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): April 8, 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 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

	(
Che	k 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	rities 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				
	ate 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 (§240.12b-2 of this chapter).				

Emerging growth company \square 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 April 8, 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 April 8, 2021.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 <u>Corporate presentation, dated April 8, 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: April 8, 2021

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





NASDAQ: DARE www.darebioscience.com

Daré Bioscience

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

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Corporate Presentation: April 8, 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," "BELLIEVE," "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 STATEMENT SINVOLVE 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

- ✓ Diverse pipeline including four clinical development stage candidates
- ✓ Independent outcomes product candidates utilize different APIs and target different indications
- ✓ Large market potential first-line and first-in-category product opportunities
- √ 505(b)(2) FDA pathway planned for multiple candidates novel delivery of well-characterized APIs to address unmet needs
- ✓ Commercial value in women's health evidenced by recent transformational pharma transactions

Anticipated Program Milestones*

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



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

* Would require a priority review designation from the FDA DARE-BV1 has Fast Track and Qualified Infectious Disease Product designations from the FDA for treatment of bacterial vaginosis.

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 with Industry Leaders



We partner to...

Drive innovation and develop new solutions

Accelerate novel products to address persistent unmet needs

Become a pipeline resource for large and emerging commercial companies

We partner with...











Advancing Products Women Want



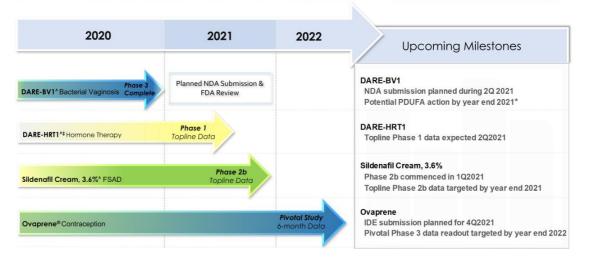


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Near Term Catalysts to Drive Value





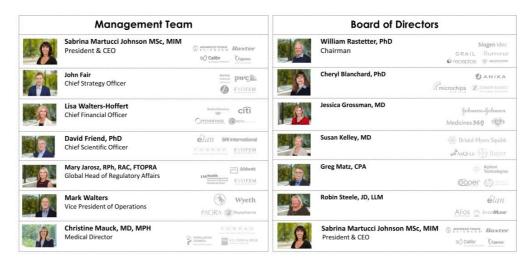
DARE-BV1 NDA filing and two top-line data readouts targeted for 2021

meline reflects management's current estimates and constitutes a forward-locking statement subject to qualifications noted elsewhere in this presentation. Actual development timelines may be substantially longer, and Daré is under no obligation to update or review these estimates. *Would require



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

Planned NDA submission 2Q 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



Bacteria vaginosis product data: http://www.clindesse.com/pdfPLpdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/2052238000bl.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223800bl.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223800bl.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223800bl.pdf; http://www.accessdata.fda.gov/d



