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): **June 8, 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 June 8, 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 June 8, 2020.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate presentation, dated June 8, 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.

Date: June 8, 2020

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.**"

June 8, 2020

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 TERM SUCH AS "MAY," "WILL," "EXPECT," "PLAN," "ANTICIPATE," "STRATEGY," "DESIGNED," "COULD," "INTEND," "BELIEVE," "ESTIMATE," "TARGET," C "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.

WE ARE **ACCELERATING INNOVATION** IN WOMEN'S HEALTH

We're driven by a mission to accelerate a diverse portfolio of novel therapies for women that **expand treatment options, improve outcomes and facilitate convenience.**

With clinical trials underway, our initial **focus areas include contraception, fertility, and sexual and vaginal health.**

daré bio

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…

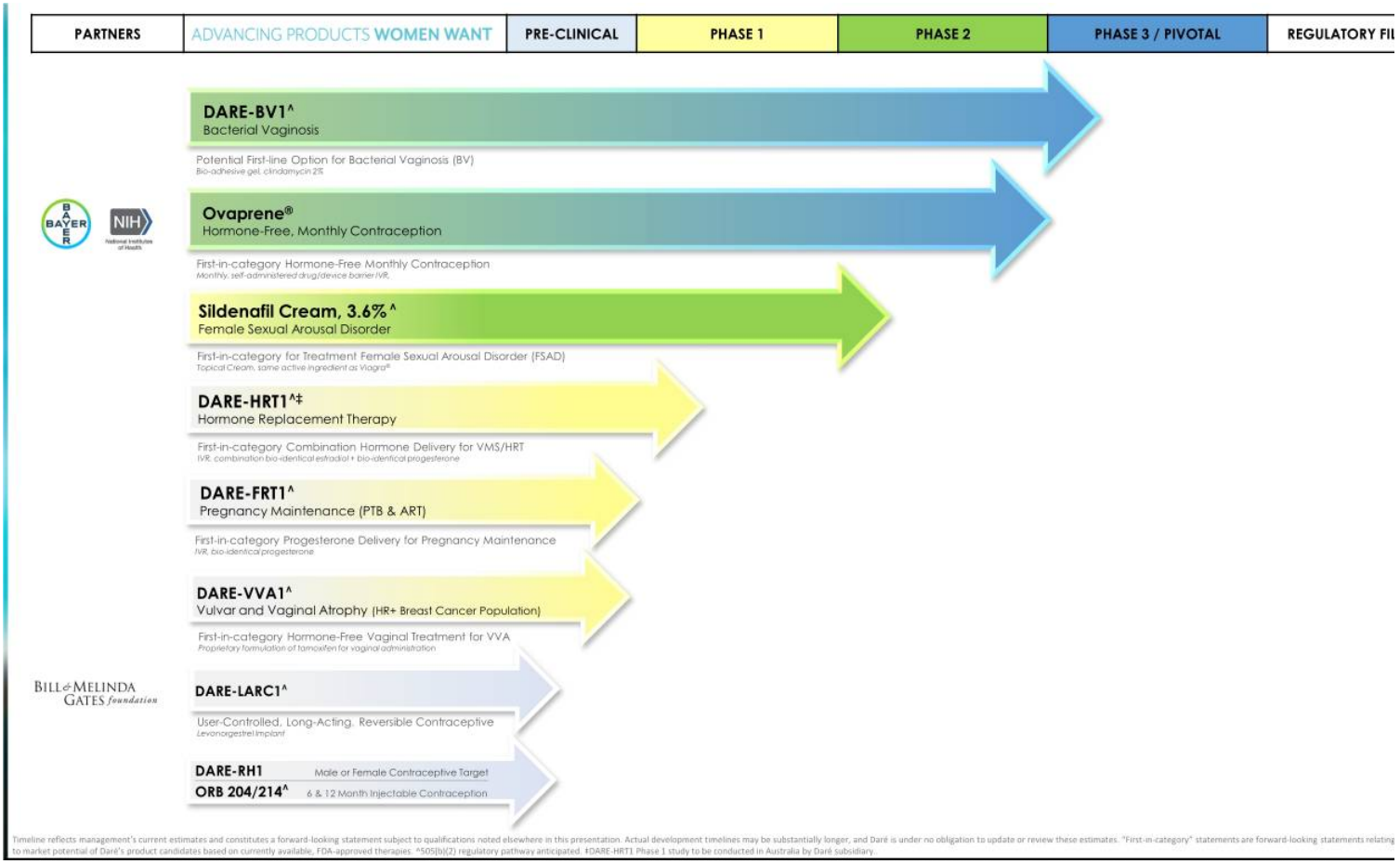
BAYER

BILL & MELINDA GATES *foundation*

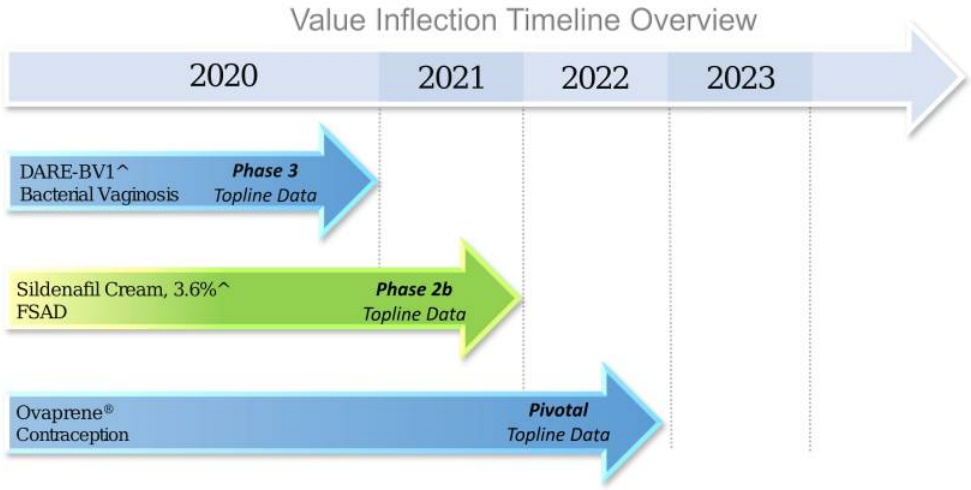
Health Decisions

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


PARTNERS
ADVANCING PRODUCTS WOMEN WANT
