

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): November 18, 2020

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
(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
Common stock

Trading Symbol(s)
DARE

Name of each exchange on which registered
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 November 18, 2020, 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 November 18, 2020.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate presentation, dated November 18, 2020

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.

Dated: November 18, 2020

DARÉ BIOSCIENCE, INC.

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



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" 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 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 SECURITIES AND EXCHANGE COMMISSION.

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.



We partner so we can...

Accelerate exciting new products

Develop new solutions to **address persistent unmet needs**

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

Drive **new innovation**

We look for...

Highly **differentiated products** with attractive market opportunities

Proof-of-concept and/or the ability to leverage a 505(b)(2) regulatory pathway

First-in-category or first-line opportunities

Personalized for women (non-systemic delivery)

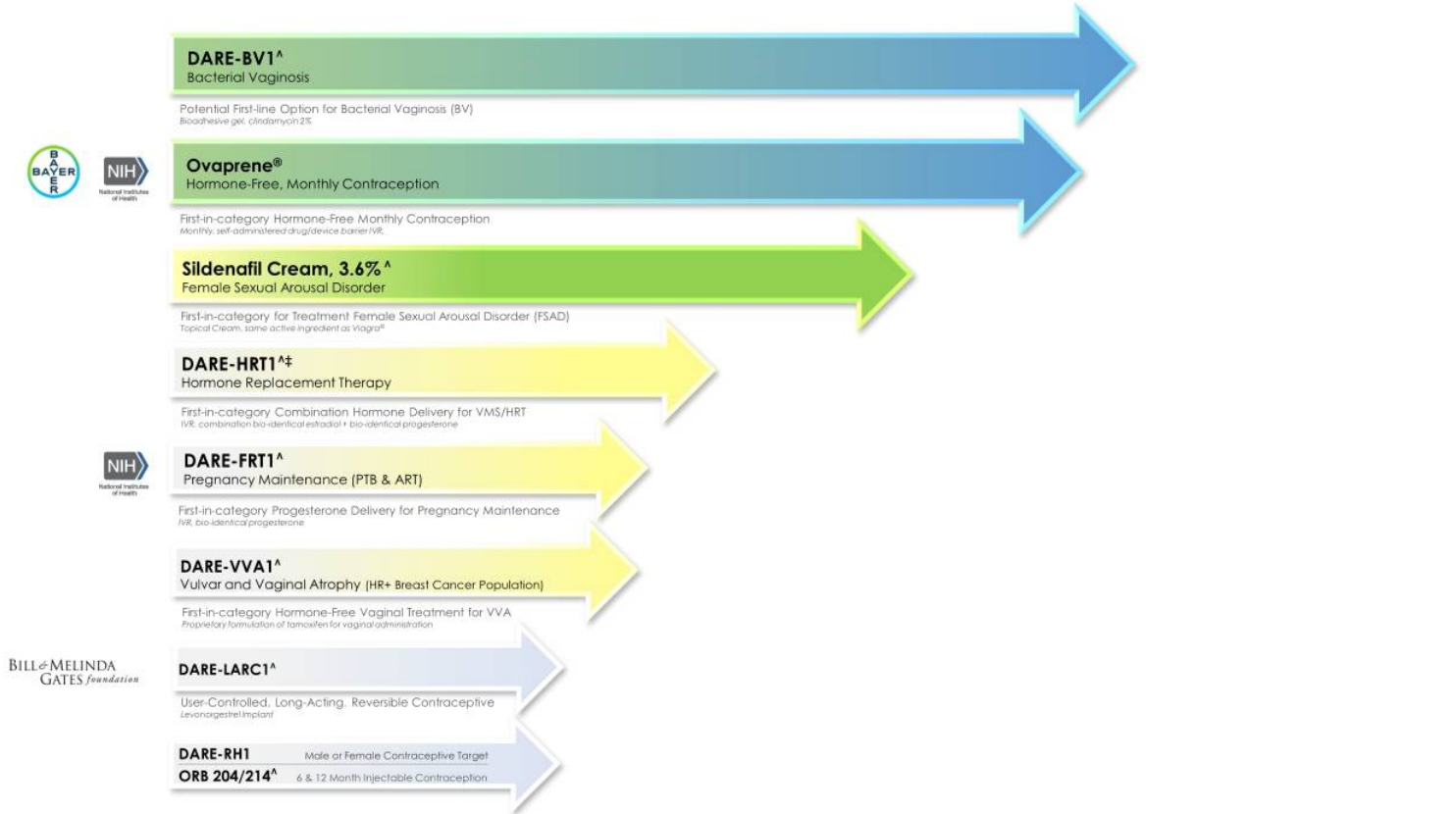
We partner with...