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 Topline data			
Ф	DARE-BV1 (Investigational) (clindamycin phosphate vaginal gel, 2%)	1 time, 5g applicator, applied vaginally	DARE-BVFREE (Day 21-30) Modified-Intent-to-Treat Population at 21-30 Days	DARE-BV1 (N=121) Placebo (N=59)	70.2% 35.6%	
darébio			DARE-BVFREE (Day 7-14) Modified- Intent-to-Treat Population at 7-14 Days	DARE-BV1 (N=121) Placebo (N=59)	76.0% 23.7%	
			DARE-BVFREE (Day 21-30) Per Protocol Population at 21-30 Days	DARE-BV1 (N=101) Placebo (N=47)	77.2% 42.6%	
			DARE-BVFREE (Day 7-14) Per Protocol Population at 7-14 Days	DARE-BV1 (N=101) Placebo (N=47)	81.2% 29.8%	
	Two Randomized, Placebo-Controlled Phase 3 Studies ²					
LUPIN	Solosec [®] (secnidazole 2g oral granules)	1 time, 2g dose, taken orally	Study 1 (Day 21-30) Modified-Intent-to-Treat Population at 21-30 Days	SOLOSEC (N=62) Placebo (N=62)	67.7% 17.7%	
			Study 2 (Day 21-30) Modified-Intent-to-Treat Population at 21-30 Days	SOLOSEC (N=107) Placebo (N=57)	53.3% 19.3%	
			Study 2 (Day 7-14) Modified- Intent-to-Treat Population at 7-14 Days	SOLOSEC (N=107) Placebo (N=57)	57.9% 24.6%	
			Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study ³			
	Clindesse*	1 time, 5g applicator, applied vaginally	Study 1 (Day 21-30)	Clindesse (N=78)	41.0%	
Perrigo	(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) Modified-Intent-to-Treat Population at 21-30 Days	Clindesse Single Dose (N=221) Clindamycin Vaginal Cream, 7 doses (N=211)	53.4% 54.0%	
			Study 2 (Day 21-30) Per Protocol Population at 21-30 Days	Clindesse Single Dose (N=126) Clindamycin Vaginal Cream, 7 doses (N=125)	64.3% 63.2%	
	Nuvessa™	1 time, 5g applicator, applied vaginally	Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study 4			
Exeltis	(metronidazole vaginal gel 1.3%)	, -g -p	Study 1 (Day 21-30)	NUVESSA (N=292) Vehicle Gel (N=285)	37.0% 26.7%	
			Study 1 (Day 7)	NUVESSA (N=292) Vehicle Gel (N=285)	41.1% 20.0%	

^{1.} Data on file



SOLOSEC PRESCRIBING INFORMATION https://doilymed.nlm.nih.gov/doilymed/ida/IdaDrugXsi.cfm?setid=551e43d5-f700-4d6e-8029-026f8a8932ff8.type=display

Clindesse PRESCRIBING INFORMATION https://www.clindesse.com/pdf/Pl.pdf
NUVessa PRESCRIBING INFORMATION https://www.nuvessa.com/pu/vessa.flex/Nuvessa520PP5202018-08

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
- Based on pre-NDA meeting with FDA early 2021, targeting NDA submission by end of 2Q2021.
- NDA may qualify for priority review and, if granted, receive a 2021 PDUFA date, permitting potential 2022 commercial launch in the U.S.



Supports request for Priority Review

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

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 bacterial wagness thereone. It has been supported by the 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 bacterial wagness thereone.





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.*

FSAD



HSDD

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 arounal disorder as a pensistent or recurrent inability to attain or to maintain until completion of the sexual activity, an adequate lubrication-ewelling response of sexual excitement. The diagnostic orderia 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.

https://drgeo.com/womens-sexual-health-overview/;
 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%.

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





^{2.} Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LL



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



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.









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

Partnered with





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.

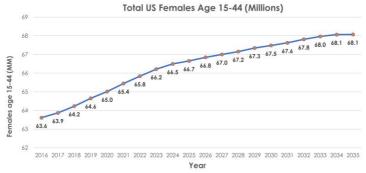
https://ir.darebioscience.com/news-releases/news-release-details/baver-and-dare-bioscience-announce-exclusive-licensing-agreemen



Contraception: Large Market Opportunity



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



Successful Contraceptive Brands 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)



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



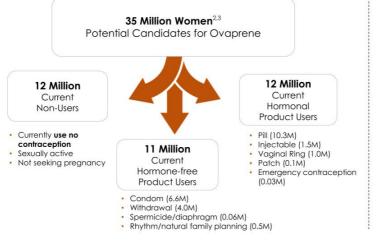
Monthly vaginal ring 2019 worldwide sales: \$879 million (Merck)³



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-chail

Programory 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 insistent). For more information on the chance of getting regnant within using a method or not her insists of a specifier product, please check the product label or Trussel, J. (2011). "Scientification" in the United States." Contraceptive failures in the United States."



