

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): **January 7, 2019**

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))

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 Bioscience, Inc. ("Daré") and its product candidates, dated January 7, 2019, 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 January 7, 2019.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate presentation, dated January 7, 2019

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: January 7, 2019

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

*Delivering innovation by
daring to be different*



January 7, 2019



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," OR "POTENTIAL" AND OTHER SIMILAR EXPRESSIONS, OR THE NEGATIVE OF THESE TERMS. 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; 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.

What We Do



Vision: To become the coordinating presence in women's health.

Mission: We achieve this by identifying, unlocking and advancing innovation that improves health outcomes and promotes a better quality of life for women.

Daring to be different

A pure play biopharmaceutical company focused on improving the health and well being of women. At Daré, we focus on targeted delivery of products to address persistent unmet needs in women's health. Our focus areas include:

- Pregnancy Prevention
- Sexual Health
- Vaginal Health
- Fertility

Acquisition, Licensing & Partnering Strategy:

- Products that are commercially viable and **attractive to strategic partners**
- Products that have a **data package** including a proof-of-concept and/or the ability to leverage a 505(b)(2) regulatory pathway
- Products that **address a persistent unmet needs** in women's health
- The ability to deliver products in a more **personalized** way for women

Value Creation Strategy:

- The portfolio is well positioned to drive upside value by capitalizing on market misalignments
- The majority of assets are well positioned to be **first-in-category opportunities and are therefore attractive partnering candidates**

Delivering clinical milestones are key value drivers for a development stage company. **We expect to deliver against multiple milestones over the next 12 - 24 months including:**

- Advancing our Bacterial Vaginosis (BV) program into a Phase 3 trial
- Topline readouts from our two pre-pivotal programs Ovaprene (2H 2019) and Sildenafil Cream, 3.6%, (4Q 2020)
- Initiating development activities on the DARE-IVR programs - Hormone Replacement Therapy (HRT/VMS) program phase 1/2a (2019)

Coordinating Presence in Women's Health Market Misalignment = A Value Creation Opportunity

Innovators seeking development partners to advance products to commercialization in women's health.

Network of Product Developers



Large and mid-tier companies prefer to acquire or license products that are later-stage or ready for commercialization.

Network of Potential Commercial Partners*

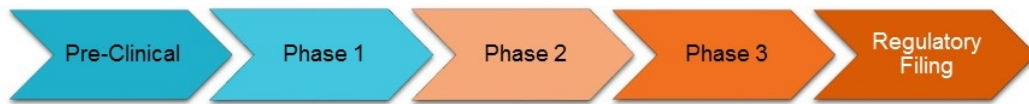


Global Women's Health Market Worth \$51 Billion
by 2025 - CAGR: 3.9% ¹

*Company names and logos are for illustrative purposes only.



1. <https://www.pme.wis.wire.com/news-releases/women-s-health-market-size-worth-51-billion-by-2025-cagr-39-grand-view-research-inc-651064753.html>



Vaginal Gel Clindamycin	DARE-BV1 ^A Formerly MP-101	Phase 3 Initiation 2H 2019	Bacterial Vaginosis
Barrier IVR Ferrous gluconate	Ovaprene® (PCT)*	Top line 2H 2019	CDRH / Device Lead Non-Hormonal, Monthly Contraception
Topical Cream Sildenafil	Sildenafil Cream, 3.6% ^A	Top line 4Q 2020	Female Sexual Arousal Disorder
IVR Natural Estradiol + Natural progesterone	DARE-HRT1 ^{†‡} Topline 2H 2019	Formerly JNP-0201	Hormone Replacement Therapy

Accelerating pre-clinical programs with collaborations and non-dilutive funding whenever possible

IVR Natural progesterone	DARE-FRT1 [*]	Formerly JNP-0301	Pregnancy Maintenance (PTB & ART)
IVR Oxybutynin	DARE-OAB1 [*]	Formerly JNP-0101	Over-Active Bladder
Vaginal Insert SERM (tamoxifen)	DARE-VVA1 [*]	Formerly PT-101	Vulvar and Vaginal Atrophy (HR+ Breast Cancer Population)
Ca2+ Target	DARE-RH1	Formerly CalSper	Non-Hormonal Male & Female Contraceptive Target
Injectable Etonogestrel	ORB 204 & 214 [*]		6 & 12 Month Injectable Contraception