BILL & MELINDA
GATES foundation

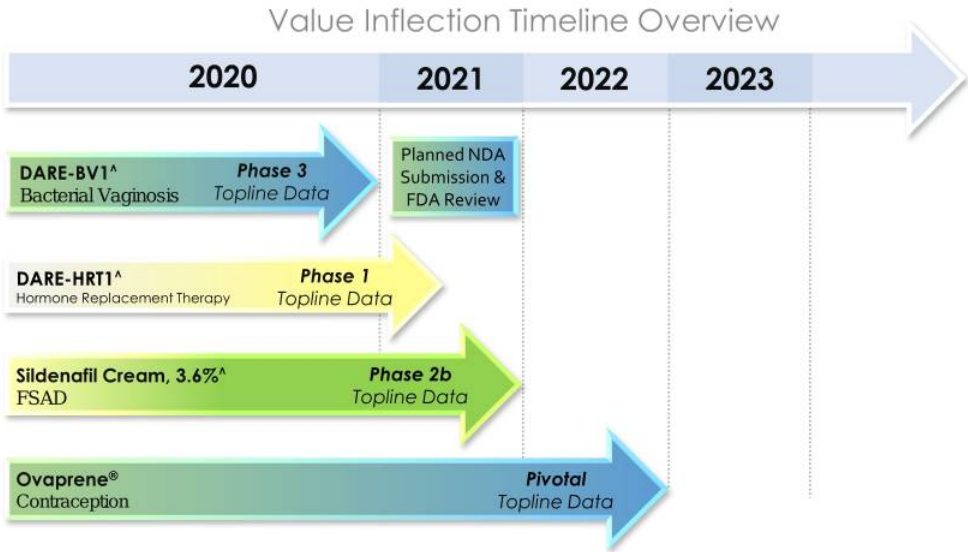


PARTNERS	ADVANCING PRODUCTS WOMEN WANT	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	REGULATORY FIL
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Timeline reflects management's current estimates and constitutes a forward-looking statement subject to qualifications noted elsewhere in this presentation. Actual development timelines may be substantially longer, and Dare is under no obligation to update or review these estimates. "First-in-category" statements are forward-looking statements relating to market potential of Dare's product candidates based on currently available, FDA-approved therapies. ^AOSIb(2) regulatory pathway anticipated. [†]DARE-HRT1 Phase 1 study being conducted in Australia by Dare subsidiary.

WE ARE ACCELERATING INNOVATION IN WOMEN'S HEALTH



Timeline reflects management's current estimates and constitutes a forward-looking statement subject to qualifications noted elsewhere in this presentation. Actual development timelines may be substantially longer, and Dan6 is under no obligation to update or review these estimates. [^]505(b)(2) regulatory pathway anticipated



DARE-BV

Clindamycin 2% gel for Bacterial Vaginosis

Bacterial Vaginosis (BV) - What is the clinical issue?

Frequently recurring infection that can be difficult to treat

- The most common vaginal infection in women ages 15-44¹
- Estimated to affect ~21 million women in the U.S.¹
- Current prescription drugs are less than optimal with clinical cure ranging from 37-68%²



BV increases clinical risks³

- Preterm birth – BV is linked to premature deliveries and low birth weight babies
- Sexually transmitted infections – BV makes women more susceptible to sexually transmitted infections, such as HIV, herpes simplex virus, chlamydia or gonorrhea
- BV may increase the risk of developing a post-surgical infection after gynecologic procedures
- BV can sometimes cause pelvic inflammatory disease (PID), an infection of the uterus and the fallopian tubes that can increase the risk of infertility


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

2. BV Product Data: <http://www.clintrials.com/jdt071.pdf>, http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000bl.pdf, http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000bl.pdf

3. <https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-20352279>

CURATIVE POTENTIAL FOR THE MOST COMMON VAGINAL INFECTION (WOMEN AGES 15-44)