U. S. Food and Drug Administration Drug Data Prescribing information for a recently approved vaginal pal, Phiexxi™ provides that in a multicenter, open-label, single-arm clinical final in the U.S. (AMPOIZ; NCT00243309), the 7-cycle cumulative programory rate was 73.7% (69% Ct: 10.0%, 17.5%), excluding 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.accessdatast.da.gov/drugsatista/scoordalabe/2020/20332/200001bi.ddf

Ovaprene® Investigational Hormone-Free, Monthly Contraceptive



Desired F	eatures of Birth Control Products:1-4	Design Features of Ovaprene:5-7	Physical Barrier 6 Three-dimensional, knitted polymer
+ Effice	асу	86% - 91% Expected Typical Use Effectiveness Approaching Hormone Contraception	barrier barrier
+ Horm	none Free	No Hormones in the API Unique dual action MOA (spermiostatic & barrier)	
+ Con	venience	Monthly Ring Form Women choose monthly intravaginal products for the convenience of a non-daily option	
+ Favo	orable 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	Spermiostatic Environment Contraceptive-loaded silicone ring
+ Easily	y Manage Fertility	No Systemic/Long-term Activity Inserted and removed without a provider allowing for immediate return to fertility	releasing non-hormonal active Ferrous gluconate





Early-Stage Portfolio

Innovative prescription drug delivery programs

DARE-HRT1

DARE-FRT1

DARE-VVA1

DARE-LARC1

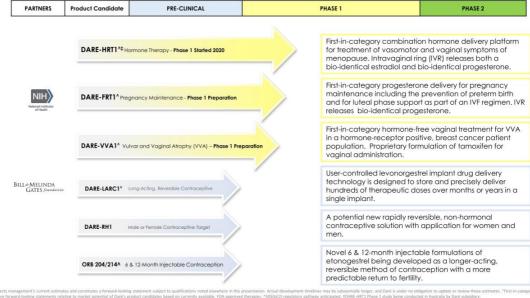
DARE-RH1

ORB 204 & 214



Advancing Products Women Want







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 Bloscience. 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 relugalik 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

- https://www.businesswire.com Dare Bioscience
- https://www.businesswire.com KaNDy-Therapeutics-Ltd
- 8. http://www.pharmatimes.com_acquisition_of_allergan
- 4. https://www.biopharmadive.com/news/astellas-ogeda-womens-health-deal
- 5. https://www.globenewswire.com The-Cooper-Companies-Announces-Definitive-Agreement-to-Acquire-PARAGARD-IUD-From Teva.
- https://www.gobenewswire.com ine-Cooper-Companies-Announces-Definitive-Agreement-to-Acquire-Puts.
 https://www.statnews.com merck-to-spin-off-new-6-5-billion-firm-focused-on-womens-health-older-drugs/
- https://www.statnews.com_merck-to-spin-off-new-6-5-billion-firm-focused-on-womens-health-older-drugs/
 https://www.nfizer.com/news/nress.release/nress.release.detail/myovant-sciences.and-off-zer.announce-collaboration-develor



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

coint: Clinical Cure (Day 21-30 visit): Resolution of the abnormal vaginal discharge associated with BV; Negative 10% KOH "whilf test"; Clue cells < 20% of the total epithelial cells in the saline wet mount. indpoints: Proportion of subjects with Clinical Cure, Bacteriological Cure and Therapeutic Cure at Day 7-14 Visit ndary endpoints: Proportion of subjects with Clinical Cure, Beriological Cure: a Nugent score < 4.

speutic 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® Investigational Hormone-Free, Monthly Contraceptive

The U.S. contraceptive market size is projected to reach USD 9.6 billion by 2027 expanding at a CAGR of ~4.2%

~37 million U.S. women of reproductive age are estimated to currently use a contraceptive method

