

## Dare Bioscience (NASDAQ/DARE)

### BUY Let's Talk About Women's Health

*Dare is focused on creating innovative solutions for the most common female health issues: bacterial vaginosis, contraception, and Female Sexual Arousal Disorder. By addressing these three common issues, Dare hopes to improve the quality of life for millions of women across the world.*

### Investment Highlights

**One and Done for BV.** DARE-BV1 is in development for bacterial vaginosis (BV). Differentiating characteristics include a gel technology which allows for local delivery and a onetime application. With high cure rates, (as high as 86%), the product appears superior to the standard of care treatments that average 50%.

**Filling A Gap.** In today's age of choices and liberation and equality of the sexes, large gaps still exist among the various contraception modalities. Whether it's hormonal or mechanical, no one product seems to meet the needs of all comers. Ovaprene has been designed to partially address this gap (which includes ~40M women in the U.S. alone) as a hormone-free, effective, and monthly self-administered mechanical device, easy to use product.

**Female Viagra. Yes, Its time.** Female Sexual Arousal Disorder – FSAD is real, and Sildenafil cream (the active ingredient of Viagra) has shown efficacy to address a segment of the female population (10M plus sexually active women) that are currently living with the disorder. Although FSAD affects more women than erectile dysfunction affects men, there are currently no approved products on the market

**A Large Opportunity for Ovaprene.** In 2016, contraception products had more than \$6B in sales. Bayer's Mirena IUS and Merck's NuvaRing are the leading products in this space. However, each of these administers hormones to their patients, despite recent trends toward nonhormonal methods. Other important factors include convenience, efficacy, and favorable side effects. Dare's Ovaprene fulfills all four features, creating a brand new product category for contraception. Dare hopes to not only attract consumers who already use nonhormonal methods but also convert those who currently use hormonal products.

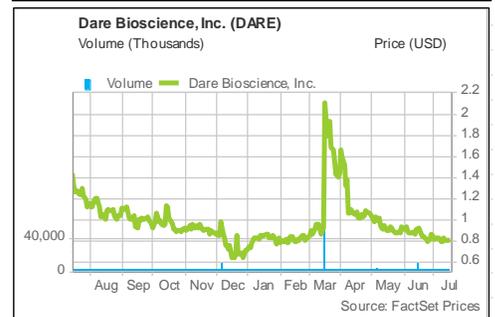
**Opportunity for DARE-BV1.** The current market for the treatment of bacterial vaginosis is highly genericized. Symptoms often reoccur even after current antibiotic treatments, leaving room for a more effective, one-time solution. DARE-BV1 has the same API (clindamycin) as some currently approved treatments, leaving them to believe that their path to approval will be successful.

July 18, 2019

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Current Price **\$0.81**  
 Price Target **\$4.00**

Estimates	F2019E	F2020E	F2021E
<b>Expenses (\$000s)</b>	\$ 12,624	\$ 13,851	\$ 15,199
1Q March	\$ 3,083	\$ 3,324	\$ 3,648
2Q June	\$ 3,388	\$ 3,199	\$ 3,510
3Q September	\$ 3,410	\$ 3,592	\$ 3,943
4Q December	\$ 2,743	\$ 3,735	\$ 4,099
	F2019E	F2020E	F2021E
<b>EPS (diluted)</b>	\$ (0.84)	\$ (0.50)	\$ (0.32)
1Q March	\$ (0.27)	\$ (0.12)	\$ (0.08)
2Q June	\$ (0.29)	\$ (0.12)	\$ (0.07)
3Q September	\$ (0.16)	\$ (0.13)	\$ (0.09)
4Q December	\$ (0.13)	\$ (0.13)	\$ (0.09)
<b>EBITDA/Share</b>	(\$0.65)	(\$0.44)	(\$0.35)
<b>EV/EBITDA (x)</b>	0.0	0.0	0.0
Stock Data			
<b>52-Week Range</b>	\$0.60	-	\$3.25
<b>Shares Outstanding (mil.)</b>	16.7		
<b>Market Capitalization (mil.)</b>	\$13		
<b>Enterprise Value (mil.)</b>	\$10		
<b>Debt to Capital</b>	0%		
<b>Book Value/Share</b>	\$2.20		
<b>Price/Book</b>	1.2		
<b>Average Three Months Trading Volume (K)</b>	314		
<b>Insider Ownership</b>	20.3%		
<b>Institutional Ownership</b>	8.4%		
<b>Short interest (mil.)</b>	4.4%		
<b>Dividend / Yield</b>	\$0.00/0.0%		



Transfer of Coverage - July 18, 2019 - Buy - Price Target \$4.00

**Opportunity for Sildenafil cream.** In a press release, the FDA recognized Female Sexual Dysfunction as one of 20 diseases of "high priority and focused attention." In June 2019, they also approved Vyleesi, a treatment for hypoactive sexual desire disorder. These two factors speak to their motivations about future drug approval, leaving them to predict a high probability of approval. Oral sildenafil has already proved statistically significant results in increasing genital blood flow in women, further bolstering the probability of success for the product.

**Valuation:** We assume that DARE-BV1 will be commercialized in 2021 and that Ovaprene will be commercialized in the U.S. in 2023 and in the EU in 2025. For Sildenafil cream, we expect commercialization in the U.S. in 2024 and in the EU in 2026. We assume a 30% discount rate in our Free Cash Flow to the Firm (FCFF), Discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models due to the reasonable risk associated with each product. This results in models which are equally weighted and rounded to the nearest whole number with a \$4.0 price target. We acknowledge that our risk rate (30%) combined with our probability of success factors in our model combine to restrain the target valuation. On clinical and commercial progress, we would need to re-evaluate these assumptions, suggesting more upside exists with positive progress.

**Risk to our thesis, include the following:** (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property. We review these and other risks in the risk section of this report.

*A special thanks to Chase Shea - Georgetown University, Alex Levy - University of Wisconsin-Madison, Jesse Clark - University of Florida, Ryan Swiezbin - Quinnipiac University, Tucker Kolbert - University of Wisconsin -Madison, Clayton Berger – Skidmore College for their research contributions to this report.*

**Company Overview.** Dare Bioscience is a clinical-stage bio pharmaceutical company founded in 2015. President and CEO Sabrina Johnson have focused the company's goals on creating innovative products for women's health. This includes focuses on pregnancy prevention, sexual and vaginal health, as well as women's fertility. Currently, the company is looking to fill the gap between early innovation and commercialization for women's health products. Their mission statement acknowledges their vision for addressing women's health by targeting unmet needs and promoting a high quality of life.

