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): October 6, 2020

DARÉ BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36395**	**20-4139823**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3655 Nobel Drive, Suite 260
San Diego, CA 92122
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(858) 926-7655**

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock	**DARE**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

Included as Exhibit 99.1 to this report is a presentation about Daré and its product candidates, dated October 6, 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 October 6, 2020.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate presentation, dated October 6, 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.

DARÉ BIOSCIENCE, INC.

Dated: October 6, 2020

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

dare

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

Forward-Looking Statements

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," O "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; INCLUDIN 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.

darébio

Partnering is core to our strategy

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…

AVOMEEN

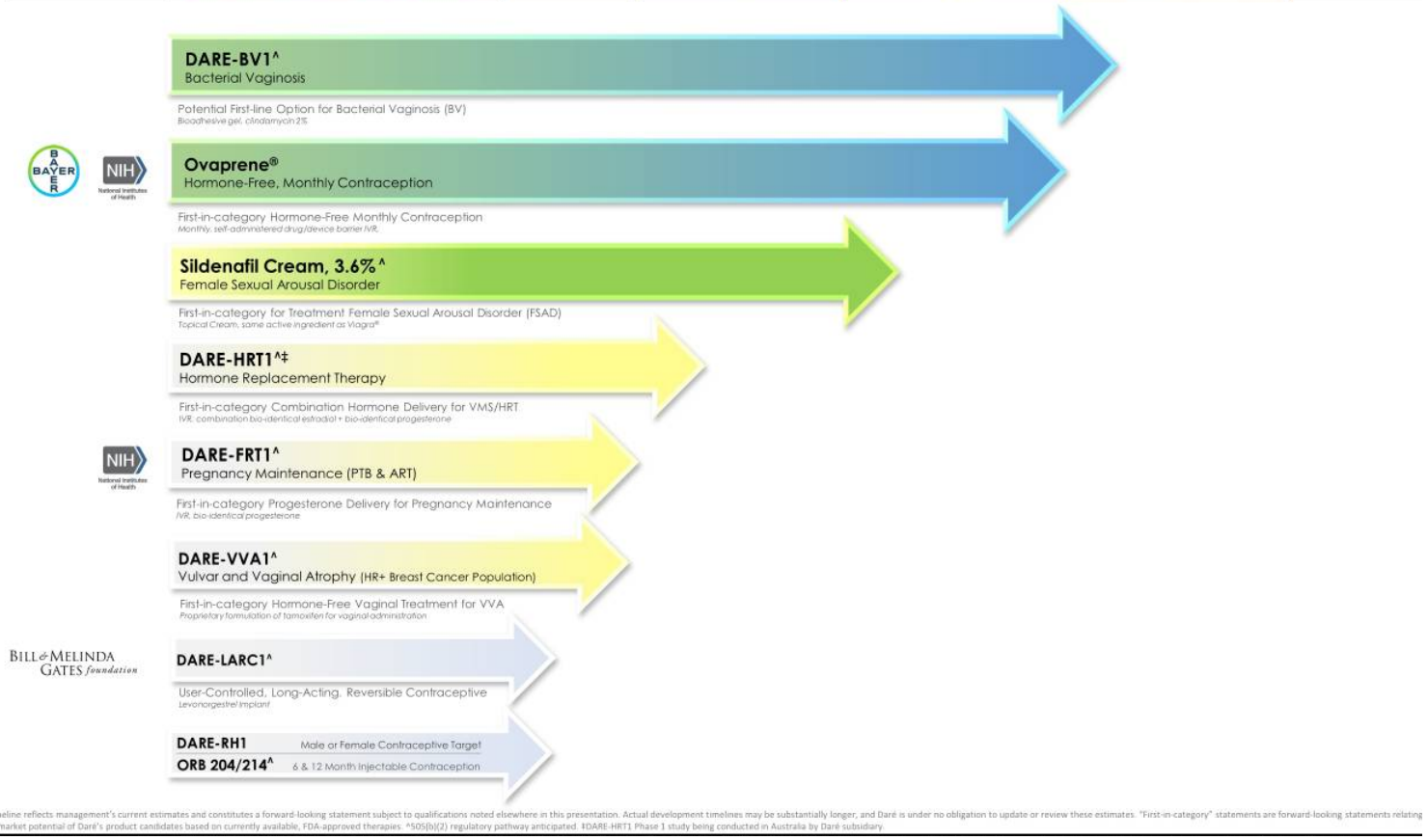
BAYER

BILL & MELINDA GATES foundation

Health Decisions

