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Daré Bioscience, Inc. (DARE-NASDAQ)

DARE: Ovaprene PCT Continues. TS Content Validity Study, Thermographic Study Underway

We use 5.0x sales and discount revenue at 20%, 15% and 10% reflecting bear, base and bull cases, respectively. Base case puts fair value of DARE at approximately $6.75/share.

Current Price (11/30/18)	$0.86
Valuation	**$6.75**

OUTLOOK

DARE's Ovaprene PCT continues enrollment and is pacing as management had hoped. Expectations remain that the study will read-out in 2H 2019 and, if all goes well, an IDE for a pivotal RCT will be filed shortly afterwards.

In the meantime, Topical Sildenafil program is also progressing. Following Type C meeting with FDA in Q3, Content Validity study and thermographic feasibility study commenced. Both are expected to inform on the design of the at-home portion of the Ph2 study. Thermography study is a new development and of particular interest as it appears to address one of the 'unknowns' as to potential endpoints. Specifically, as it relates to a potential physiological (non-subjective) measure of 'arousal'. Another interesting element of DARE's press release is that it mentions that Dr. Irwin Goldstein is the principal investigator of the thermography feasibility study. Dr. Goldstein is widely recognized as a renowned expert in the field of female sexual dysfunction and led Pfizer's sildenafil programs as well as Boehringer Ingelheim's flibanserin development. Dr. Goldstein's involvement with DARE suggests to us that they are in good hands.

SUMMARY DATA

52-Week High	**$3.59**
52-Week Low	**$0.74**
One-Year Return (%)	**-65.34**
Beta	**3.93**
Average Daily Volume (sh)	**116,578**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$10**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2018	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2019					
2020					

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.27 A	-$1.42 A	-$0.33 A	-$1.48 A	-$3.56 A
2018	-$0.88 A	-$0.32 A	-$0.23 A	-$0.27 E	-$1.57 E
2019					-$0.91 E
2020					-$0.74 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

WHAT'S NEW

Q3 / Pipeline Update
Daré (DARE) reported financial results for their third quarter and provided an operational update. Relative to the financials, operating expenses were $2.6M, or about 12% less than our estimate. We, do, however continue to expect R&D expense and opex as a whole to increase with further progression of DARE's two lead development programs; Ovaprene and Topical Sildenafil.

Cash balance remains at healthy levels, ending Q3 at $9.5M. Cash used in operating activities was $2.8M and $7.6M ($2.5M and $8.1M, ex-changes in working capital) in the three and nine months ending 9/30/18, compared to $1.4M and $1.6M ($1.3M and $2.1M, ex-changes in working capital) in the comparable prior-year periods.

In terms of the operational update…
DARE appears to be making substantive progress on both of their lead programs as well as on earlier-stage pipeline candidates. Recent and anticipated near-term development-related milestones include;

Ovaprene
- Post-coital test (PCT) commenced in May. Per Q3 call, enrollment is progressing as planned
- Data from PCT expected 2H'19
- Assuming positive results (i.e. finding five or fewer sperm per high-powered field in the cervical mucus), will then file IDE to FDA seeking approval to conduct a pivotal randomized controlled study

Topical Sildenafil
- Type C meeting with FDA in Q3'18 regarding development program including design of Ph2b clinical trial
- Nov 27th: DARE announces commencement of Thermographic Feasibility Study. See our discussion below
- Content validity study commences, Nov. 29th press release
- Following completion of CVS, will request another Type C meeting with FDA for additional guidance prior to commencing at-home portion of Ph2b study

Refresher on DARE's Two Lead Programs; Ovaprene and Topical Sildenafil

Ovaprene
A post-coital trial (PCT) is ongoing and currently anticipated to have topline data in 2H 2019. (For reference, the clinicaltrials.org posting is here: NCT03598088). As a reminder, DARE plans to use results (assuming positive) of this trial to petition FDA for IDE approval of a pivotal randomized controlled study.

The PCT is a single-arm, 25-participant trial assessing the ability of Ovaprene to prevent sperm from penetrating the cervical mucus. Secondary measure is the change in ferrous gluconate (i.e. Ovaprene's spermiostasis agent) in the cervicovaginal fluid from pre to post-coital. Inclusion criteria requires participants to have previous had tubal sterilization.

Each participant will be followed over the course of five menstrual cycles and cervical mucus will be evaluated as follows; baseline at cycle 1 with use of no contraception, cycle 2 with use of Caya diaphragm, and cycles 3 through 5 with use of Ovaprene. The purpose of the Caya diaphragm (in cycle 2) is just to validate that the study conditions do not influence results as compared to what would be expected in the real world. 'Success' of effectiveness, which will be defined as finding five or fewer sperm per high-powered field in the cervical mucus, means that DARE would expect to move immediately towards an IDE package for approval to conduct a pivotal study.