DARE-BV1 is the company's most advanced product. In an investigator based proof-of-concept study, the product demonstrated effectiveness against BV, with 86% of patients enrolled meeting clinical cure endpoints after only one dose of the drug. Currently approved treatments have cure rates as low as 37% and require repeated treatment due to reoccurrence. What makes DARE-BV1 special is the solution to gel transition, which keeps the product at the application site. In addition, their sustained-erosion feature allows for maximum exposure over multiple days to allow for only one dose of the product. Another driver for Dare is Ovaprene, a new option for the 40M women currently using contraceptives. The current market is driven by products such as Lo Loestrin, NuvaRing, and Mirena, all of which administer hormones. However, a study found that 53% of women have concerns about additional estrogen entering their body, and 74% prefer estrogen-free methods. Ovaprene provides a convenient, effective, and hormone-free option for these women looking for a better solution. In 2009, a postcoital test clinical study found that there was no viable sperm in the cervical mucus postcoital, without any serious adverse effects. Their current path to approval involves one postcoital test (PCT) assessing safety, PK, acceptability, fit, and ease of use. Dare expects data from these 25 women within the second half of 2019. The second step involves a single pivotal clinical trial enrolling about 250 women over six months. This will have primary endpoints of safety and efficacy (pregnancy probability) and will also evaluate acceptability, product fit, ease of use, and overall vaginal health. The last value driver we model is a Sildenafil cream, addressing Female Sexual Arousal Disorder. During their proof-of-concept study, Dare observed increased genital blood flow in pre and postmenopausal patients. Although the FDA has identified FSAD as a distinct disorder, there are currently no approved products on the market. With 10M women actively seeking treatment, this leaves room for an effective product. Their successful Phase 2a study showed increased blood flow in the genital tissue in 31 women. This leads them to their Phase 2b at-home study, which is expected to start in 2019 and receive data in 2020. Due to the fact that Sildenafil cream has the same API as Viagra, Dare views this as a way to prove their safety to the FDA. Dare hopes to license out all three products to partners in both the U.S. and the EU. As a core part of their revenue model, finding partners is a critical part of their commercial success.

### Exhibit 1. Dare Bioscience Catalysts

Product	Geography	Event	Timeline	Impact
DARE- BV1	USA	505(b)(2) Regulatory pathway, Phase 3 Initiation	4Q19	*
DARE- BV0	USA	Phase 3 results	2Q20	***
DARE- BV1	USA	US regulatory review	2Q21	*
DARE- BV1	USA	Potential US approval	3Q21	**
DARE- BV1	USA	Partner signed	4Q21	***
DARE- BV1	USA	Potential US launch	1Q22	**
Ovaprene (PCT)	USA	Top line results of postcoital test	4Q19	**
Ovaprene (PCT)	USA	Begin single Phase 3 pivotal trial	3Q20	*
Ovaprene (PCT)	USA	Regulatory review	2Q22	**
Ovaprene (PCT)	USA	Potential US approval and launch	1Q23	**
Ovaprene (PCT)	EU	Regulatory review	2Q24	*
Ovaprene (PCT)	EU	Potential EU approval and launch	1Q25	**
Sildenafil Cream, 3.6%	USA	502(b)(2) Regulatory pathway, Phase 2b begins	4Q19	*
Sildenafil Cream, 3.6%	USA	Phase 2b results	4Q20	**
Sildenafil Cream, 3.6%	USA	Begin Phase 3 trial	1Q21	*
Sildenafil Cream, 3.6%	USA	Phase 3 results	1Q23	**
Sildenafil Cream, 3.6%	USA	Regulatory review	2Q23	*
Sildenafil Cream, 3.6%	USA	Partner signed	3Q23	***
Sildenafil Cream, 3.6%	USA	Potential US approval and launch	1Q24	**
Sildenafil Cream, 3.6%	EU	502(b)(2) Regulatory pathway, Phase 2b begins	4Q20	*
Sildenafil Cream, 3.6%	EU	Phase 2b results	4Q21	**
Sildenafil Cream, 3.6%	EU	Begin Phase 3 trial	1Q22	*
Sildenafil Cream, 3.6%	EU	Phase 3 results	1Q24	**
Sildenafil Cream, 3.6%	EU	Regulatory review	2Q24	*
Sildenafil Cream, 3.6%	EU	Partner signed	3Q24	***
Sildenafil Cream, 3.6%	EU	Potential EU approval and launch	1Q25	**

Stock Significance Scale: + of moderate importance; ++ higher level; +++ very important