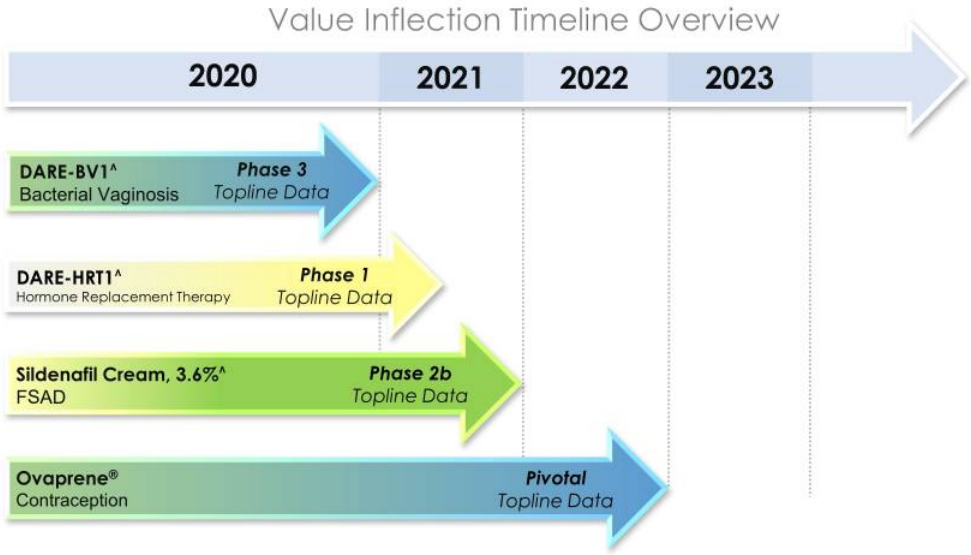
NIH National Institutes of Health

*The Ovaprene PCT clinical study (clinicaltrials.gov identifier: NCT03598088), which was conducted with support from the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the National Institutes of Health under Award Number R44HD095724



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 Daré is under no obligation to update or review these estimates. "First-in-category" statements are forward-looking statements relating to market potential of Daré's product candidates based on currently available, FDA-approved therapies. ^505(b)(2) regulatory pathway anticipated. ‡DARE-HRT1 Phase 1 study being conducted in Australia by Daré 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 Daré is under no obligation to update or review these estimates. ^505(b)(2) regulatory pathway anticipate

DARE-BV

Clindamycin 2% gel for Bacterial Vaginos

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 15-44[1]
- 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 risks[3]

- 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.clindesse.com/pdf/PI.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf
3. https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-20352279

DARE-BV1

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

Investigator Initiated Proof of Concept Study[1]