PRE-CLINICAL
PHASE 1
PHASE 2
PHASE 3 / PIVOTAL
REGULATORY FIL
DARE-BV1^
Bacterial Vaginosis
Potential First-line Option for Bacterial Vaginosis (BV)
Bio-adhesive gel, clindamycin 2%
Ovaprene®
Hormone-Free, Monthly Contraception
First-in-category Hormone-Free Monthly Contraception
Monthly, self-administered drug/device barrier IVR,
Sildenafil Cream, 3.6% ^
Female Sexual Arousal Disorder
First-in-category for Treatment Female Sexual Arousal Disorder (FSAD)
Topical Cream, same active ingredient as Viagra®
DARE-HRT1^‡
Hormone Replacement Therapy
First-in-category Combination Hormone Delivery for VMS/HRT
IVR, combination bio-identical estradiol + bio-identical progesterone
DARE-FRT1^
Pregnancy Maintenance (PTB & ART)
First-in-category Progesterone Delivery for Pregnancy Maintenance
IVR, bio-identical progesterone
DARE-VVA1^
Vulvar and Vaginal Atrophy (HR+ Breast Cancer Population)
First-in-category Hormone-Free Vaginal Treatment for VVA
Proprietary formulation of tamoxifen for vaginal administration
DARE-LARC1^
User-Controlled, Long-Acting, Reversible Contraceptive
Levonorgestrel Implant
DARE-RH1
Male or Female Contraceptive Target
ORB 204/214^
6 & 12 Month Injectable Contraception
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 to be 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