Source: Dawson James

## Investment Summary

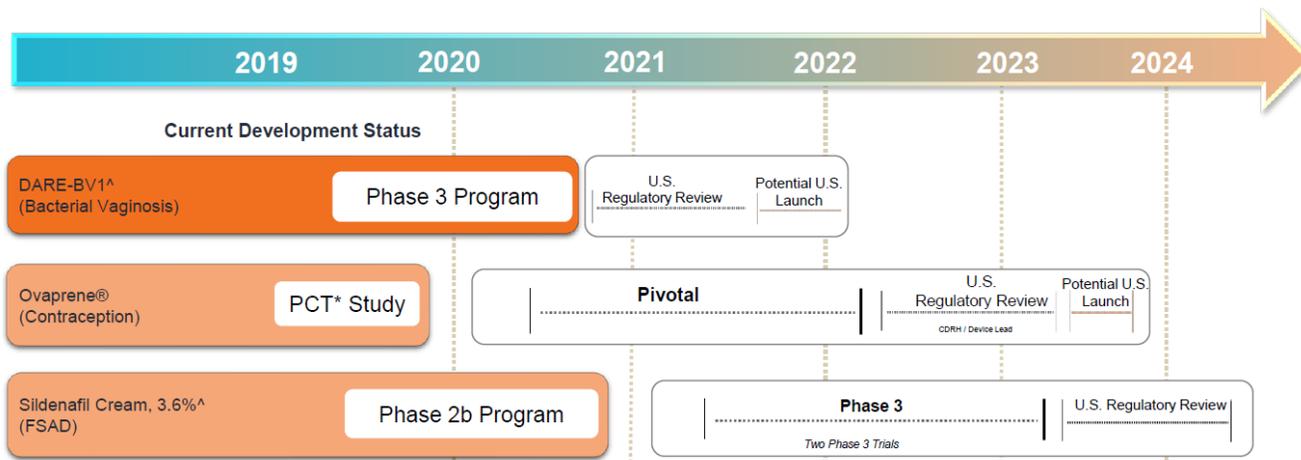
**Bull Case.** Bulls see an opportunity with Dare' through a combination of very efficient operations (low development costs) coupled with reduced clinical risks and large markets (BV, contraception, and FSAD) to suggest a positive outlook. DARE-BV1, for the treatment of bacterial vaginosis, should begin a single Phase 3 trial in 4Q19. There is a high potential for success. This is based on the fact that the API of the product has already been approved. The proof-of-concept clinical study demonstrated that 86% of patients met their clinical cure endpoints. This, along with the convenience of "one and done," that is one local application of DARE-BV1, suggests a significant opportunity to provide patients with a greater quality of life. With a small market share of just 10% by 2024, we estimate that DARE-BV1 could generate up to \$100M in revenues, (which we haircut by 50% for conservatism in our model). Ovaprene, Dare's contraception solution, has the potential to become its own category of product within the market. Contraception is expected to be a \$33B global market by 2023, leaving room for a product with differentiating properties. Even a 1% market share at that time would generate almost \$400M in revenues for the product (we apply a 50% probability of success in our model). Currently, women are focusing more and more on convenient, effective, and hormone-free products, although there are currently none approved. Given positive data from the company's "PCT" trial and the Pivotal study, we believe Dare' could establish a new category of contraception that fills an existing gap in the market. It is also possible that the company will have the opportunity to file for approval in Europe using U.S. data alone, speeding up the commercialization process within this market. The FSAD market is a real opportunity, and a viable product is needed. It is estimated that there are as many as ~10M sexually active women in the U.S. who would use such a product. The FDA has acknowledged and formally classify the distinct disorders that make up Female Sexual Dysfunction. FSAD remains its own category yet holds not approved products. Dare expects to begin their Phase 2b trial in 4Q19 with data by 2020, and conservatively, approval in 2024.

**Bear Case.** Despite the low development costs, and the significant market opportunity, Dare is attempting to enter widely developed markets, traditionally dominated by big pharma with deep pockets. Contraception and bacterial vaginosis represent markets with many established products. Gaining market share could prove difficult as a result of market competition. Ovaprene and Sildenafil cream are still in the early stages of development and possess some clinical risk. If these products are delayed, the company will be dependent on its BV product alone. A major element of the Dare story has been cost control. There is an expectation that the company can maintain low operating costs by licensing these products internationally. Despite expressed interest from licensees, a failure to establish these partnerships could slow down the commercialization timeline and or force the company to raise dilutive capital.

**Our Take.** Despite some moderate clinical risks associated with two of the three leading value drivers for Dare, we see upside driven by the unique combination of low development costs and substantial market opportunity. With a cure rate more potentially superior to the leading standard of care and a healthier, and easy to use, one and done product, DARE-BV1 has the potential to acquire significant market size. The current clinical data sets have shown high cure rates as well as the approval of drugs with the same active ingredient suggest low clinical risk and high potential rates of adoption. We anticipate approval of Ovaprene by the FDA due to the Affordable Care Act as well as the success within the proof-of-concept study. Due to the hormone-free nature of Dare's vaginal ring, we see the establishment of a new category and therefore, approval by the FDA due to the Affordable Care Act. With ~45 million women using contraception in the U.S. and trends shifting to convenient, hormone-free alternatives, we see the potential for Ovaprene to penetrate the market. With a market share of just 2% in 2024, the product can generate ~\$290M after adjusting for a 50% probability of success. Dare's Sildenafil cream is another product that lacks the backing of clinical trial results. However, the FDA has explicitly expressed its desire to focus on the importance of Female Sexual Disorders (FSD). They have even defined the four different types of FSD, with FSAD being the only one without approved treatments. The company is on track to achieve approval in 2024 in the U.S. Given the high margins within this space and a small assumed market share of 5% in 2024; the product can generate ~\$555M after adjusting for a 50% probability for success.

**Financials.** As of 1Q19, Dare has reported \$3.5M in cash, and 0 debt. In April 2019, they had an underwritten public offering of 5.3M common shares for net proceeds of approximately \$5.2M.

**Exhibit 2. Dare Bioscience Pipeline.**



Source: Dare Presentation

**Bacterial Vaginosis or BV.** BV is characterized by the overgrowth of bacteria naturally found in the vagina. It is essentially the imbalance of these natural bacteria and is more likely to be found in sexually active women. The condition displays very irritating and uncomfortable symptoms in women and can last for weeks.

**Exhibit 3. DARE-BV1** provides the market with a gel solution for BV. Although the product uses similar solutions as other standards of care, its gel technology provides patients with unparalleled advantages. With body temperature as a trigger for increasing viscosity, the product can be cleanly and directly applied to the infection site with a mesh. The product was also designed to provide patients with maximum exposure time for optimized results.

Features	Description	Innovative Product Profile
In-Situ Gelation	Undergoes solution to gel (sol-to-gel) transition using body temperature as the trigger	<ul style="list-style-type: none"> <li>Allows product to be easily and directly placed at the site of infection</li> <li>Increased viscosity following application keeping the product at the site of application</li> </ul>
Sustained-Erosion	Platform can be optimized to erode over a period of hours to multiple days	<ul style="list-style-type: none"> <li>Designed for a dual-release pattern providing maximal exposure time and amount of drug at the site of action</li> <li>Allows optimization of dosing duration for clindamycin – a time dependent antibiotic</li> </ul>
Bio-Resorption and Adhesion	Hydrophilic ingredients are compatible with a variety of APIs	<ul style="list-style-type: none"> <li>Reinforces ability of product to bio-adhere at the site of application</li> <li>Eliminates need to remove product following completion of treatment regimen</li> </ul>

Source: Dare Presentation

**Market Opportunity.** Bacterial vaginosis is the single most common bacterial infection in women ages 15-44, effecting ~21 million women (in the U.S. alone). Existing drugs today still have relatively low cure rates (between 37% and 68%) and women often come back even after treatment.