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

* Based on data from 7 evaluable patients

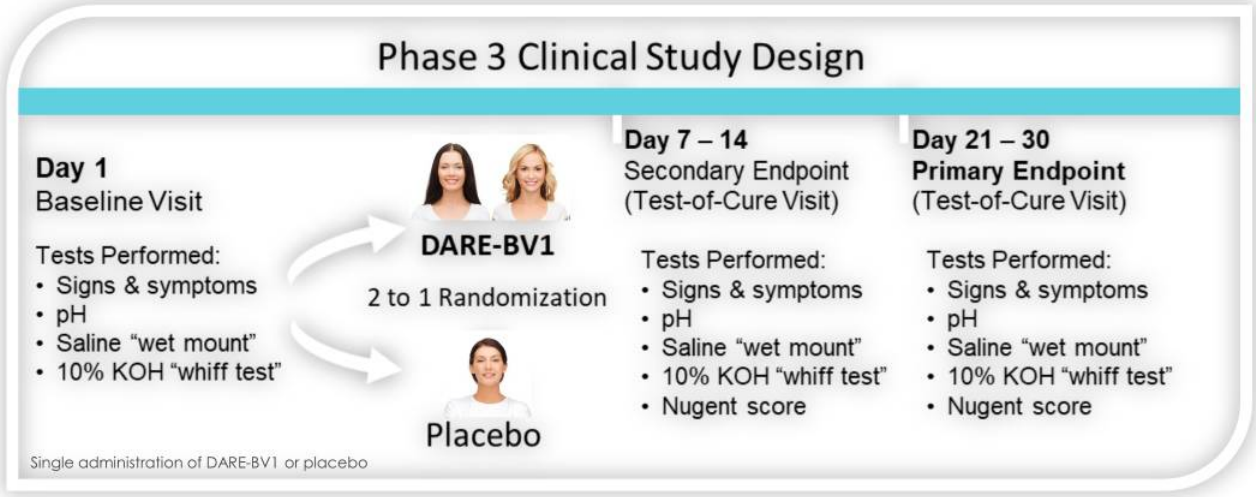
DARE-BV1 is a thermosetting vaginal gel formulated with clindamycin phosphate 2%, a well known and well characterized antibiotic, that is designed for prolonged, localized release.

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. Dupre, 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.imrpress.com/EN/10.31083/j.ceog.2020.04.5304 No clinical studies have been conducted to evaluate the efficacy o 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/fdaDrugXsl.cfm?setid=551e43d5-f700-4d6e-8029-026f8a8932ff&type=display. Cure rate range reflects low and high cure rates across multiple studies.
3. http://www.clindesse.com/pdf/PI.pdf. Cure rate range reflects low and high cure rates across multiple studies
4. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf

DARE-BV1 (Ongoing Phase 3 Study)



N~280 subjects (age 12 and above)
Duration ~30 days per subject
Diagnosis - Bacterial vaginosis

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.

Aggregate costs of program through NDA filing, including Phase 3, nonclinical studies, manufacturing activities, and NDA filing, anticipated to be approximately $10.0m.

Ovaprene®

Investigational Hormone-Free, Monthly Contraceptiv

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** (

Lower hormone levels and more convenient delivery platforms

1. https://www.bayer.com/en/bayer-ag-annual-report-2019.pdfx. Includes sales for Mirena®, Kyleena® and Jaydess® / Skyla®
2. https://www.prnewswire.com/news-releases/allergan-reports-fourth-quarter-and-full-year-2019-financial-results-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

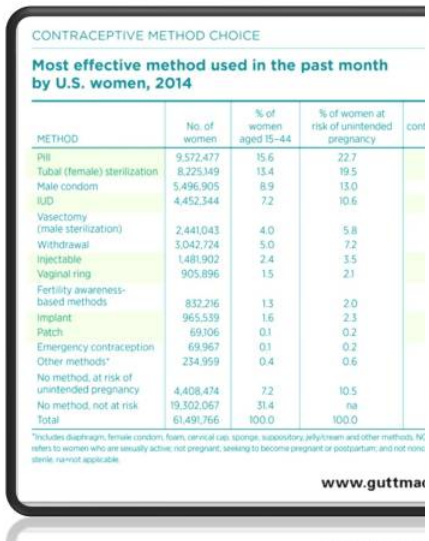
- A majority of women prefer a monthly option with a lower hormone dose than the standard birth control pill.[1]

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
Pill	9,572,477	15.6	22.7
Tubal (female) sterilization	8,225,149	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	832,216	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 nonc sterile. na=not applicable.

www.guttmac

1. Hooper, DJ, Clin Drug Investig. 2010;30(11):74963
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? [1,2]

Spermicides / Vaginal Gels
- Effectiveness (*72% Typical Use*)
- Woman controlled

Condoms
- Effectiveness (*82% Typical Use*)
- Not woman controlled

Diaphragms
- Effectiveness (*88% Typical Use*)
- Woman controlled

Long-acting Copper IUD
- Effectiveness (*99% Typical Use*)
- Not woman controlled

Least Effecti

Most Effecti

1. Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.
2. http://www.contraceptivetechnology.org/wp-content/uploads/2013/09/CTFailureTable.pdf

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

Spermicides / Vaginal Gels

Condoms

Diaphragms

?