Investigator Initiated Proof of Concept Study¹

Product	Clinical (Amsel) Cure	Bacteriologic (Nugent) Cure	Therapeutic Cure
 DARE-BV1	86%	57%*	57%*
Solosec ^{®2} <small>(secnidazole 2g oral granules)</small>	53-68%	40-46%	35-40%
Clindesse ^{®3} <small>clindamycin phosphate Vaginal Cream, 2%</small>	41-64%	45-57%	30-42%
Metronidazole gel, 1.3% ⁴	37%	20%	17%

* Based on data from 7 evaluable patients

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

Proof of Concept Study: 28 of 30 women completed the study

Primary endpoint: Test-of-Cure Visit (Day 7 – 14)

- **24 of 28 (86%) women achieved clinical cure based on Amsel criteria**
- 4 of 7 (57%) women had bacteriologic cure and 4 of 7 (57%) had therapeutic cure
- Continued clinical response visit (Day 21 – 30)
- **22 of 24 (92%) women showed continued clinical cure**
- 7 of 9 women had bacteriologic cure and 6 of 9 had therapeutic cure

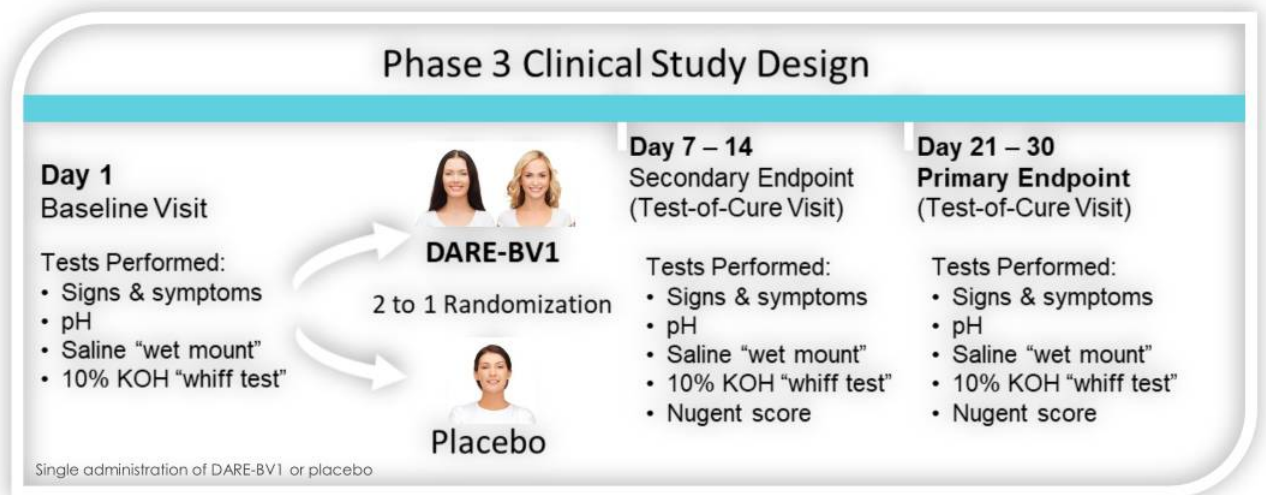
1. Dugao, A. et al. 2020. Proof of concept study of a novel Bioadhesive clindamycin phosphate 2% vaginal gel to treat bacterial vaginosis. Clin. Exp. Obstet. Gynecol. Vol. 47, n.4:516-18, available at <https://ceog.impress.com/EN/10.31083j/ceog.2020.04.5304>; No clinical studies have been conducted to evaluate the efficacy of DARE-BV1 compared to any FDA-approved products. The cure rates presented for the FDA approved products identified in the table are based on information provided in the product's label.

2. <https://dailymed.nlm.nih.gov/dailyMed/fda/labelDrugXcl.cfm?product=551e4345-f700-4dfe-8029-0238fa3937&type=display>. Cure rate range reflects low and high cure rates across multiple studies.

3. <http://www.clindesse.com/pdfs/P1.pdf>. Cure rate range reflects low and high cure rates across multiple studies.

4. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223a000018.pdf

DARE-BV1 (Completed Phase 3 Study)*



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

*Topline data forthcoming

Definitions:

Primary Endpoint: Clinical Cure (Day 21-30): 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

Bacteriological Cure: a Nugent score < 4.