**Exhibit 4. Proof-of-Principle Design Study.** Within this study, a single dose of DARE-BV1 held high clinical cure rates (86%) in comparison to those of Solesec by Lupin (53%-68%), Clindesse by Perrigo (41%-64%), and Metrogel by Allergan (37%).

Product	Clinical (Amsel) Cure	Bacteriologic (Nugent) Cure	Therapeutic Cure
 DARE-BV1 <small>novel gel (clindamycin)</small>	86%	57%*	57%*
 Solesec® <sup>1</sup> <small>(tecnidazole 2g oral granules)</small>	53-68%	40-46%	35-40%
 Clindesse® <sup>2</sup> <small>clindamycin phosphate Vaginal Cream, 2%</small>	41-64%	45-57%	30-42%
 Metrogel, 1.3% <sup>3</sup>	37%	20%	17%

Source: Dare Presentation

**Pathway to Regulation.** One major component of DARE-BV1 is clindamycin phosphate 2%, which is the same API as all currently approved treatments. They will be conducting their final test of the technology in a single Phase 3 trial, in hopes of establishing a partner along the way. This, along with the clindamycin basis of the product, leads us to believe that the product will be approved by 2021.

**Contraception.** Contraception methods are used by 40 million women (62%) of reproductive age, representing \$6B in sales in 2016 in the US alone. Current means of contraception have been described as difficult to use, ineffective, and causing side effects such as reduced sexual pleasure. Only 40% of women have stated that they are satisfied with their current method.

**Ovaprene** is a newly developed vaginal ring as a form of contraception for women that prevents sperm from entering the cervical canal. It is a silicone ring matric with a 3-D, non-braided, fluid-permeable mesh barrier that will be OB/GYN distribution upon approval. Upon insertion, Ovaprene will provide the consumer with multiple weeks of protection, without the use of hormones in order to fill the market gap of hormone-free contraception. Instead of releasing hormones, the ring will administer a non-hormonal ferrous gluconate (an iron supplement). The expected effectiveness of Ovaprene is 88% in comparison to 91% for hormone-based contraception.

**New Contraception Options.** Recent contraception options have focused on reducing hormone dosage, adjusting the duration of protection, and optimizing methods of administration. Major players within this space are Mirena by Bayer, which is a physician inserted intrauterine system (IUS), representing \$1.14B in 2018 (globally). The NuvaRing, produced by Merck, is a plastic vaginal ring which can be personally inserted once a month. This contraception method held sales of \$902M worldwide sales in 2018. Lo Loestrin by Allergan, provides women with an oral form of contraception with the lowest amount of daily estrogen on the market.

**Unmet Need.** While current contraception methods are focusing on a lower dose of estrogen and progestin hormones, there is a gap of hormone-free alternatives that are effective and easy to use. Typically, a product is either effective OR easy to use, but the market is lacking a product that is both.

**Exhibit 5. The Hormone-Free Product Landscape.**



**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

Source: Dare Presentation

**Exhibit 6. Women's Preferences for Contraceptive Methods.** As of 2014, 70% of women who practiced some method of contraception did so in non-coital ways.<sup>1</sup> Women have also expressed a preference for a lower hormone dose than the pill, as well as a convenient product form as characterized by the vaginal ring.<sup>2</sup>

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 <sup>3</sup>	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

<sup>3</sup>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

Source: Dare Presentation

<sup>1</sup> <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>

<sup>2</sup> Lessard, L, Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012

**Proof-of-Concept Study.** The proof-of-concept study in 2009 was used in order to test the effectiveness of Ovaprene in 20 women in a postcoital assessment. The results revealed that with the use of the Ovaprene vaginal ring, there was no viable sperm in the cervical mucus postcoital. In addition, there were no vaginal/cervix abnormalities, no significant changes in the vaginal flora, and no serious side effects.

**U.S. Regulatory Strategy.** The road to regulatory review for Ovaprene has been anticipated based on the Postcoital Test (PCT). The first step is expected to report data in 2019 and will involve 50 couples/25 women with a total of 21 visits (5 menstrual cycles). The primary endpoints of this study will be the measurement of progressively motile sperm (PMS) per high powered field (HPF) in the cervical mucus. In order to reach this endpoint, they will reach <5 PMS per HPF. Another important factor to the success of the PCT will be the safety, PK, acceptability, fit, and ease of use of the ring. Step 2 of reaching regulatory approval involves a Pivotal Study in 2020/2021. It is anticipated that this will involve ~250 women, with the primary endpoints being safety and efficacy. Secondary endpoints will include acceptability, product fit, ease of use, and vaginal health.

**Female Sexual Arousal Disorder or FSADS.** FSAD is characterized by the inability to maintain enough physical sexual arousal, affecting more than 10M women in the U.S. alone. Recently, the FDA has acknowledged the distinctiveness of the condition as one of four Female Sexual Dysfunctions. However, FSAD currently has no approved treatments available on the market.

**Exhibit 7. Unmet Need.** The FDA has recently acknowledged four classes of Female Sexual Dysfunction: dyspareunia, vulvar-vaginal atrophy, hypoactive sexual desire disorder and FSAD. Of the four, Female Sexual Arousal Disorder is the only without an approved product.



Source: Dare Presentation

**Sildenafil cream, 3.6%** was initially tested as an oral sildenafil for increasing vaginal blood flow. These initial studies displayed statistically significant data, as patients expressed improvement in sensation during intercourse or stimulation. However, the side effects of the oral administration led Dare to begin testing of a new topical route.

**Phase 1 and Phase 2a Studies.** During Dare’s Phase 1 study, they were able to identify the correct dosing for topical sildenafil as well as establish its safety and favorable product characteristics (easy use and absorption). During their Phase 2a study, patients demonstrated increased blood flow in the genital tissue compared to the placebo.

**Phase 2b.** The Phase 2b study will begin in 4Q19, with data collected in 2020. Sildenafil cream 3.6% will be put head to head with placebo as patients use the products within their homes.