Easy-to-use, monthly option with effectiveness approaching hormonal methods

Long-acting Copper IUD

Least Effecti

Most Effecti

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

Physical Barrier [8]

Three-dimensional, knitted polyr barrier

Spermiostatic Environme

Contraceptive-loaded silicone r releasing non-hormonal active l gluconate

1. https://www.urban.org/urban-wire/women-want-effective-birth-control
2. Lessard, L.,Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012
3. Hooper, DJ, Clin Drug Investig. 2010;30(11):74963
4. Ersek, J, Matern Child Health J (2011) 15:497–506
5. https://ir.darebioscience.com/news-releases/news-release-details/dare-bioscience-announces-positive-findings-postcoital-test
6. Journal of Reproductive Medicine 2009; 54: 685-690
7. Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.
8. Journal of Reproductive Medicine 2009; 54: 685-90

U.S. Regulatory Strategy[1]

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 Endpoint [2]

Ovaprene prevented the requisite number of sperm from reachin 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 t midcycle cervical mucus collected two to three hours after intercourse with Ov in place.
- Women enrolled in the study who completed at least one Ovaprene PCT (N=26 **mean of 27.21 PMS/HPF in their baseline cycle (without any contraceptive devic** mean of 0.22 PMS/HPF in their diaphragm cycle (in the presence of an FDA-clea diaphragm with spermicide), **and a mean of 0.48 PMS/HPF in their Ovaprene PC cycles (in the presence of the Ovaprene device), with a median of zero PMS.**

	Mean (Progressively Motile Sperm)	Median (Progressively Motile Sperm)	Standard Deviation	Interc 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.

Ovaprene® Investigational Hormone-Free, Monthly Contraceptive

Ovaprene Commercial License Agreement with Bayer[1]

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 i 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 SHS data.
1. https://ir.darebioscience.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 - 2

Sildenafil Cream, 3.6%

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 the 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 (DSM IV TR), defines female sexual arousal disorder as a persistent or recurrent inability to attain or to maintain until completion of the sexual activity, an adequate lubrication-swelling response of sexual excitement. The diagnostic criteria also state that the inability causes marked distress or interpersonal difficulty, is not better accounted for by another Axis I disorder (except another sexual dysfunction) and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

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

FSAD - what is the incidence?

Meta-analysis of 95 studies from 2000-2014 indicated 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.

Sildenafil Cream, 3.6%

Topically administered Sildenafil Cream[1] is…

- 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

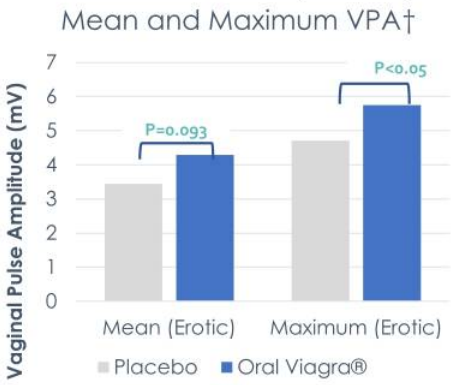
There are no FDA-approved treatments for FSAD

1. Sildenafil Cream, 3.6%, (formerly SST-6007)

Sildenafil Cream, 3.6%

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

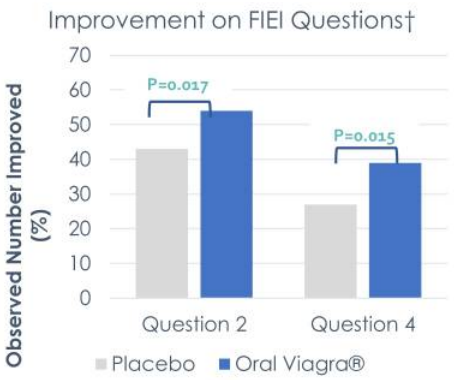
Pfizer *VPA Clinical Lab Study – Oral Viagra*



† Twelve healthy premenopausal women were studied.