Therapeutic Cure: both a Clinical Cure and Bacteriological Cure.



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

Contraception: what kinds of products are successful?



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** (Allergan)³

Lower hormone levels and more convenient delivery platforms

1. <https://www.bayer.com/en/kayer-sg-annual-report-2019.pdf>. Includes sales for Mirena®, Kyleena® and J ayless® / Skyla®
2. <https://www.pressewire.com/news-releases/allergan-reports-fourth-quarter-and-full-year-2019-financial-results-301001646.html>
3. https://s21.q4cdn.com/488056881/files/doc_financials/2019/q4/2019-Form-10-K-Final.pdf

Contraception: what features are women seeking?

Effectiveness (pregnancy prevention)

Less Hormones

- A majority of women prefer a monthly option with a lower hormone dose than the standard birth control pill.¹

Convenient dosing forms

- Independent surveys revealed that the vaginal ring has many of the features women deemed extremely important.²

Defined coverage periods

- ~70% of women who practice contraception use non-coital (not in the moment) methods.³

CONTRACEPTIVE METHOD CHOICE

Most effective method used in the past month by U.S. women, 2014

METHOD	No. of women	% of women aged 15-44	% of women at risk of unintended pregnancy	cont
Pill	9,572,477	15.6	22.7	
Tubal (female) sterilization	8,225,349	13.4	19.5	
Male condom	5,496,905	8.9	13.0	
IUD	4,452,344	7.2	10.6	
Vasectomy (male sterilization)	2,441,043	4.0	5.8	
Withdrawal	3,042,724	5.0	7.2	
Injectable	1,481,902	2.4	3.5	
Vaginal ring	905,896	1.5	2.1	
Fertility awareness-based methods	812,216	1.3	2.0	
Implant	965,539	1.6	2.3	
Patch	69,106	0.1	0.2	
Emergency contraception	69,967	0.1	0.2	
Other methods*	234,959	0.4	0.6	
No method, at risk of unintended pregnancy	4,408,474	7.2	10.5	
No method, not at risk	19,302,067	31.4	na	
Total	61,491,766	100.0	100.0	






*Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream and other methods. NC refers to women who are sexually active, not pregnant, seeking to become pregnant or postpartum, and not none. None, not applicable.

www.guttmac

1. Hooper, D.J., Clin Drug Investg. 2010;30(11):749-63
2. Lessard, L., Perspectives on Sexual and Reproductive Health, Volume 44, Number 3, 9-2012
3. <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>

Contraception: what products are hormone-free?



Hormone-free Options	Number of pregnancies expected (per 100 women)*	Least Effective
 Spermicides & Vaginal Gels ²	>27 (greater than 27 pregnancies)	
 Condoms (male)	18	
 Diaphragms (with a spermicide)	12	
 Copper IUD	<1 (less than 1 pregnancy)	

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

2. U.S. Food and Drug Administration Drug Data Prescribing information for a recently approved vaginal gel, Phexxi™ provides that in a multicenter, open-label, single-arm clinical trial in the U.S. (AMPD02; 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: 23.3–33.5%). https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208352s000lbl.pdf

* The 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 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

Contraception: what's missing from hormone-free options?



Hormone-free Options	Number of pregnancies expected (per 100 women) ^{1*}	Least Effective
 Spermicides & Vaginal Gels ²	>27 (greater than 27 pregnancies)	
 Condoms (male)	18	
 Diaphragms (with a spermicide)	12	
 Easy-to-use monthly option	Effectiveness approaching hormonal methods	
 Copper IUD	<1 (less than 1 pregnancy)	

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

2. U.S. Food and Drug Administration Drug Data Prescribing information for a recently approved vaginal gel, Phexxi™ provides that in a multicenter, open-label, single-arm clinical trial in the U.S. (AMPD02; NCT03243305), the 7-cycle cumulative pregnancy rate 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: 23.3–33.5%). https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208352s000lbl.pdf

* The 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 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

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 (spermistatic & 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
+ Easily Manage Fertility	No Systemic/Long-term Activity Inserted and removed without a provider allowing for immediate return to fertility

Physical Barrier⁶

Three-dimensional, knitted poly
barrier



Spermistatic Environme

Contraceptive-loaded silicone
releasing non-hormonal active
gluconate

1. <https://www.urban.org/urban-wires/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 Invest. 2010;30(11):740-63.

