreglacy) seemed to be (10) more than before, to [les 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; wasse than before taking study medication, (c) unchanged; no difference, or (d) pleasant; but still not like it used to be or I would like if to be." 202 pastmenopaoust women with \$5.40 who had protocal specified estradia and free lestastence concentrations, and/or were receiving estragen and/or androgen replacement them.





Sildenafil Cream, 3.6% - Phase 1/2a 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.

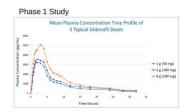
- Sildenafil Cream had significantly lower systemic exposure compared to a 50 mg oral sildenafil dose
 - AUC 3-6%
 C_{max} 1-2%
- Sildenafil Cream was safe and well tolerated at clinically relevant doses (1-2g)
- Favorable product characteristics as self-reported by subjects

 - Easy to use
 Readily absorbed

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

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.

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





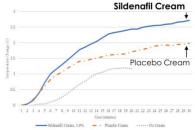
Sildenafil Cream, 3.6% - Thermography Study Review



Positive Data- (See Figure 1)

- Positive cognitive arousal responses were noted.
- Significantly greater increases in genital temperature after application of Sildenafil Cream compared to placebo cream and no 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=0)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.





Intravaginal Ring Technology (IVR) Highlights



The Vaginal Route of Drug Administration



- 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 Intravaginal Ring (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.



DARE-HRT1



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





★ 45M women in U.S. approaching or in menopause

Hormone Replacement Therapy (HRT)

HRT 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 HRT in peri-and post-menopausal

NAMS observes: non-oral routes may offer advantages over oral routes of administration.

Ongoing Phase 1 VMS/HRT 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.

505(b)(2) candidate3





DARE-FRT1



Bio-identical progesterone 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, 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 Stutiver Notional Institute of Child Health A Human Development of the Notional Institutes of Health Award Number R44 HD101149.

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.
- ~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 ferlility problems.⁵



505(b)(2) candidate





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 vulvar and vaginal atrophy (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 patients HR+ breast cancer, including women currently on anti-cancer therapy.

505(b)(2) candidate



DARE-VVA1 Proof of Concept



This exploratory study¹ 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, 2015

S 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.cfr





DARE-LARC1: Design Features of the Technology



User-Controlled Long-Acting Reversible Contraception

Drug Storage

- Individual doses stored in micro-reservoir arrays
- Reservoirs are hermetically sealed at room temperature
- Thin membranes over each reservoir protect drug post-sealing

• Drug Release

- Drug doses initiated automatically on schedule or wirelessly on-demand by the patient
- Reservoirs are opened via electrothermal ablation of membranes
- Upon opening, interstitial fluid diffuses in and drug diffuses out

505(b)(2) candidate

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



DARE-LARC1 Grant Funding



The Bill & Melinda Gates Foundation has strong interest in family planning

~215 million women in developing countries lack access to contraception

Funding 2013

Grant to understand user needs and define the product concept

Favorable response from Sub-Saharan Africa

- Sub-dermal implant use is growing

- 87% of women surveyed said they would use the proposed implant

- 74% of healthcare workers said they would use the proposed implant in their practice

Funding 2014 - 2021

Grant to develop implant concept and technology

Currently executing a 4th supplemental grant funding to demonstrate multiple drug releases in vivo, after successfully completing additional market research and concept development in the 3rd supplemental grant





Daré Financial Summary



Q3-2020 Financial Highlights:

- Cash provided from financing activities* through 9/30/20: \$16.7 million (net)
- Cash and equivalents (as of 9/30/20): \$5.4 million

Updates from October 1 to November 11, 2020:

- Cash provided by sales of stock: \$4.5 million (net)
- · Common shares o/s: ~ 38 million
- 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



 $^{^{*}}$ Financing activities during the period included sales of stock, warrant exercises and proceeds from a PPP loan.

Non-Dilutive Funding Sources



Grant funding:

- \$1.9 million grant for Ovaprene R&D expenses from Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of National Institutes of Health (NIH).
- \$20.5 million grant funding from Bill & Melinda Gates Foundation (2013-2021) to support development of DARE-LARC1.
 - September 21, 2020 Daré announced receipt of the final ~ \$0.9 million in funding under the current grant from Bill & Melinda Gates Foundation.
- · Potential for up to \$2.3 million grant from NIH to be awarded in phases to support the DARE-FRT1 program. 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 Heal

Cost optimization and value creation through partnerships and affiliates:

- · Health Decisions, a CRO specializing in women's health; agreement will provide dedicated resources and new pricing structures, which with Health Decisions' expertise and established relationships, should accelerate development of key programs in a capital-efficient manner.
- Avomeen, an accredited, independent contract R&D and manufacturing organization specializing in chemical analysis and product development; our agreement provides a preferred discounted price structure and access to Avomeen's scientific expertise, including advanced instrumentation and development techniques.
- Australia's R&D tax incentive currently allows refundable cash credit of up to 43.5% of investments made by eligible companies in eligible R&D activity. We intend to apply for the maximum amount allowable under our DARE-HRT1 program.









DARING TO BE DIFFERENT® AND ADVANCING PRODUCTS WOMEN WANT

NASDAQ: DARE www.darebioscience.com