## Modeling Assumptions

1. We present therapeutic models for the company's three products, DARE-BV1, Ovaprene, and Sildenafil. For each of these products, we apply just a 50% probability of success. One could argue that this is conservative as each product has either demonstrated a viable mechanism of action or established proof of concept in well-designed Phase 2 trials.
  - a. DARE-BV1. We assume DARE-BV1 has a 50% probability of success, with commercialization in the U.S. in 2021 with a price of \$200. We assume modest price increases of just 1% annually.
  - b. Ovaprene. We assume Ovaprene has a 50% probability of success, with commercialization in the U.S. in 2023 and in the EU in 2025. We note that an EU trial may not be required to file, depending on U.S. results; however, for conservatism, we assume an EU trial. We assume Ovaprene will have a price comparable to NuvaRing, beginning at \$1650 per year and a y/y price increase of 1%.
  - c. Sildenafil. We assume Sildenafil has a 50% probability of success, with commercialization in the U.S. in 2024 and in the EU in 2025. We assume Sildenafil will have a price comparable to Viagra for men, beginning at \$1950 per year and a y/y price increase of 1%.
2. We assume a royalty product model for all three products. We model a 25% royalty to Dare based on top-line revenues. As part of our calculus, we assume research and development expenses are offset by a partnership that will reduce the financial burden. We do not assume zero R&D, as we expect the company to remain active in both new product development and in the participation of existing products. These assumptions also impact of SG&A line, where we estimate just 10% annual growth in expenses. Our COGS assumptions are set to 17% of revenues, and this may prove to be conservative.
3. Our company valuation is based on a fully diluted out year share count, with capital raises and issued shares in 3Q19 and 1Q20. We use a 30% risk rate in our FCFE, dEPS, and SOP models. This risk rate is in addition to our therapeutic models "probability factor."

### Exhibit 8. Ovaprene (U.S.)

U.S. - Ovaprene													
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Women using contraceptives ('000)	41,650	42,500	43,350	44,217	45,101	46,003	46,923	47,862	48,819	49,796	50,791	51,807	52,843
40% unsatisfied	16,660	17,000	17,340	17,687	18,041	18,401	18,769	19,145	19,528	19,918	20,317	20,723	21,137
50% shorter-acting & reversible	8,330	8,500	8,670	8,843	9,020	9,201	9,385	9,572	9,764	9,959	10,158	10,361	10,569
22% on non-hormonal methods	9,163	9,350	9,537	9,728	9,922	10,121	10,323	10,530	10,740	10,955	11,174	11,398	11,626
Target Patient Population ('000)	20,825	21,250	21,675	22,109	22,551	23,002	23,462	23,931	24,410	24,898	25,396	25,904	26,422
Market share						1%	2%	2%	3%	3%	4%	4%	5%
Patients treated						230,017	351,926	478,619	610,239	746,933	888,850	1,036,145	1,188,977
Cost \$1500/year (NuvaRing) 10% premium						\$ 1,650	\$ 1,667	\$ 1,683	\$ 1,700	\$ 1,717	\$ 1,734	\$ 1,752	\$ 1,769
Price Change							1%	1%	1%	1%	1%	1%	1%
Revenues ('000)						\$ 379,528	\$ 586,484	\$ 805,595	\$ 1,037,405	\$ 1,282,481	\$ 1,541,414	\$ 1,814,817	\$ 2,103,327
Probability of Success						50%	50%	50%	50%	50%	50%	50%	50%
<b>Adjusted Revenues (M)</b>						<b>\$ 189,764</b>	<b>\$ 293,242</b>	<b>\$ 402,797</b>	<b>\$ 518,702</b>	<b>\$ 641,241</b>	<b>\$ 770,707</b>	<b>\$ 907,408</b>	<b>\$ 1,051,664</b>
Assume Royalty Model 25%						\$ 47,441	\$ 73,311	\$ 100,699	\$ 129,676	\$ 160,310	\$ 192,677	\$ 226,852	\$ 262,916

Source: Dawson James

### Exhibit 9. Ovaprene (EU)

EU - Ovaprene													
Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Women using contraceptives ('000)	45,815	46,750	47,685	48,639	49,611	50,604	51,616	52,648	53,701	54,775	55,871	56,988	58,128
40% unsatisfied	18,326	18,700	19,074	19,455	19,845	20,241	20,646	21,059	21,480	21,910	22,348	22,795	23,251
50% shorter-acting & reversible	9,163	9,350	9,537	9,728	9,922	10,121	10,323	10,530	10,740	10,955	11,174	11,398	11,626
22% on non-hormonal methods	10,079	10,285	10,491	10,701	10,915	11,133	11,355	11,583	11,814	12,051	12,292	12,537	12,788
Target Patient Population ('000)	22,908	23,375	23,843	24,319	24,806	25,302	25,808	26,324	26,851	27,388	27,935	28,494	29,064
Market share						0%	0%	1%	1%	2%	2%	3%	3%
Patients treated						-	-	131,620	268,505	410,813	558,706	712,350	871,916
Cost \$1500/year (NuvaRing) 10% premium						\$ 1,650	\$ 1,667	\$ 1,683	\$ 1,700	\$ 1,717	\$ 1,734	\$ 1,752	\$ 1,769
Price Change							1%	1%	1%	1%	1%	1%	1%
Revenues ('000)						\$ -	\$ -	\$ 221,539	\$ 456,458	\$ 705,365	\$ 968,889	\$ 1,247,687	\$ 1,542,440
Probability of Success								50%	50%	50%	50%	50%	50%
<b>Adjusted Revenues (M)</b>						<b>\$ -</b>	<b>\$ -</b>	<b>\$ 110,769</b>	<b>\$ 228,229</b>	<b>\$ 352,682</b>	<b>\$ 484,444</b>	<b>\$ 623,843</b>	<b>\$ 771,220</b>
Assume Royalty Model 25%						\$ -	\$ -	\$ 27,692	\$ 57,057	\$ 88,171	\$ 121,111	\$ 155,961	\$ 192,805