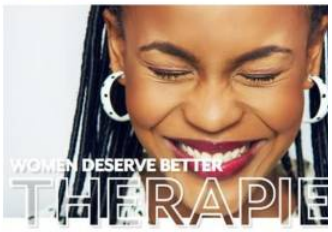
DARE-BV1

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 15-44[1]
- Estimated to affect ~21 million women in the U.S.[1]
- Current prescription drugs are less than optimal with clinical cure rates 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

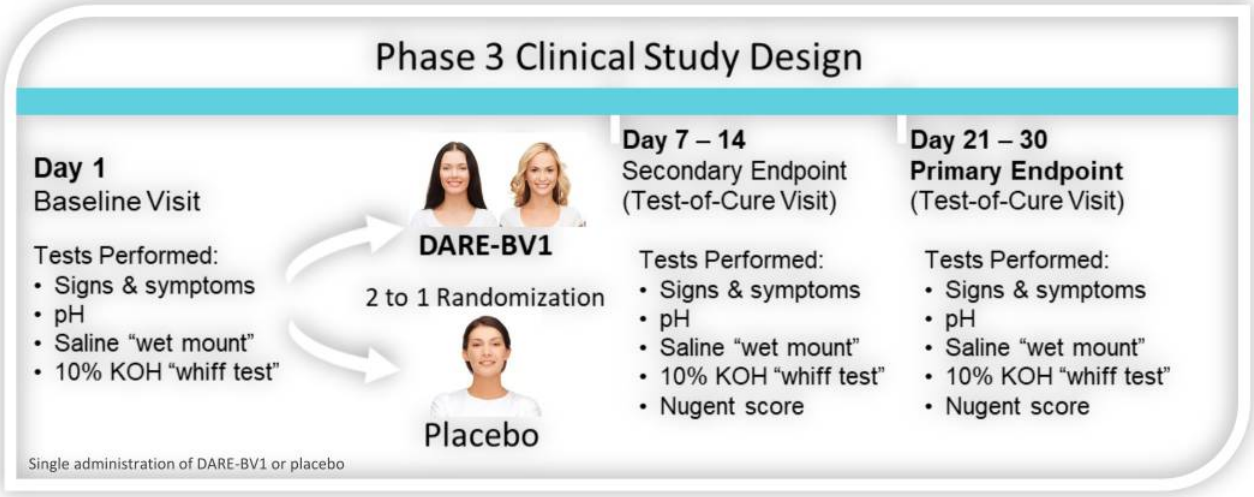
DARE-BV1 is a thermosetting vaginal gel formulated with clindamycin phosphate 2%, a well known and well characterized antibiotic, that is designed for prolonged, localized release.

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. No clinical studies have been conducted to evaluate the efficacy of DARE-BV1 compared to any FDA-approved products. The proof of concept study enrolled 30 women, ages 18-50, and assessed the safety and efficacy of DARE-BV1 to treat BV after a single administration. 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-8029-026ffa8932ff&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



N ~220 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 Contraceptive

The U.S. contraceptive market size is projected to reach USD 9.6 billion by 2027 expanding at a CAGR of ~4.2%[1]

~37 million U.S. women of reproductive age are estimated to currently use a contraceptive method[2]

1. Grand View Research report, Feb 2020, https://www.grandviewresearch.com/industry-analysis/us-contraceptive-market
2. The Guttmacher Institute, Contraceptive Use in the United States, Fact Sheet, April 2020, https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states#

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 (M

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 kinds of features are women seeking

Effective 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	% of contraceptive users
Pill	9,572,477	15.6	22.7	25.3
Tubal (female) sterilization	8,225,149	13.4	19.5	21.8
Male condom	5,496,905	8.9	13.0	14.6
IUD	4,452,344	7.2	10.6	11.8
Vasectomy (male sterilization)	2,441,043	4.0	5.8	6.5
Withdrawal	3,042,724	5.0	7.2	8.1
Injectable	1,481,902	2.4	3.5	3.9
Vaginal ring	905,896	1.5	2.1	2.4
Fertility awareness-based methods	832,216	1.3	2.0	2.2
Implant	965,539	1.6	2.3	2.6
Patch	69,106	0.1	0.2	0.2
Emergency contraception	69,967	0.1	0.2	0.2
Other methods*	234,959	0.4	0.6	0.6
No method, at risk of unintended pregnancy	4,408,474	7.2	10.5	na
No method, not at risk	19,302,067	31.4	na	na
Total	61,491,766	100.0	100.0	100.0

*Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream and other methods. NOTE: "At risk" refers to women who are sexually active, not pregnant, seeking to become pregnant or postpartum, and not noncontraceptively sterile. na=not applicable.

www.guttmacher.org

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 optio

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	No Colposcopic Abnormalities No significant changes in vaginal flora and no serious adverse effects observed in prior published study
+ 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 polymer ba

Spermiostatic Environment [8]

Contraceptive-loaded silicone ring rele
non-hormonal active Ferrous gluconat

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

Ovaprene®
Investigational Hormone-Free, Monthly Contraceptive

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 reaching the cervix across all women and all cycles evaluated.

- Specifically, in 100% of women and cycles, an average of less than five (<5) progre motile sperm (PMS) per high-powered field (HPF) were present in the midcycle cervical 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 m 27.21 PMS/HPF in their baseline cycle (without any contraceptive device), a mean o 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 pres the Ovaprene device), with a median of zero PMS.

	Mean Progressively Motile Sperm	Median Progressively Motile Sperm	Standard Deviation	Inte
Baseline PCT's	27.21	23.20	17.88	
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, marketers 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 IU** in the US*

- 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 n sales in the double-digits.
- Bayer supports the development and regulatory process by providing up to two full-time equivalent (internal experts), or FTEs, in an advisory capacity, which gives us access to their global manufactur 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/
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 - 2023[1]

1. https://www.businesswire.com/news/home/20190628005277/en/Global-Female-Sexual-Dysfunction-Treatment-Market-2019-2023

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://drugeo.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]

- 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 systemi 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 - m improve genital arousal response and overall sexual experience for women as it does in me

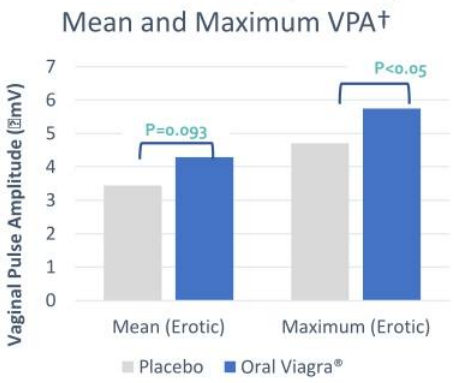
There are no FDA-approved Treatments for FSAD

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

Sildenafil Cream, 3.6%

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

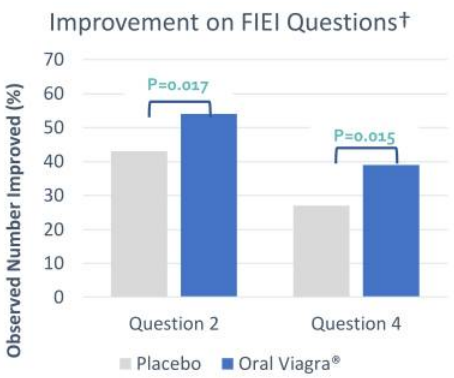
Pfizer VPA Clinical Lab Study – Oral Viagra



† 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® studie

- Increased blood flow and clinic efficacy observed with oral silden (Viagra®) in women.
- The side effect profile of the oral formulation was not optimal fo - leading to the exploration of alt delivery options including a topic 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]

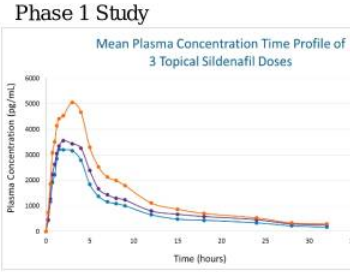
Normal healthy postmenopausal women were dosed with escalating doses of Sildenafil Cream, 3.6%, using a cross-over study design.