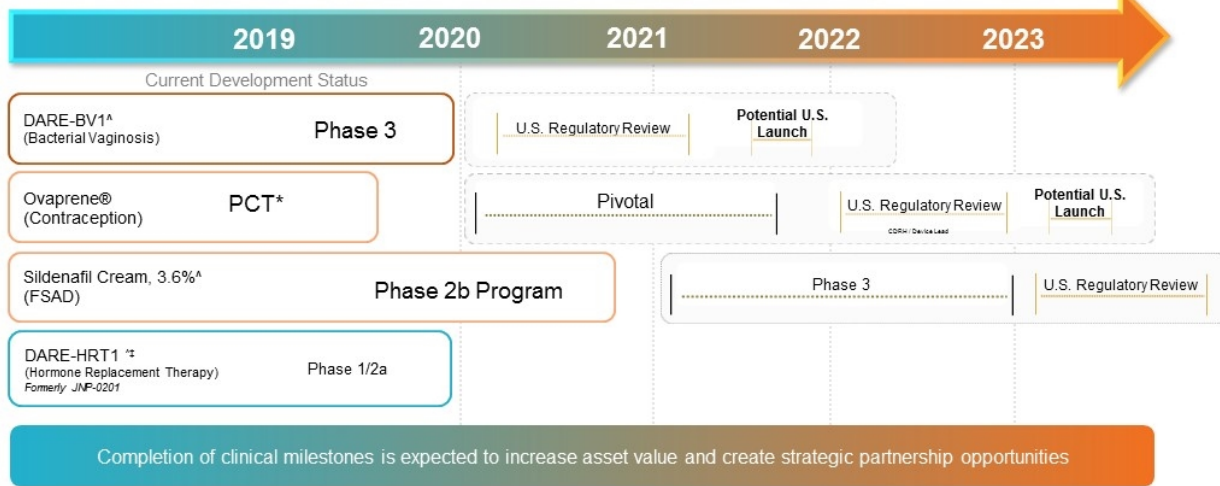
Timeline reflects management's current estimates and constitutes a forward looking statement subject to qualifications elsewhere in the presentation. Actual development timeline may be substantially longer, and Daré is under no obligation to update or review this estimate.

^A505(b)(2).

*Ovaprene Post Coital Test (PCT) is a pre-pivotal clinical study.

[‡]HRT Phase 1 study to be conducted in Australia by Daré subsidiary.

Portfolio Timeline Overview



Pre-Clinical Programs – Lead Identification, Formulation and Manufacturing Optimization

Hormone-Free Contraception	Longer-Acting Injectable Contraceptives [*]	Vaginal Drug Delivery [*]
DARE-RH1	ORB- 204 ORB- 214	DARE-FRT1 DARE-OAB1 DARE-VVA1

Timeline reflects management's current estimates and constitutes a forward looking statement subject to qualifications elsewhere in the presentation. Actual development timeline may be substantially longer, and Daré is under no obligation to update or review this estimate.

^a505(b)(2).

^{*}Ovaprene Post Coital Test (PCT) is a pre-pivotal clinical study.

[‡]HRT Phase 1 study to be conducted in Australia by Daré subsidiary.

Investment Highlights

Financial Profile

Background

- NASDAQ:DARE
- Publicly traded via reverse merger that closed July 19, 2017

Balance sheet, September 30, 2018:

- \$9.5 million in cash
- Non-dilutive NIH SBIR Award:
 - In Q2-2018, Daré received a Notice of Award for the first \$224,665 of an anticipated \$1.9 million in grant funding from a division of the National Institutes of Health.
- 11.4 million common shares and 3.7 million warrants outstanding
- No debt

Management Team

Daré Bioscience

Sabrina Martucci Johnson, MSc, MIM President and CEO	Cypress Bioscience, WCG, Calibr Advanced Tissue Sciences, Baxter Healthcare
Lisa Walters-Hoffert Chief Financial Officer	ROTH Capital Partners, Citicorp Securities, Bank of America, Oppenheimer & Co.
David Friend, PhD Chief Scientific Officer	Evofem Biosciences, CONRAD, Elan Corporation
John Fair Chief Business Officer	Evofem Biosciences, WCG, Gemini Healthcare, Aegis plc
Mark Walters Vice President, Operations	Pacira, SkyePharma, Alliance Pharmaceuticals, American Home Products
Mary Jarosz, RPh, RAC, FTOPRA Global Head of Regulatory Affairs	Evofem Biosciences, WCG, Abbott Laboratories
Christine Mauck, MD, MPH Medical Director	CONRAD, Population Council, RW Johnson, FDA
Bridget Martell, MD, MA Medical Affairs	Juniper Pharmaceuticals, Purdue Pharma, Pfizer
Nadene Zack, MSc Sr. Director Clinical Operations	Retrophin, Aragon, Cypress Bioscience, Pfizer

Board of Directors

Daré Bioscience

Roger Hawley (Chairman)	Zogenix, Alios Biopharma, Cypress Bioscience, InterMune, Elan Corporation, GSK
Jessica Grossman, MD	Medicines360, Sense4Baby, Johnson & Johnson
Susan Kelley, MD	Cerulean, Bayer, BMS, ArQule
Greg Matz	CooperSurgical, Cooper Companies, Hewlett Packard
William Rastetter, PhD	Cerulean, GRAIL, Receptos, Illumina, IDEC
Robin Steele, JD, LL.M	InterMune, Elan Corporation, Alveo, Alios Biopharma
Sabrina Martucci Johnson, MSc, MIM	Cypress Bioscience, WCG, Advanced Tissue Sciences, Baxter Healthcare



Program Overview



DARE-BV1 (Formerly MP-101)
Clindamycin 2% gel for Bacterial Vaginosis



DARE-BV1 Overview

Bacterial Vaginosis (BV)



Successful Proof of Concept

- Vaginal application of DARE-BV1 (clindamycin phosphate 2%) demonstrated effectiveness against BV in a proof-of-concept investigator initiated study in women (n=30):¹
 - 88% of evaluable subjects met clinical cure endpoint at Test-of-Cure visit after single dose administered
 - Favorable efficacy profile over currently approved treatments

505(b)(2) Regulatory Pathway

- Single Phase 3 clinical trial planned for FDA approval

Attractive Market Opportunity

- BV is the most commonly reported vaginal infection in women ages 15-44 ²
- U.S. prevalence estimated to be ~21 million among women ages 14-49 ²
- Approved prescription drugs have less than optimal clinical cure rates (37-67%) ³
- Opportunity for significant upside and market expansion