Source: Dawson James

**Exhibit 10. DARE-BV1**

	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total BV Population ('000)	21,200	21,836	22,491	23,166	23,861	24,577	25,314	26,073	26,856	27,661	28,491	29,346	30,226
19% unsatisfied/Target patient population ('000)	4028	4149	4273	4402	4534	4670	4810	4954	5103	5256	5413	5576	5743
Market share				3%	5%	7%	10%	11%	12%	12%	12%	12%	12%
Patients treated				132,045	226,677	326,869	480,964	544,933	612,306	630,675	649,595	669,083	689,156
Price				\$200	\$202	\$204	\$206	\$208	\$210	\$212	\$214	\$217	\$219
Price Change					1%	1%	1%	1%	1%	1%	1%	1%	1%
Revenues ('000)				\$ 26,409	\$ 45,789	\$ 66,688	\$ 99,108	\$ 113,412	\$ 128,708	\$ 133,895	\$ 139,291	\$ 144,904	\$ 150,744
Probability of Success				50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
<b>Adjusted Revenues (M)</b>				<b>\$ 13,205</b>	<b>\$ 22,894</b>	<b>\$ 33,344</b>	<b>\$ 49,554</b>	<b>\$ 56,706</b>	<b>\$ 64,354</b>	<b>\$ 66,947</b>	<b>\$ 69,645</b>	<b>\$ 72,452</b>	<b>\$ 75,372</b>
Assume Royalty Model 25%				\$ 3,301	\$ 5,724	\$ 8,336	\$ 12,388	\$ 14,176	\$ 16,088	\$ 16,737	\$ 17,411	\$ 18,113	\$ 18,843
Revenue to Daré				\$ 3,301	\$ 5,724	\$ 8,336	\$ 12,388	\$ 14,176	\$ 16,088	\$ 16,737	\$ 17,411	\$ 18,113	\$ 18,843

**Exhibit 11. Sildenafil Cream (U.S.)**

Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total FSAD Population ('000)		20,625	21,038	21,458	21,887	22,325	22,772	23,227	23,692	24,165	24,649	25,142	25,645
% seeking treatment 50% ('000)		10,313	10,519	10,729	10,944	11,163	11,386	11,614	11,846	12,083	12,324	12,571	12,822
Market share							5%	8%	11%	13%	14%	14%	14%
Patients treated							569,292	929,084	1,303,040	1,570,756	1,725,415	1,759,923	1,795,122
Price							\$ 1,950	\$ 1,989	\$ 2,029	\$ 2,069	\$ 2,111	\$ 2,153	\$ 2,196
Price Change								1%	1%	1%	1%	1%	1%
Revenues ('000)							\$ 1,110,119	\$ 1,847,948	\$ 2,643,582	\$ 3,250,452	\$ 3,641,907	\$ 3,789,040	\$ 3,942,117
Probability of Success							50%	50%	50%	50%	50%	50%	50%
<b>Adjusted Revenues (M)</b>							<b>\$ 555,059</b>	<b>\$ 923,974</b>	<b>\$ 1,321,791</b>	<b>\$ 1,625,226</b>	<b>\$ 1,820,953</b>	<b>\$ 1,894,520</b>	<b>\$ 1,971,059</b>
Assume Royalty Model 25%							\$ 138,765	\$ 230,994	\$ 330,448	\$ 406,307	\$ 455,238	\$ 473,630	\$ 492,765

Source: Dawson James

**Exhibit 12. Sildenafil Cream (EU)**

Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total FSAD Population ('000)			20,625	21,038	21,458	21,887	22,325	22,772	23,227	23,692	24,165	24,649	25,142
% seeking treatment 50% ('000)			10,313	10,519	10,729	10,944	11,163	11,386	11,614	11,846	12,083	12,324	12,571
Market share							5%	5%	8%	11%	13%	14%	14%
Patients treated								569,292	929,084	1,303,040	1,570,756	1,725,415	1,759,923
Price								\$ 1,950	\$ 1,989	\$ 2,029	\$ 2,069	\$ 2,111	\$ 2,153
Price Change									1%	1%	1%	1%	1%
Revenues ('000)								\$ 1,110,119	\$ 1,847,948	\$ 2,643,582	\$ 3,250,452	\$ 3,641,907	\$ 3,789,040
Probability of Success								50%	50%	50%	50%	50%	50%
<b>Adjusted Revenues (M)</b>								<b>\$ 555,059</b>	<b>\$ 923,974</b>	<b>\$ 1,321,791</b>	<b>\$ 1,625,226</b>	<b>\$ 1,820,953</b>	<b>\$ 1,894,520</b>
Assume Royalty Model 25%								\$ 138,765	\$ 230,994	\$ 330,448	\$ 406,307	\$ 455,238	\$ 473,630

Source: Dawson James

**Valuation.** We apply therapeutic probabilities of success in our product models, see model assumptions for complete details. For all three products, we apply a 50% probability. To this we then apply a 30% discount rate on our Free Cash Flow to the Firm, Discounted EPS and Sum-of-the-Parts models which are equally weighted, averaged and rounded to the nearest whole number to derive our \$4.00 price target. Our assumptions are based on out year estimates (2030) and assume a fully diluted share count (assume multiple capital raises).

### Exhibit 13. Free Cash Flow Model

Average												
	4											
Price Target	3											
Year	2019											

DCF Valuation Using FCF (mln):												
units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(12,502)	(13,723)	(11,764)	(10,831)	37,584	65,705	121,958	181,506	243,102	308,391	377,298	449,780
Tax Rate	0%	0%	0%	0%	0%	0%	15%	20%	30%	33%	37%	37%
EBIT (1-t)	(12,502)	(13,723)	(11,764)	(10,831)	37,584	65,705	103,664	145,205	170,171	206,622	237,697	283,361
CapEx	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	1	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(12,501)	(13,723)	(11,764)	(10,831)	37,584	65,705	103,664	145,205	170,171	206,622	237,697	283,361
PV of FCF	(12,501)	(10,556)	(6,961)	(4,930)	13,159	17,696	21,477	23,141	20,861	19,484	17,242	15,811
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	986,879											
Terminal Value YE2030	55,066											
NPV	168,991											
NPV-Debt												
Shares out ('000)	48,502	2030E										
NPV Per Share	3											

Source: Dawson James

### Exhibit 14. Discounted-EPS Model

Current Year	2019
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 9.27
NPV	5