- 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 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.

Sildenafil Cream, 3.6%

Positive Data – Thermography Study*

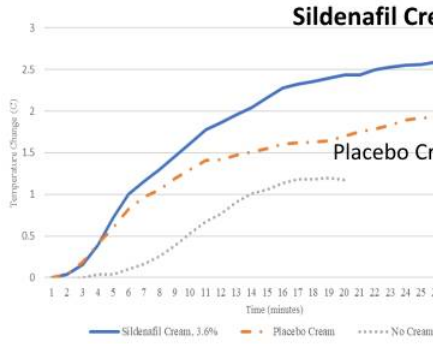
Positive findings for Sildenafil Cream, 3.6% (as shown in Figure 1.)

- 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 f



Statistically significant greater linear slope during m
11-15 of the sexually explicit stimuli as compared to the
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

Vaginal Drug Delivery Technology - IVR

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 recommends non-oral route over oral.[2]

Planned Phase 1 VMS/HRT STUD

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) i Healthy Post-Menopausal Women

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)

The rate of premature birth in the United States rose in 2018 for the fourth straight year after a steady decline from 2007 to 2014.[2]

- In 2018, ~10% of babies were born preterm (less than 37 weeks) in the US.[3]

Assisted Reproductive Technologies (ART)/IVF

An estimated 12-15% of couples are unable to conceive after 1-year of unprotected sex.[4]

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

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 local ap
of tamoxifen to mitigate the symptoms
for patients HR+ breast cancer, includ
women currently on anti-cancer thera

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

Vaginal Tamoxifen – Proof of Concept Study[1]

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

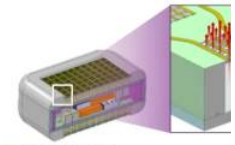
1. Clin. Exp. Obstet. Gynecol. - ISSN: 0390-6663 XLVI, n. 2, 2019
2. https://www.medicalnewstoday.com/articles/322537.php
3. US Food and Drug Administration: "Drug Approval Package: Nolvadex (Tamoxifen Citrate) NDA# 21-109.2002". Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21109_Nolvadex.cfm

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

DARE-LARC1

User-Controlled Long Acting Reversible Contraception

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

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

Q1-2020 Financial Highlights:

- Net cash raised from stock sales, warrant exercises and license fee: $7.9 million
- Cash and equivalents (3/31/2020): $5.0 million

Updates through May 12, 2020:

- Net cash raised from stock sales: $2.0 million
- Common shares o/s: 26.6 million
- Warrants o/s: ~2 million
- Purchase agreement executed for potential stock sales of up to $15 million over a 36-month period ending May 2023

Non-dilutive Grant Funding:

- NIH SBIR: $730,722 final award notice (announced 4/1/2020) of a $1.9 million grant for Ovaprene 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.
- Bill & Melinda Gates Foundation: eligible for up to $2.5 million in additional funding to support development of a wireless, patient controlled, implantable long-acting, reversible contraceptive technology; $17.9 million of up to $20.5 million in total grant funding previously received.

WE ARE **ACCELERATING INNOVATION** IN WOMEN'S HEALTH

MANAGEMENT TEAM

Sabrina Martucci Johnson MSc, MIM, President & CEO

David Friend, PhD, Chief Scientific Officer

Lisa Walters-Hoffert, Chief Financial Officer

John Fair, Chief Strategy Officer

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

Mark Walters, Vice President of Operations

Christine Mauck, MD, MPH, Medical Director

BOARD OF DIRECTORS

William Rastetter, PhD. Chairman

Cheryl Blanchard, PhD

Jessica Grossman, MD

Susan Kelley, MD

Greg Matz, CPA

Robin Steele, JD, LLM

Sabrina Martucci Johnson MSc, MIM, President & CEO

WE ARE DELIVERING **INNOVATION** BY **DARING TO BE DIFFERENT®**


DARE
NASDAQ: DARE
darébio
www.darebioscience.com
TO BE