4. Ensek, 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.

6. Muck C, Vincent K. Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437-444

7. Journal of Reproductive Medicine 2009; 54: 695-698

8. Trussell, J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Polcar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.

U.S. Regulatory Strategy¹

Premarket approval (PMA) with 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 2022 pivotal study readout
- Conduct pivotal study
 - Topline data expected by year-end 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 Endpoint²

Ovaprene prevented the requisite number of sperm from reaching 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 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 <small>Progressively Motile Sperm</small>	Median <small>Progressively Motile Sperm</small>	Standard Deviation	Inter Ra
Baseline PCT's	27.21	23.20	17.88	2
Ovaprene PCT's	0.48	0.00	1.18	

¹ Anticipated regulatory pathway and timelines.

² 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. Muck C, Vincent K. *Biology of Reproduction*, Volume 103, Issue 2, August 2020, Pages 437-444

Ovaprene Commercial License Agreement with Bayer¹



January 2020 - Bayer, marketer of the \$1 billion Mirena contraceptive franchise, and Daré announced that the companies signed a license agreement under which Bayer may commercialize Ovaprene in the United States once approved by the FDA.

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

- Bayer received the right to obtain exclusive rights to commercialize the product in the U.S. following completion of the pivotal clinical trial if Bayer, in its sole discretion, makes payment to Daré of \$20 million.
- Daré may receive up to \$310 million in commercial milestone payments plus tiered royalties on net sales in the double-digits.
- Bayer supports the development and regulatory process by providing up to two full-time equivalents (internal experts), or FTEs, in an advisory capacity, which gives us access to their global manufacturing, regulatory, medical and commercial internal expertise.

We believe the licensing agreement with Bayer is validation of our broader corporate strategy and confirmation of Ovaprene's market potential as the first monthly non-hormonal contraceptive product in the US market.

* <https://www.mirena-us.com/>, supported by 2014-2016 SFS data.

1. <https://ir.darbioscience.com/news-releases/news-release-details/bayer-and-dare-bioscience-announce-exclusive-licensing-agreement>



Sildenafil Cream, 3.6%

Female Sexual Arousal Disorder (FSAD)

The global female sexual dysfunction treatment market is expected to grow at ~37% CAGR from 2019 - 2025

FSAD - what is the clinical issue?

- Female Sexual Arousal Disorder (FSAD) is characterized primarily by an inability to attain or maintain sufficient genital arousal during sexual activity and, of the 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 the orgasmic disorder (anorgasmia) and hypoactive sexual desire disorder (HSDD), which is characterized as a 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 (DSMIV 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://drugs.com/women-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 the prevalence of Female Sexual Dysfunction in premenopausal women worldwide is 40.9%, and difficulty with arousal alone is 23%.¹

Market research estimates:

- 33% of women in the U.S. age 21 to 60 (approximately 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.

Topically administered Sildenafil Cream is...¹

- A PDE5 inhibitor utilized in ED medications for men (Viagra®)
- Designed to increase local blood flow to provide an improvement in genital arousal response
- Applied topically, avoiding hepatic first-pass metabolism response resulting in lower systemic exposure resulting in reduced side effects compared to oral sildenafil, including Viagra®
- Given the similarities between ED and FSAD, the active ingredient in Viagra® - sildenafil - 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)

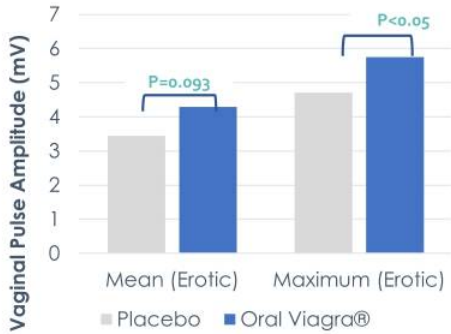
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Sildenafil Cream, 3.6%

Statistically significant increases in Vaginal Pulse Amplitude (VPA)¹

Pfizer VPA Clinical Lab Study – Oral Viagra

Mean and Maximum VPA†

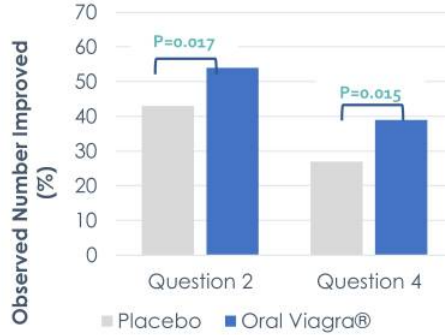


† Twelve healthy premenopausal women were studied.