Discount Rate and Earnings Multiple Varies, Year is Constant							
Earnings Multiple		Discount Rate					
		5%	10%	15%	20%	25%	30%
0	0	0	0	0	0	0	0
5	27.10	16.25	9.96	6.24	3.98	2.59	
10	54.20	32.49	19.93	12.48	7.96	5.17	
15	81.30	48.74	29.89	18.71	11.94	7.76	
20	108.40	64.98	39.85	24.95	15.93	10.35	
25	135.50	81.23	49.81	31.19	19.91	12.93	
30	162.60	97.47	59.78	37.43	23.89	15.52	
35	189.70	113.72	69.74	43.67	27.87	18.10	

Source: Dawson James

### Exhibit 15. Sum-of-the-Parts Model

	LT Gr	Discount Rate	Yrs to Peak	% Success	Peak Sales (MM's)	Term Val
<b>US - Ovaprene</b>	1%	30%	11	75%	\$263	\$907
NPV						\$0.4
<b>EU - Ovaprene</b>	1%	30%	11	75%	\$193	\$665
NPV						\$0.3
<b>US - DARE-BV1</b>	1%	30%	11	75%	\$19	\$65
NPV						\$0.0
<b>US - Sildenafil Cream</b>	1%	30%	11	75%	\$493	\$1,699
NPV						\$0.7
<b>EU - Sildenafil Cream</b>	1%	30%	11	75%	\$474	\$1,633
NPV						\$0.7
Net Margin						50%
MM Shrs OS (2030E)						49
Total						\$2

Source: Dawson James

**Exhibit 16. Income Statement**

DARE: Income Statement (\$000)																					
12 Months Ending	2018A	1Q19A	2Q19E	3Q19E	4Q19E	2019E	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2Q28E	2Q29E	2Q30E
<b>Revenue:</b>																					
DARE-BV1												13,205	22,894	33,344	49,554	56,706	64,354	66,947	69,645	72,452	75,372
Ovaprene														189,764	293,242	513,567	746,931	993,923	1,255,152	1,531,252	1,822,884
Sildenafil Cream															555,059	1,479,033	2,245,765	2,947,017	3,446,180	3,715,473	3,865,579
<b>Total Product Sales</b>												<b>13,205</b>	<b>22,894</b>	<b>223,108</b>	<b>897,855</b>	<b>2,049,306</b>	<b>3,057,050</b>	<b>4,007,888</b>	<b>4,770,977</b>	<b>5,319,177</b>	<b>5,763,834</b>
DARE-BV1 Royalty Revenue (US)												3,301	5,724	8,336	12,388	14,176	16,088	16,737	17,411	18,113	18,843
Ovaprene Royalty Revenue (US)														47,441	73,311	100,699	129,677	160,310	192,677	226,852	262,916
Ovaprene Royalty Revenue (EU)																27,692	57,057	88,171	121,111	155,961	192,805
Sildenafil Cream Royalty Revenue (US)															138,765	230,994	330,448	406,307	455,238	473,630	492,765
Sildenafil Cream Royalty Revenue (EU)															138,765	230,994	330,448	406,307	455,238	473,630	492,765
<b>Total royalties, collaborative revenue</b>												<b>3,301</b>	<b>5,724</b>	<b>55,777</b>	<b>224,464</b>	<b>512,326</b>	<b>764,263</b>	<b>1,001,972</b>	<b>1,192,744</b>	<b>1,329,794</b>	<b>1,440,959</b>
<b>Total Revenue Received by Dare</b>												<b>3,301</b>	<b>5,724</b>	<b>55,777</b>	<b>224,464</b>	<b>512,326</b>	<b>764,263</b>	<b>1,001,972</b>	<b>1,192,744</b>	<b>1,329,794</b>	<b>1,440,959</b>
<b>Expenses:</b>																					
Costs of Goods Sold												561	973	9,482	38,159	87,096	129,925	170,335	202,767	226,065	244,963
<b>%COGS</b>			17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%
General & Administrative	4,656	1,277	1,405	1,419	1,020	5,121	1,352	1,296	1,465	1,521	5,634	6,197	6,817	7,498	8,248	9,073	9,980	10,978	12,076	13,284	14,612
Research & Development	6,414	1,693	1,863	1,881	1,618	7,055	1,863	1,785	2,018	2,095	7,761	8,537	9,391	10,330	11,363	11,135	10,913	10,694	10,267	9,856	9,659
License Expense	625	113	120	110	105	448	110	119	110	119	456	466	489	513	539	566	594	624	655	688	722
Impairment of Goodwill	5,188	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Expenses</b>	<b>16,882</b>	<b>3,083</b>	<b>3,388</b>	<b>3,410</b>	<b>2,743</b>	<b>12,624</b>	<b>3,324</b>	<b>3,199</b>	<b>3,592</b>	<b>3,735</b>	<b>13,851</b>	<b>15,199</b>	<b>16,696</b>	<b>18,341</b>	<b>20,150</b>	<b>20,774</b>	<b>21,487</b>	<b>22,297</b>	<b>22,998</b>	<b>23,828</b>	<b>24,993</b>
Operating Income (Loss)	(16,882)	(3,083)	(3,388)	(3,410)	(2,743)	(12,624)	(3,324)	(3,199)	(3,592)	(3,735)	(13,851)	(11,898)	(10,973)	37,436	65,549	121,794	181,334	242,921	308,201	377,098	449,571
Other income (expense)	143	31	32	30	29	122	30	35	32	32	128	135	141	149	156	164	172	181	190	199	209
<b>Pretax Income</b>	<b>(16,739)</b>	<b>(3,052)</b>	<b>(3,356)</b>	<b>(3,380)</b>	<b>(2,714)</b>	<b>(12,502)</b>	<b>(3,295)</b>	<b>(3,165)</b>	<b>(3,560)</b>	<b>(3,703)</b>	<b>(13,723)</b>	<b>(11,764)</b>	<b>(10,831)</b>	<b>37,584</b>	<b>65,705</b>	<b>121,958</b>	<b>181,506</b>	<b>243,102</b>	<b>308,391</b>	<b>377,298</b>	<b>449,780</b>
Income Taxes																					
<b>Tax Rate</b>															0%	15%	20%	30%	33%	37%	37%
<b>GAAP Net Income (Loss)</b>	<b>(16,817)</b>	<b>(3,044)</b>	<b>(3,356)</b>	<b>(3,380)</b>	<b>(2,714)</b>	<b>(12,494)</b>	<b>(3,295)</b>	<b>(3,165)</b>	<b>(3,560)</b>	<b>(3,703)</b>	<b>(13,723)</b>	<b>(11,764)</b>	<b>(10,831)</b>	<b>37,584</b>	<b>65,705</b>	<b>121,958</b>	<b>181,506</b>	<b>243,102</b>	<b>308,391</b>	<b>377,298</b>	<b>449,780</b>
Fx Translation	(79)	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>GAAP Total Comprehensive Income (Loss)</b>	<b>-</b>	<b>(3,037)</b>	<b>(3,356)</b>	<b>(3,380)</b>	<b>(2,714)</b>	<b>(12,494)</b>	<b>(3,295)</b>	<b>(3,165)</b>	<b>(3,560)</b>	<b>(3,703)</b>	<b>(13,723)</b>	<b>(11,764)</b>	<b>(10,831)</b>	<b>37,584</b>	<b>65,705</b>	<b>121,958</b>	<b>181,506</b>	<b>243,102</b>	<b>308,391</b>	<b>377,298</b>	<b>449,780</b>
<b>GAAP-EPS</b>	<b>(1.57)</b>	<b>(0.27)</b>	<b>(0.29)</b>	<b>(0.16)</b>	<b>(0.13)</b>	<b>(0.84)</b>	<b>(0.12)</b>	<b>(0.12)</b>	<b>(0.13)</b>	<b>(0.13)</b>	<b>(0.50)</b>	<b>(0.32)</b>	<b>(0.29)</b>	<b>0.95</b>	<b>1.60</b>	<b>2.86</b>	<b>4.08</b>	<b>5.26</b>	<b>6.41</b>	<b>7.53</b>	<b>8.63</b>
<b>Fully Diluted EPS</b>	<b>(1.68)</b>	<b>(0.20)</b>	<b>(0.22)</b>	<b>(0.15)</b>	<b>(0.12)</b>	<b>(0.68)</b>	<b>(0.11)</b>	<b>(0.10)</b>	<b>(0.11)</b>	<b>(0.12)</b>	<b>(0.44)</b>	<b>(0.35)</b>	<b>(0.31)</b>	<b>1.02</b>	<b>1.72</b>	<b>3.07</b>	<b>4.39</b>	<b>5.65</b>	<b>6.88</b>	<b>8.09</b>	<b>9.27</b>
Wgtd Avg Shrs (Bas) - '000s	10,732	11,422	11,536	21,352	21,565	16,469	26,781	27,049	27,319	27,592	27,185	36,410	37,888	39,427	41,028	42,694	44,427	46,231	48,108	50,062	52,094
Wgtd Avg Shrs (Dil) - '000s	11,422	15,172	15,324	22,977	23,207	19,170	30,939	31,248	31,561	31,876	31,406	33,899	35,276	36,708	38,199	39,750	41,364	43,043	44,791	46,610	48,502