Patent Coverage

- Patents covering the licensed technology have been granted with terms through 2028
- Additional patents pending would have terms through 2035



1. Data on file
2. <https://www.cdc.gov/std/bv/stats.htm>
3. BV Product Data: <http://www.clindeesse.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

Bacterial Vaginosis

Symptoms & Causes of BV

- BV is the most commonly reported vaginal infection in women ages 15-44.¹ BV is characterized by a shift in the vaginal flora from the dominant *Lactobacillus* to a polymicrobial flora.²
- BV has been associated with serious health issues, including preterm births, pelvic inflammatory disease, increased susceptibility to sexual transmitted infections (including HIV infection) and other chronic health problems.^{1,2}
- A number of potential microbial pathogens, singly and in combinations, have been implicated in the disease process.
 - The list of possible agents includes *Gardnerella*, *Atopobium*, *Prevotella*, *Peptostreptococcus*, *Mobiluncus*, *Sneathia*, *Leptotrichia*, *Mycoplasma*, and BV-associated bacterium 1 (BVAB1) to BVAB3.¹

Bacterial Vaginosis

Symptoms & Causes of BV

- BV is characterized by the presence of three of the following four criteria:
 - Vaginal pH of >4.5
 - Clue cells on saline wet mount
 - Release of a fish amine odor
 - A characteristic thin, homogenous vaginal discharge
 - In 1991, Nugent et al. described a Gram stain scoring system of vaginal smears to diagnose BV. ^{1,3}
- The Nugent score is calculated by assessing for the presence of large gram-positive rods (*Lactobacillus morphotypes*; decrease in *Lactobacillus* scored as 0 to 4), small gram-variable rods (*G. vaginalis morphotypes*; scored as 0 to 4), and curved gram-variable rods (*Mobiluncus spp. morphotypes*; scored as 0 to 2) and can range from 0 to 10. A score of 7 to 10 is consistent with BV. ^{1,3}
- BV is not considered to be a sexually transmitted infection, but it is more common in women who are sexually active.



Bacterial Vaginosis

Market Opportunity

- In the US, an estimated 21 million women aged 14-49 years (approximately 29%) are infected with BV.^{1,2}
 - BV leads to symptoms including abnormal vaginal discharge and odor that are unpleasant and disrupt and interfere with a woman's relationships and general quality of life.
- According to IMS/IQVIA data, the 2016 U.S. annual sales figures for BV prescriptions were in excess of \$150 million including utilization of oral and vaginal forms of Clindamycin and Metronidazole.³
 - Lupin's 1x oral Solosec[®] launched in May of 2018.⁴

1. <https://www.cdc.gov/std/bv/stats.htm>
2. Sucher, Allana et al., "Bacterial Vaginosis: A Review," US Pharmacist 2018; 43(9):32-33
3. IMS/IQVIA data (2016). Data on file
4. <http://www.lupinpharmaceuticals.com/lupin-launches-solosec-secnidazole-2g-oral-granules-in-the-us.htm>

Bacterial Vaginosis

DARE-BV1 (Formerly MP-101) Proof of Principle Study Design

Study Objective: Study the Efficacy and Safety of DARE-BV1 in the Treatment of Bacterial Vaginosis

Proof of Principle Study Design (n = 30)

Day 1 Baseline Visit	Day 7 - 14 Test-of-Cure Visit	Day 21 - 30 Continued Clinical Response Visit
<ul style="list-style-type: none"> • Single dose administered 	<ul style="list-style-type: none"> • Patients questioned regarding comfort level & re-examined 	<ul style="list-style-type: none"> • Patients questioned regarding experience & re-examined
<p>Tests Performed:</p> <ul style="list-style-type: none"> • Physiological symptoms • pH • Saline "wet mount" • 10% KOH "whiff test" • Urine pregnancy (if needed) 	<p>Tests Performed:</p> <ul style="list-style-type: none"> • Physiological symptoms • pH • Saline "wet mount" • 10% KOH "whiff test" • Urine pregnancy (if needed) 	<p>Tests Performed:</p> <ul style="list-style-type: none"> • Physiological symptoms • pH • Saline "wet mount" • 10% KOH "whiff test" • Urine pregnancy (if needed)
<ul style="list-style-type: none"> • Eligibility: Female subjects 18 years or older with confirmed clinical diagnosis of BV • Primary Endpoint: Clinical Cure at Test-of-Cure visit (defined as resolution of clinical findings from baseline visit); • Secondary Endpoints: Proportion of patients with therapeutic and bacteriologic cures,^{1,2} • Safety: Patients were questioned about their comfort level and adverse reactions they experienced. 		