Statistically significant improvement in genital stimulation (FIEI)²

Pfizer Clinical Field Study – Oral Viagra

Improvement on FIEI Questions†



Female Intervention Efficacy Index (FIEI)

† **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® study

- 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 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

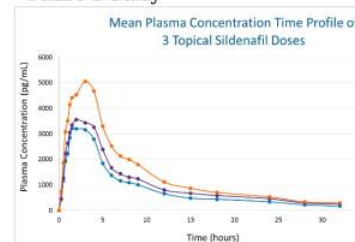
Phase 2a Study of SST-6007 (Sildenafil Cream, 3.6%)¹

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)
Topical Sildenafil 1 g of cream	20	35 mg	3.4	2.37
Topical Sildenafil 2 g of cream	20	71 mg	3.8	2.27
Topical Sildenafil 4 g of cream	19	142 mg	5.3	2.22

Phase 1 Study



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

Positive Data – Thermography Study*

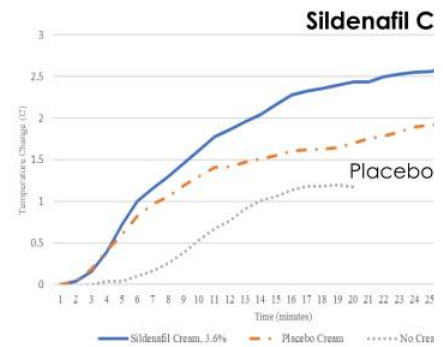
Positive findings for Sildenafil Cream, 3.6% (as shown in Figure 1.)

- 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.

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).

Figure 1. Clitoral temperature change during the sexually explicit



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

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.

Phase 2b – At Home Study

The Phase 2b study is designed to evaluate Sildenafil Cream versus placebo over twelve weeks of dosing following both a non-drug and placebo run-in period.

- In the Phase 2b study women will use Sildenafil Cream and placebo in their home setting.
- Primary endpoint patient reported outcome (PRO) instruments to measure **improvement in localized genital sensations of arousal** and **reduction in the distress** that women with FSAD experience.
- Several exploratory efficacy endpoints will be measured and could potentially prove to be additional measurements of efficacy in a future Phase 3 program.





Vaginal Drug Delivery

New prescription drug delivery options for women

The Vaginal Route of Drug Administration¹

- Vaginal drug delivery offers many potential advantages due to the large surface area, a 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 a single or multiple active drugs
- No need for a membrane or reservoir to contain the active drug(s) or control the release

1. Soniá, 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

A combination bio-identical estradiol + bio-identical progesterone IVR for hormone replacement therapy

Hormone Replacement Therapy (HRT)

HRT remains the most effective treatment for vasomotor symptoms (VMS) and the 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 that **non-oral routes may offer advantages** over oral routes of administration.²

Ongoing Phase 1 VMS/HRT S

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

N=30

45M women in U.S. approaching or in menopause³

505(b)(2) candidate¹

¹ Anticipated regulatory pathway. Dard has not had any communications with the FDA regarding the specific marketing approval requirements for DARE-HRT1 or DARE-FRT1.

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

DARE-FRT1

A bio-identical progesterone IVR for the prevention of preterm birth and IVF/fertility support

Prevention of Preterm Birth (PTB)

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



NIH Grant Funding for DARE-FRT1 (PTB)

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

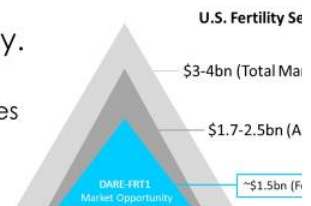
- Notice of award for initial \$300,000 in grant funding announced Aug 2020.

Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health Award Number R44 HD101169.

Assisted Reproductive Technologies (ART)/IVF

As women wait longer to have children, they increase their risk of infertility.