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

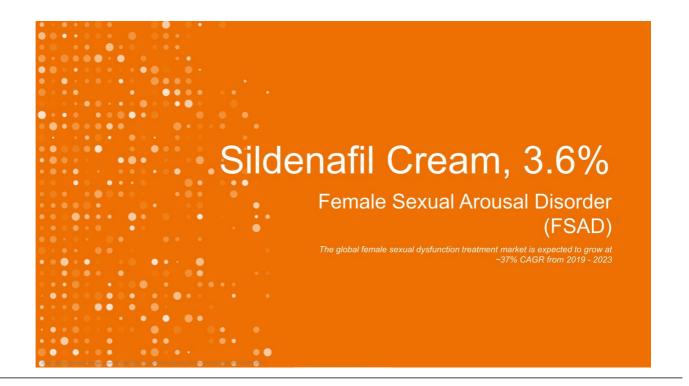
The PCT Clinical Study Met its Primary Endpoint 2

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 Spress	Median Progressively Alexin Sperin	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



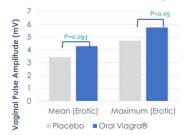


Oral Sildenafil provided a compelling proof of concept for FSAD



Statistically significant increases in Vaginal Pulse Amplitude (VPA)

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

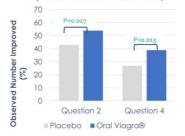


† Twelve healthy premenopausal women were studied.

Statistically significant improvement in genital stimulation (FIEI)²

Pfizer Clinical Field Study - Oral Viagra

Improvement on FIEI Questions†



Cev 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 a alternative delivery options including a topical route of administration.

Female Intervention Efficacy Index (FIEI)

† Question #2 - "After toking study medication, the sensation/feeling in my genital (vaginal, labia, caltois, celloris area during infercourse or stimulation (foreglacy) seemed to be (10 more than before, b) less than before or (c) unchanged." Question #4 - "After taking the study medication, intercourse and/or foreglacy 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 pastmenopausd women with \$5AD who had protocal specified estraction and free testasterone 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.

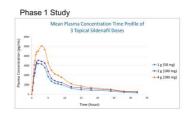
- Sildenafil Cream had significantly lower systemic exposure compared to a 50 mg oral sildenafil dose
 - AUC 3-6%
 C_{max} 1-2%
- Sildenafil Cream was safe and well tolerated at clinically relevant doses (1-2g)
- Favorable product characteristics as self-reported by subjects

 - Easy to use
 Readily absorbed

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





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.

Sildenafil Cream 25 Placebo Cream 65

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

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30

Thermography Study Design & Methodology (N=6)

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).



^{*} 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 therapy following menopause



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

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 HRT in peri-and post-menopausal women.²

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

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.

N=30

505(b)(2) candidate3

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

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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

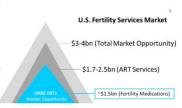
Potential for up to \$2.3 million in NIH grant funding to support DARE-FRT1 development

Notice of award for initial \$300,000 in grant funding announced Aug 2020.
Eunice Kennedy Striver Notional Institute of Child Health A Human Development of the National Institute 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



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 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.
- Localized estrogen therapy for VVA may be contraindicated for women diagnosed with, or at risk of recurrence of, ER-positive and PR-positive
- VVA prevalence in postmenopausal breast cancer survivors is estimated at 42 to 70%.



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



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, 201

US Food and Drug Administration: "Drug Approval Package: Nolvadex (Tamoxifen Citrate) NDA# 21-109.2002". Available at: https://www.accessdata.fda.gov/drugsaffda_docs/nda/2002/21109_Nolvadex.cfm



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

Anti-instact sensition nothing. Dark has not had any communications with the EDA recording the energic marketing annual requirements for DARS-LARC'S



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



FY 2020 Financial Highlights:

- Cash provided from financing activities* through 12/31/20: \$25.1 million (net of fees)
- · Cash and equivalents (as of 12/31/20): \$4.7 million

1Q2021 Update (January 1 to March 29, 2021):

- Cash provided by sales of common stock: \$11.3M (net of fees)
- Common shares o/s: ~ 47.3M 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



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







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