Bacterial Vaginosis

DARE-BV1 (Formerly MP-101) Proof-of-Principle Study Summary

A single dose of DARE-BV1 demonstrated high clinical cure rate compared to other approved products

Efficacy of MP-101 gel for the Treatment of Bacterial Vaginosis			
Product	Clinical Cure	Nugent Cure	Therapeutic Cure
DARE-BV1 novel gel (clindamycin)	88%	67%*	55%*
Solosec® ¹ (secnidazole 2g oral granules)	53-68%	40-46%	35-40%
Clindesse® ² clindamycin phosphate Vaginal Cream, 2%	41-64%	45-57%	30-42%
Metronidazole vaginal gel, 1.3% ³	37%	20%	17%



↓ LUPIN

Perrigo

Allergan

* Based on data from 9 evaluable patients

- 30 subjects; 26 subjects were evaluable
- Test-of-Cure Visit (Day 7 – 14):
 - **88% (n = 23) subjects achieved clinical cure**
 - 5 of 9 subjects had therapeutic cure and 6 of 9 had bacteriologic cures
- Continued Clinical Response Visit (Day 21 – 30):
 - **92% (n = 24) subjects showed continued clinical cure**
 - 6 of 9 subjects had therapeutic cure and 7 of 9 had bacteriologic cures



1. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=551e43d5-f700-4d6e-8029-026f6a8932f8&type=display>. Cure rate range reflects low and high cure rates across multiple studies.
 2. <http://www.clindesse.com/pdf/PI.pdf>. Cure rate range reflects low and high cure rates across multiple studies
 3. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf



Contraception

Expected to be a \$33 billion global category by 2023¹



1. Global Market Insights, <https://globenewswire.com/news-release/2016/05/19/841462/0/en/Contraceptives-Market-size-to-exceed-33-Billion-by-2023-Global-Market-Insights-Inc.html>

New Contraceptive Option

Ovaprene® Overview



Successful Proof of Concept Study

- Ovaprene demonstrated effectiveness in preventing sperm from entering the cervical canal in a proof-of-concept study in women (n=20):¹
 - No viable sperm in the cervical mucus
 - No colposcopic abnormalities

CDRH (Device) Regulatory Pathway

- Single pivotal clinical trial expected for FDA approval

Attractive Market Opportunity

- >\$6 billion in US Rx sales of contraceptive products (2016).²
- 40 million women of reproductive age currently use a contraceptive method.³

Patent Coverage

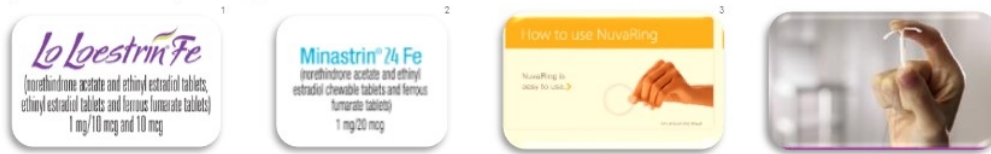
- Patents covering the licensed technology have been granted with terms through 3Q 2028
- Opportunity for Patent Term Extension (PTE) and potential new patents

New Contraceptive Option

Ovaprene® Overview

Innovation in Contraception

Advances in hormone products have largely focused on reducing the hormone dosage, adjusting or extending the duration of protection and optimizing methods of administration.



Convenience is driving new innovation

- NuvaRing®
 - Monthly, convenient vaginal ring product form.
 - 2017 worldwide sales: \$761 million (Merck)⁵
- Mirena® Product Family
 - Physician inserted, long-acting.
 - Low/locally delivered hormone IUS.
 - 2017 worldwide sales: \$1.12 billion (Bayer)⁷

1. Lo Loestrin Fe contains a low-dose combination of two female hormones. <https://www.loloestrin.com/loloestrin/about-lo-estrin>. Lo Loestrin® and its design are registered trademarks of Allergan Pharmaceuticals International Limited.

2. Minastrin <https://www.minastrin24.com>. Minastrin® is a registered trademark of Allergan Pharmaceuticals International Limited.

3. <https://www.nuvaring.com/how-nuvaring-works/>

4. <https://www.mirena-us.com/about-mirena/>

5. Annual Report on Form 10-K for fiscal year ended December 31, 2017

6. Bayer Annual Report 2017. Includes sales for Mirena®, Kyleena® and Jaydess®/Skyla®

New Contraceptive Option

Ovaprene® Overview

Women's Preferences

- Effective Pregnancy Prevention
- Convenient Product Forms
 - Independent surveys revealed that the vaginal ring has many of the features women deemed extremely important.¹
- **Less Hormones**
 - A majority of women prefer a monthly option with a lower hormone dose than the pill.²
- Methods **not in the moment (noncoital)**
 - **77% of women** who practice contraception currently 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

What's Missing in Contraception?

Hormone free alternatives that are effective and easy to use

Least Effective

100% Effective = 0% Risk of Pregnancy ^{1,2}

Method	Perfect Use	Typical Use
Spermicide* / Vaginal Gels	82.00%	72.00%
Sponge-Parous*	80.00%	76.00%
Sponge-Nulliparous*	91.00%	88.00%
Condom (male)*	98.00%	82.00%
Diaphragm*	94.00%	88.00%
Combined Pill & Progestin only*	99.70%	91.00%
Evra Patch*	99.70%	91.00%
Nuva Ring*	99.70%	91.00%
Depo-Provera*	99.80%	94.00%
IUD- ParaGard (Copper T)*	99.40%	99.80%
IUD- Mirena (LNg)*	99.80%	99.80%
Implanon*	99.95%	99.95%
Female Sterilization*	99.50%	99.50%
Male Sterilization*	99.90%	98.85%

Most Effective

Hormone Free Product Landscape¹

Marketed or in development



- Spermicides / Vaginal Gels**
- ⬇️ Effectiveness (72% Typical Use)
 - 👤 Woman controlled
 - 🕒 Used "in the moment"