Source: Company reports and Dawson James

**Risk Analysis**

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Dare are as follows:

**Financial risk.** The company may need to raise capital in the marketplace in order to successfully push their products into the next phase, and there can be no assurances that the company will be able to successfully raise capital and or do so, on favorable terms.

**Clinical and regulatory risk.** Lead products must start and complete clinical trials. Trials may not produce results sufficient for regulatory approval.

**Partnership risk.** Dare may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the company will be able to secure a favorable partnership.

**Commercial risk.** There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

**Legal and intellectual property risk.** The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third party's patents.

Companies mentioned in this report:

Lupin (NSE: LUPIN)

Perrigo (NYSE: PRGO)

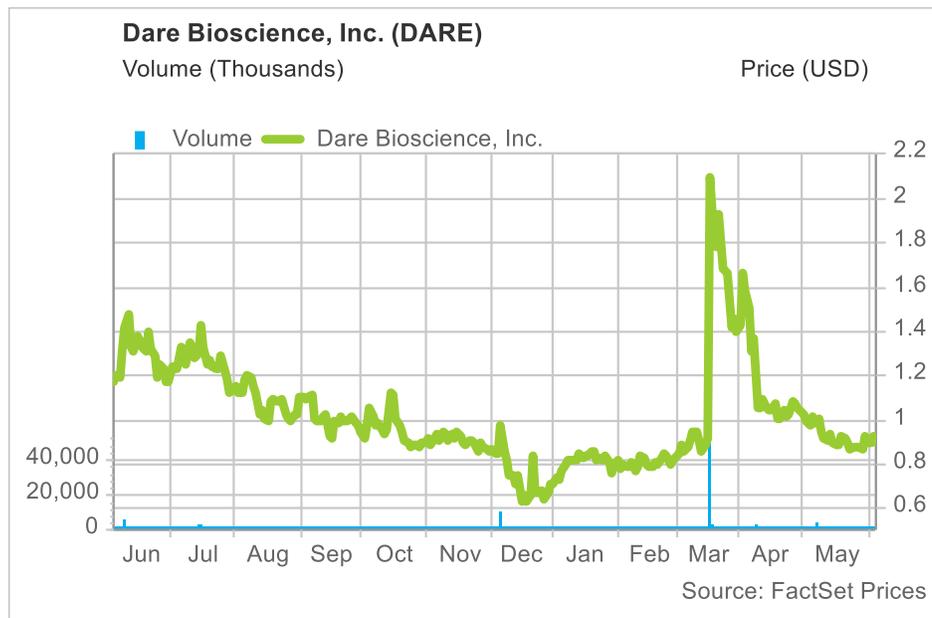
Allergan (NYSE: AGN)

Bayer (OTCMKTS: BAYRY)

Merck (NYSE: MRK)

**Important Disclosures:**

**Price Chart:**



**Price target and rating changes over the past three years:**

Initiation – Buy – 7/18/2018 – Price Target \$8.00  
 Transfer of Coverage – Buy – 7/17/2019 – Price Target \$4.00

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**Rating Definitions:**

- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	40	85%	12	30%
Market Perform (Neutral)	7	15%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	47	100%	12	26%

**Analyst Certification:**

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.