- An estimated 12-15% of couples are unable to conceive after 1-year of unprotected sex.⁴
- Approximately 20% of U.S. women have their first child after age 35 and about 1/3 of couples in which the woman is older than 35 years have fertility problems.⁵



505(b)(2) candidate¹

¹ Anticipated regulatory pathway. Dant has not had any communications with the FDA regarding the specific marketing approval requirements for DARE-FRT1 or 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 Retrieved May 26, 2020 from <https://www.nichd.nih.gov/health/topics/infertility/conditioninfo/common>
⁵ Retrieved May 26, 2020 from <https://www.cdc.gov/reproductivehealth/infertility/index.htm>
⁶ Harte Williams & Co. Fertility market overview, May 2015.

Vaginal Drug Delivery Technology

DARE-VVA1

A proprietary formulation of tamoxifen for vaginal administration

Vulvar and vaginal atrophy (VVA)

A chronic condition characterized by pain during intercourse, vaginal dryness and irritation

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

- Approximately 3.8 million women in the U.S. have a history of breast cancer and 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 to be between **42 and 70%**.³



Daré is developing this novel application of tamoxifen to treat symptoms of VVA for patients with breast cancer, including women currently on anti-cancer therapy.

505(b)(2) candidate¹

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>

Vaginal Drug Delivery Technology

This exploratory study 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, the 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.medicineswebtoday.com/articles/322537.php>

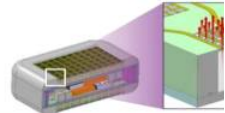
3. US Food and Drug Administration: "Drug Approval Package: Nolvadex (Tamoxifen Citrate) NDA# 21-109-2002". Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21109_Nolvadex.cfm



User-Controlled Long-Acting Reversible Contraception (UC-LARC) / Microchips Technology

Design Features of the Technology:

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



Pre-programmed or wireless activation

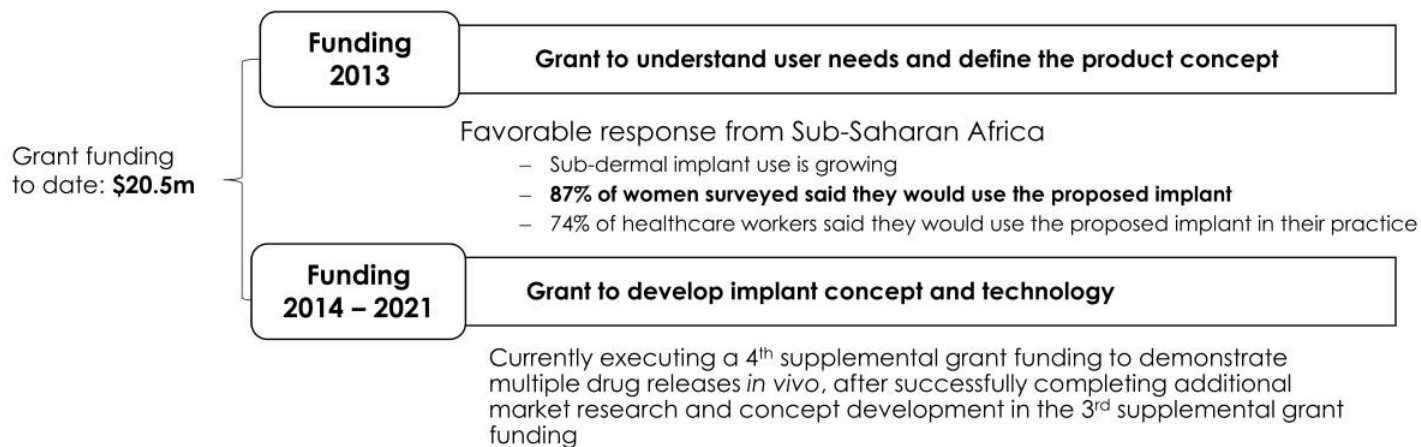
505(b)(2) candidate¹

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

DARE-LARC1

User-Controlled Long Acting Reversible Contraception

The Bill & Melinda Gates Foundation has strong interest in family planning. An estimated 215 million women in developing countries do not have access to contraception.



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

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

Daré Non-Dilutive Funding Sources















Grant funding:















- \$1.9 million grant for Oviprene R&D expenses from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH).
 - Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health Award Number R44 HD095724-
- \$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 the Bill & Melinda Gates Foundation.
- Potential for up to \$2.3 million grant from the 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 Health Award Number R44 HD101169.

Cost optimization and value creation through partnerships and affiliates:

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

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	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 

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