- Condoms**
- ⬇️ Effectiveness (82% Typical Use)
 - ⬇️ Not woman controlled
 - 🕒 Used "in the moment"



- Diaphragms**
- ⬆️ Effectiveness (88% Typical Use)
 - 👤 Woman controlled
 - 🕒 Used "in the moment"



- Long-acting IUD**
- ⬆️ Effectiveness (99% Typical Use)
 - ⬇️ Not woman controlled
 - 👤 Physician inserted

New Contraceptive Option

Ovaprene® Overview

Ovaprene® Non-hormonal, Monthly Vaginal Ring

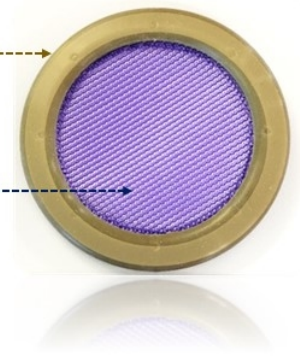
Spermiostatic Environment¹

- Achieved through a contraceptive-loaded silicone ring matrix.
- Releasing non-hormonal active Ferrous gluconate.

Physical Barrier¹

- 3-D, non-braided, fluid-permeable mesh barrier.

Rx distribution (OB/GYN) – anticipated upon approval.



New Contraceptive Option

Ovaprene® Overview

Ovaprene successfully prevented sperm from reaching the cervical canal in a previous human postcoital test (PCT) clinical study.

- 2009 - Postcoital Assessment:¹
 - Open-label, single-arm, pilot safety and tolerability study.
 - Published in the Journal of Reproductive Medicine, 2009.
- Patients:
 - N= 20; all women completed one cycle of use.
- Results:
 - **Postcoital testing revealed no viable sperm in the cervical mucus.**
 - No colposcopic abnormalities, no significant changes in vaginal flora and no serious adverse effects observed.

2,3

Birth Control Effectiveness		
Method	Perfect Use	Typical Use
Spermicide* / vaginal gels	82.00%	72.00%
Sponge-Parous*	80.00%	76.00%
Sponge-Nulliparous*	91.00%	88.00%
Condom (male)*	98.00%	82.00%
Diaphragm*	94.00%	88.00%
Combined Pill & Progestin only*	99.70%	91.00%
Evra Patch*	99.70%	91.00%
Nuva Ring*	99.70%	91.00%
Depo-Provera*	99.80%	94.00%
IUD- ParaGard (Copper T)*	99.40%	99.80%
IUD- Mirena (LNg)*	99.80%	99.80%
Implanon*	99.95%	99.95%
Female Sterilization*	99.50%	99.50%
Male Sterilization*	99.90%	98.85%

In PCT studies of similar size, products (diaphragms) with no motile sperm in the cervical mucus during their PCT assessments demonstrated “typical use” contraceptive effectiveness of 88% in pivotal contraceptive studies evaluating pregnancy rates over time.

1. Journal of Reproductive Medicine 2009; 54: 685-690
 2. 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.
 3. <http://www.contraceptivetechnology.org/wp-content/uploads/2013/09/CTFailureTable.pdf>

New Contraceptive Option

Ovaprene® Overview

U.S. Regulatory Strategy

- PMA with CDRH (Medical Device Division) as lead review division.
- Pathway expected to be based on similar CDRH approvals - Example: Caya® diaphragm.*

• Step 1 – Postcoital test (PCT) 2018 / 2019*

- The study is enrolling 50 couples.
 - 25 women complete a total of 21 visits
- Evaluated over the course of five menstrual cycles.
- Each woman's cervical mucus will be examined at several points during the study:
 - Cycle 1 - Baseline (excludes the use of any product),
 - Cycle 2 - Use of a barrier method (diaphragm),
 - Cycles 3,4 and 5 - Ovaprene vaginal ring.
- Assess motile sperm per high powered field (HPF) in the cervical mucus, post coitus.
- Safety assessments, PK, acceptability, fit, and ease of use.






- Data from the study is expected to be available in the second half of 2019.
- **If there is demonstration of feasibility in the PCT clinical trial, the Company intends to prepare and file an Investigational Device Exemption (IDE) with the FDA to commence a pivotal clinical trial** to support marketing approvals of Ovaprene in the United States, Europe and other countries worldwide.

→ Step 2 – Pivotal Study 2020 / 2021*

- Single pivotal clinical (expected).
- N= ~250 completers over 6 months of use.
 - Primary Endpoints: Safety & Efficacy
 - Pregnancy probability.
 - Secondary Endpoints:
 - Acceptability/product fit/ease of use.
 - Assessments of vaginal health.

New Contraceptive Option

Ovaprene® Overview

Features Desired Most in Birth Control: ^{1,4}	Design Features of Ovaprene: ^{5,6}
 Convenience (Easy to Use & Easy to Remember)	Monthly Ring Product Form <i>Women chose rings for the convenience of a non-daily option.</i>
 Hormone Free	No Hormones in the API <i>Unique dual action MOA (spermiostatic & barrier).</i>
 Efficacy	Expected Typical Use Effectiveness Comparable to Hormone Contraception (88% vs 91%).
 Favorable Side Effect Profile	No Colposcopic Abnormalities <i>No significant changes in vaginal flora. No serious adverse effects observed in prior published study.</i>
 Easily Manage Fertility	No Systemic Activity <i>Inserted and removed without a provider. Immediate return to fertility.</i>



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):749-63
 4. Ersek, J, Matern Child Health J (2011) 15:497-506
 5. Journal of Reproductive Medicine 2009; 54: 685-690
 6. 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.