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

Pfizer *Clinical Field Study – Oral Viagra*



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® studi

- **Increased blood flow** and clin efficacy observed with oral sil (Viagra®) in women.
- The side effect profile of the **o formulation was not optimal fo women -** leading to the explo alternative delivery options inc a **topical route of administrati**

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]

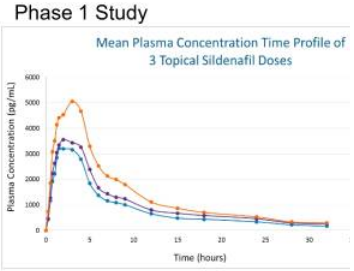
Normal healthy postmenopausal women were dosed with escalating doses of Sildenafil Cream, 3.6%, using a cross-over study design.

- 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 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



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.

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 durir
11-15 of the sexually explicit stimuli as compare
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.

Sildenafil Cream, 3.6%

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

Vaginal Drug Delivery Technology - IVR

The Vaginal Route of Drug Administration[1]

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

DARE-HRT1

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 Evaluat Pharmacokinetics and Safety o DARE-HRT1 (80 µg and 160 µg Estradiol/ 4 mg and 8 mg Progesterone Intravaginal Rings Healthy Post-Menopausal Wom

N=30

45M women in U.S. approaching or in menopause[3]

505(b)(2) candidate[1]

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

Vaginal Drug Delivery Technology - IVR

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 fo
fourth straight year in 2018 with ~10% of babies born preterm (less than 37 weeks).[3]

NIH Grant Funding for DARE-FRT1 (PTB)

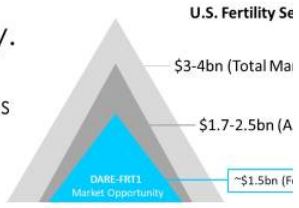
Potential for up to $2.3 million in grant funding from the NIH to support the DARE-FRT1 program

- 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) candidate[1]

1. Anticipated regulatory pathway. Daré has not had any communications with the FDA regarding the specific marketing approval requirements for DARE-HRT1 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. Harris 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 m
symptoms of VVA for patients
cancer, including women cu
anti-cancer therapy.

505(b)(2) candidate[1]

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

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

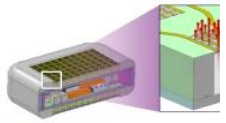
1. Clin. Exp. Obstet. Gynecol. - ISSN: 0390-6663 XLVI, n. 2, 2019
2. https://www.medicalnewstoday.com/articles/322537.php
3. US Food and Drug Administration: "Drug Approval Package: Nolvadex (Tamoxifen Citrate) NDA# 21-109.2002". Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21109_Nolvadex.cfm


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

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) candidate[1]

1. Anticipated regulatory pathway. Daré 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.

Up to $20.5m

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 funding

Daré Financial Summary

Q2-2020 Financial Highlights:

- Net cash provided from financing activities* through 6/30/20: $11.0 million (net)
- Cash and equivalents (as of 6/30/2020): $5.3 million

Updates from July 1 through August 11, 2020:

- Net cash provided by sales of stock and warrant exercises: $3.5 million (net)
- Common shares o/s: 31.6 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 Ovaprene R&D expenses from the Eunice Kennedy Shriver National Institute of Cl 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 c 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 resour and new pricing structures, which together with Health Decisions' expertise and established relationsh 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 exper including advanced instrumentation and development techniques.
- Australia's R&D tax incentive, allows for a refundable cash credit of up to 43.5% of investments made eligible companies in eligible R&D activities. We intend to apply for the maximum amount allowable under our DARE-HRT1 program.

Management Team & Board of Directors

MANAGEMENT TEAM

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