Women's Sexual Health & Wellness Female Sexual Arousal Disorder (FSAD)

World market for both male and female sexual dysfunction drugs will reach 7.7 billion in 2019¹



1. <https://www.visiongain.com/sexual-dysfunction-drugs-market-will-reach-7-7bn-in-2019-predicts-a-new-visiongain-study/>

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream, 3.6%



Successful Proof of Concept

- Sildenafil Cream, 3.6% cream improved genital blood flow in a proof-of-concept study (n=35):¹
 - Efficacy signal observed in both pre and postmenopausal patients
 - Excellent systemic/local safety and tolerability profile

505(b)(2) Regulatory Pathway

- Ability to leverage the safety and efficacy profile of sildenafil (Viagra®) for FDA submission package

Attractive Market Opportunity²

- 33% of females in the U.S. (21 to 60 years old) experience symptoms of low or no sexual arousal
- 16% are considered distressed and are seeking a solution to improve their condition

Patent Coverage

- Patents covering the licensed technology have been granted with terms through 2031
- Opportunity for Patent Term Extension (PTE)

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream 3.6%

Dyspareunia

Vulvar-Vaginal
Atrophy

Hypoactive Sexual
Desire Disorder
(HSDD)

Female Sexual
Arousal Disorder
(FSAD)

 **Intrarosa**
Prasterone VAGINAL INSERTS 6.5 mg

ESTRACE CREAM
(estradiol vaginal cream, USP, 0.01%)

addyi
(flibanserin)

No Approved
Products

Imvexxy
(estradiol vaginal insert)

Osphena
(ospemifene) tablets
60 mg

 **Premarin**
(conjugated estrogens)
vaginal cream

Rekynda
(bremelanotide)

With its approval of Addyi®, FDA has now acknowledged and formally classified the distinct and separate disorders that comprise Female Sexual Dysfunction.

Where HSDD is characterized primarily by a lack of sexual desire, **FSAD is characterized primarily by an inability to attain or maintain sufficient physical sexual arousal.**

- INTRAROSA is a registered trademark of Endoceutics, Inc.
- Imvexxy is a trademark of TherapeuticsMD, Inc.
- Osphena is a registered trademark of Duchesnay USA, Pennsylvania, USA.
- ESTRACE® is a registered trademark of Allergan Pharmaceuticals International Limited.
- Premarin is a registered trademark of Pfizer Inc.
- Addyi is a registered trademark of Sprout Pharmaceuticals, Inc.
- Bremelanotide is a registered trademark of Palatin Technologies, Inc.

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream 3.6%

FSAD is characterized primarily by an inability to attain or maintain sufficient physical sexual arousal; it is also characterized by distress or interpersonal difficulty.*

- Estimated 23-33% of women suffer from arousal disorder:
 - 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

*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. 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.

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream 3.6%

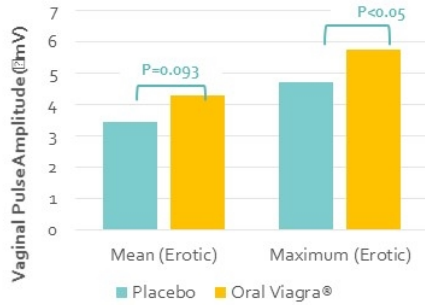
Key Takeaways:

- Oral sildenafil (Viagra) demonstrated statistically significant activity
- Side effects of the oral formulation led to the investigation of a new route of administration

Increased blood flow and clinical efficacy with oral sildenafil (Viagra®) in women:

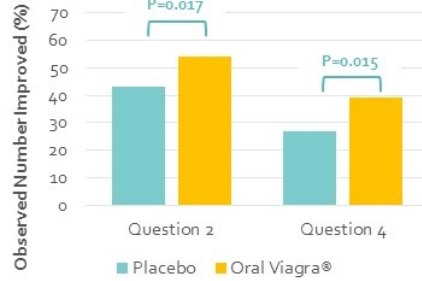
- Statistically significant increases in Vaginal Pulse Amplitude (VPA)¹
- Statistically significant improvement in genital stimulation (FIEI)²

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



† Twelve healthy premenopausal women were studied.

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 (vagina, 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.” †† 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.



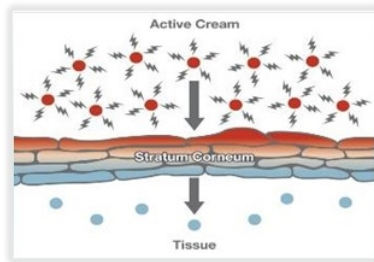
1. The Enhancement of Vaginal Vasocongestion by Sildenafil in Healthy Premenopausal Women. Journal of Women's Health & Gender-Based Medicine. Vol. 11, No. 4. 2002
 2. Safety and Efficacy of Sildenafil Citrate for the Treatment of FSAD: A Double-Blind, Placebo Controlled Study. The Journal of Urology. Vol 170, 2333-2338, December 2003.

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream 3.6%

Formulation Innovation

- Sildenafil Cream, 3.6% designed to directly increase local blood flow to the genital tissue.
- The formulation delivers localized action, with minimal systemic uptake of the active drug.¹



SST Formulation Technology

6 issued patents in the U.S. on the topical delivery of Sildenafil and other PDE-5 inhibitors.

- Leveraging the known therapeutic benefit of oral sildenafil to stimulate increased blood flow to the genital tissue.
- If approved, Sildenafil Cream, 3.6% may offer a safe, effective and 'on demand' solution to difficulties with sexual arousal.

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream 3.6%

Continue to explore additional clinical and non-clinical work that might be valuable or required to support the overall program and the anticipated design of the Phase 2b.

Content Validity

Initiated (4Q 2018)

- A content validity study is designed to help ensure the concepts we plan to measure are the most important and relevant to our target population.
- It is a focus group type study where in-depth one-to-one interviews are conducted with individuals who have FSAD.
- The interviews are conducted in a population that, as closely as is reasonable, matches the proposed clinical trial population.
- It includes an open-ended discussion in which the participant will be asked about their experience of sexual arousal problems and any associated impact. In addition, the participant will be asked to complete the patient reported outcomes (PRO instrument proposed to be used in the Phase 2b and Phase 3 clinical trials, to provide feedback on the relevance of the questions in the PRO instrument and on the clarity and understandability of all questions, instructions, and response options.
- This is a non-interventional study – participants will not be asked to use or evaluate any products.

Planned Type C Meeting

- Because our plan is for the endpoints used in the Phase 2b to reflect the endpoints used in the Phase 3 trials, after the content validity study is completed, and before we commence a Phase 2b at home trial, we will request at Type C meeting to get feedback on whether the agency agrees that the PRO instruments are **content valid** for the target population.

At Home Study

2b At Home Study Topline Data – 4Q 2020

- The Phase 2b at-home study will allow patients to use the investigational product and placebo in their home setting.
- The FDA is agreeable to a 12-week Phase 2b for Sildenafil Cream, 3.6% to assess reasonable safety and preliminary efficacy. The 2016 Draft Guidance reflects expectations regarding phase 3 study length and patient population.

Key Takeaways:

- The phase 2b program will consist of a content validation component followed by at-home dosing of the investigational product and a placebo control.
- The plan is to use the selected PRO instrument and FDA agreed upon endpoints for the phase 2b and phase 3 clinical trials.

Female Sexual Arousal Disorder (FSAD)

Sildenafil Cream 3.6%

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Vulvar-Vaginal
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Hypoactive Sexual
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(conjugated estrogens)
vaginal cream

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(If approved)

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Innovative Vaginal Drug Delivery

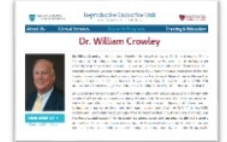
Well characterized therapeutic options



Intravaginal Ring (IVR) Technology Platform

Daré has an exclusive, global license to Juniper's novel IVR technology originally developed by Dr. Robert Langer from MIT¹ and Dr. William Crowley² from Massachusetts General Hospital and Harvard Medical School. Daré's exclusive license covers all rings in development as well as additional applications of the IVR technology platform in other therapeutic areas.

- Features of the Juniper intravaginal ring technology include:
 - Sustained drug delivery.
 - Variable dosing and duration.
 - Single or multiple drug delivery via a solid ethylene vinyl acetate polymer matrix (without the need for a membrane or reservoir to contain the active drug or control the release).
- Current 505(b)(2) candidates licensed from Juniper include:
 - **DARE-OAB1**
 - Formerly JNP-0101, an oxybutynin ring for the treatment of overactive bladder;
 - **DARE-HRT1**
 - Formerly JNP-0201, a combination bio-identical estradiol + progesterone ring for hormone replacement therapy.
 - **DARE-FRT1**
 - Formerly JNP-0301, a natural progesterone ring for the prevention of preterm birth and for fertility support as part of an IVF treatment plan.



Hormone Replacement Therapy (HRT)

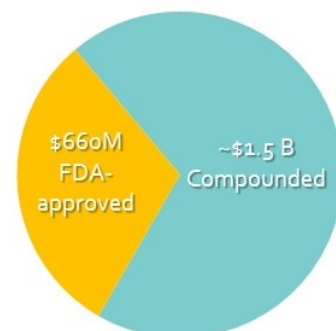
DARE-HRT1



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.¹

- 45M women in U.S. approaching or in menopause.²
- 2012 NAMS consensus statement supports HRT in peri- and post-menopausal women – estrogen to reduce symptoms and progesterone to prevent thickening of uterine wall.³
- NAMS recommends non-oral route over oral.³
- 2002 Women’s Health Initiative (WHI) study showed that the long-term use of certain synthetic hormones (a combination of medroxyprogesterone and conjugated equine estrogens) increased the risk of breast cancer, stroke, heart attack and blood clots

\$2.2 Billion U.S. Market⁴



■ Compounded ■ FDA-approved



1. 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

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

3. Menopause, Vol. 19, No. 3, 2012.

4. U.S. 2014. Source: Symphony Health Solutions Report

Hormone Replacement Therapy (HRT)

DARE-HRT1

Phase 1/2a - Hormone Replacement Therapy (HRT)

DARE-HRT1 for the treatment of VMS due to menopause – combination bio-identical estradiol and progesterone in a convenient 28 day IVR

- Proposed Study:
 - A Phase 1, Open-Label, 3-arm Parallel Group Study to Evaluate the Pharmacokinetics and Safety of DARE-HRT1 (80 µg and 160 µg Estradiol/ 4 mg and 8 mg Progesterone Intravaginal Rings) in Healthy Post-Menopausal Women.
- Primary Objectives:
 - To describe the PK parameters over 28 days using two different dose combinations of DARE-HRT1 Intravaginal ring (IVR):
 - Estradiol 80 µg/Progesterone 4 mg IVR
 - Estradiol 160 µg/Progesterone 8 mg IVR
 - Identify the steady-state PK after 28 days of each DARE-HRT1
- N=60

Vaginally Delivered Tamoxifen for VVA

DARE-VVA1

Vaginally Delivered Tamoxifen to treat VVA in HR+ Breast Cancer Patients

- DARE-VVA1 (Formerly PT-101)
 - A proprietary vaginal formulation of tamoxifen, has the potential to be a first-in-class treatment for vulvar and vaginal atrophy (VVA) in patients with hormone-receptor positive (HR+) breast cancer.
- VVA is a chronic condition characterized by pain during intercourse, vaginal dryness and irritation.
 - Most women use localized estrogen therapy which is contraindicated for the more than two million women diagnosed with, or at risk of recurrence of, ER-positive and PR-positive breast cancer.¹
 - Daré intends to develop this novel local application of tamoxifen to mitigate the symptoms of VVA for patients with or at risk for hormone-receptor-positive breast cancer, including women currently on anti-cancer therapy.
 - Due to the use of aromatase inhibitors for the treatment of HR+ breast cancer, the prevalence of VVA in postmenopausal breast cancer patients is reported to be between 42 and 70 percent.²
- If approved, DARE-VVA1 has the potential to be the first treatment specifically developed for VVA in patients with HR+ breast cancer.



Strategic Pre-Clinical Candidates

Contraceptives that address global gaps



"Innovative partnerships increase access to family planning, helping more women plan their lives and shape their futures."

Chris Elias, President Global Development Program, Bill & Melinda Gates Foundation



Major foundations contribute hundreds of millions of dollars to fund new innovation in women's reproductive health.



Development organizations screen and advance promising new innovation.

Daré has emerged as the coordinating presence among these organizations and is well positioned to partner on the product candidates with significant market potential.

Daré's
Innovation
Engine

Reproductive Health
Public & Private
Sector Funding








Daring to be different

Value Creation in Women's Reproductive Health

Addressing Global Needs
in Contraception



Daring to be different

Organization	Funding Source / Donor	Product Name	License Holder / Partner	Form	Indication	Annual Sales / Corporate Value
The Population Council	USAID Gates Foundation	Anovera 	Therapeutics MD	Ring	Pregnancy Prevention	2018 \$20M upon FDA approval; \$20M first commercial batch, milestones + royalties ¹
	USAID	Paragard 	Cooper Surgical	IUD	Pregnancy Prevention	2017 Cooper Surgical \$1.1B Acquisition from Teva ¹
	USAID	Mirena 	Bayer	IUS	Pregnancy Prevention	2017 >\$1.1B (Global sales) ²
	USAID	Jadelle 	Bayer	Implant	Pregnancy Prevention	2014 ~\$400M (Global sales) ¹
Medicines360	Large Anonymous Donor	Liletta 	Allergan	IUS	Pregnancy Prevention	2013 \$50M upfront; \$125M milestones + royalties ¹

¹ SEC Filing/IMS Data;
² Bayer Annual Report 2017. Includes sales for Mirena®, Kyleena® and Jaydess®/Skyla®

A New Contraceptive Target

DARE-RH1 CatSper

A Novel Approach To Male And Female Contraception.

- The identification of the CatSper target represents the potential to develop a novel class of non-hormonal contraceptive products for both men and women.
 - The discovery of a sperm-specific ion channel, CatSper, was validated in animal models where it was demonstrated that male mice lacking CatSper have poor sperm motility.
- CatSper proteins are ion channels expressed solely in the membranes of sperm flagellum and are essential to sperm motility.
- Pre-clinical research has demonstrated CatSper mediates hyperactive motility of sperm.
 - Sperm hyperactivity is necessary to penetrate the physical barrier known as the zona pellucida which encloses the ovum and protects the egg.¹
 - The contraceptive benefit of targeting CatSper is achieved by inhibiting sperm hyperactivity and preventing egg fertilization.

A New Long Acting Contraceptive Option

Microparticle 6 & 12 Month Injectable Contraception

ORB-204 and ORB-214, injectable etonogestrel¹

The initial development on Orbis' long-acting injectable contraceptive program was carried out under a subcontract funded by Family Health International (FHI 360) through a grant from the **Bill & Melinda Gates Foundation**.

- Pre-clinical studies for the 6- and 12- month formulations have been completed to date:
 - Establishing pharmacokinetics and pharmacodynamics profiles.

An injectable contraceptive is designed to provide discreet, non-invasive protection over several months

- Limitations of the currently marketed injectable contraceptive: provides contraceptive protection for only three months, and can delay the ability to get pregnant for up to ten months after receiving the injection.

Target product profile of long-acting injectable

- Prolonged duration (6 to 12 months), improved ease of use, with an improved side effect profile and predictable return to fertility.

Corporate & Investor Communications

NASDAQ: DARE

Trading as DARE since July 20, 2017



www.darebioscience.com