Pivotal study, as envisioned today, is expected to include ~250 participants with evaluation over 6 months. Primary endpoint would be pregnancy probability as well as safety. Secondaries are likely to include user-type feedback such as ease of use, fit, comfort, etc. So, assuming success on efficacy and in hitting their timelines in the PCT, a pivotal study is still realistic to commence in 2020/2021. If all goes well, we believe an FDA PMA filing could happen in 2021/2022 and that it is possible Ovaprene could launch in the U.S. by sometime in 2022/2023. All these timelines are unchanged from our previous estimates.

Topical Sildenafil
DARE, which licensed rights to Topical Sildenafil (TS) in February, plans to develop TS for Female Sexual Arousal Disorder (FSAD), a condition characterized by the inability to attain and/or maintain sufficient physical sexual

arousal and also characterized by stress. While FSAD is estimated to affect approximately 13M women in the U.S., no products currently exist that are indicated to treat the condition. While FDA does recognize FSAD as a distinct condition, the agency has never explicitly defined the specific symptoms or physiological traits of what constitutes FSAD. But, that's mostly because an FSAD pivotal study has not yet been successful.

The safety and tolerability profile of sildenafil, which is the active ingredient in Viagra (pill), has been well-established in men. Unlike Viagra, Topical Sildenafil is a cream and designed for local administration. This is expected to provide much more targeted therapeutic effect on the genitalia and mitigate the risk profile as compared to oral Viagra. Topical Sildenafil has already been evaluated in a phase 1 (n=21) and phase 2b study (n=31), which demonstrated that it was well tolerated and resulted in increased blood flow to the vaginal tissue in both pre- and post-menopausal women. IP includes six issued U.S. patents related to topical delivery. Given sildenafil's (i.e. Viagra's) known safety profile, a 505(b)(2) FDA NDA pathway may apply.

DARE has had several interactions with FDA focused on defining FSAD in the context of clinically meaningful endpoints and related design of their ongoing content validity study. This includes a Type C meeting with FDA in Q3'18. Another meeting is anticipated following conclusion of the content validity study in order to gain additional guidance prior to the commencement of the at-home portion of the Phase 2b study.

DARE also recently announced commencement of enrollment in a 'thermography feasibility study', which presumably could be used as part of the formal Phase 2b and eventual pivotal studies as an objective measure of 'arousal.' Per DARE's press release describing the technique, "genital temperature, a surrogate for genital blood flow, will be captured and recorded utilizing an infrared camera capable of detecting heat patterns from blood flow in body tissues. The study consists of the screening visit (visit 1), the double-blind dosing of placebo or active cream (visits 2-3) and a safety follow-up."

This is a particularly interesting development as it appears to address one of the 'unknowns' as to potential endpoints. Specifically, as it relates to a potential physiological (non-subjective) measure of 'arousal'. It is also interesting as Pfizer, when they attempted to develop oral sildenafil for female sexual dysfunction, also incorporated a physiological, genital blood flow measure in their clinical studies. Pfizer's studies used Doppler to measure clitoral blood flow and genital engorgement – and successfully demonstrated that oral sildenafil was effective on improving these endpoints. As we have discussed in prior recent reports, we believe Pfizer's failings with their 'female Viagra' were not an ability to hit endpoints but instead related to trial design. For example, while it appears that they successfully demonstrated improvement in physiological arousal, they failed in demonstrating the connection to a (psychological) desire to have sex. Further, our thesis is that it appears they used an inappropriate patient reported outcome for measuring psychological arousal. DARE's pragmatic approach is reassuring that they will not make similar mistakes.

Another interesting element of DARE's press release is that it mentions that Dr. Irwin Goldstein is the principal investigator of the thermography feasibility study. Dr. Goldstein is widely recognized as a renowned expert in the field of female sexual dysfunction and led Pfizer's sildenafil programs as well as Boehringer Ingelheim's flibanserin development. Dr. Goldstein's involvement with DARE suggests to us that they are in good hands.

Given the current ambiguity of what defines "FSAD", and the sizeable boneyard from failed attempts by others at designing a 'female Viagra', we are glad to see that DARE is taking a very pragmatic approach – as anything else could be a big mistake and waste of time and money. And while there is no precedent for what an appropriately-designed FSAD clinical study would like, FDA's Draft Guidance for *Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment*, published in October 2016, provides at least a starting point to work from.

We also think it is important to keep in mind that while there remains ambiguity in terms of how to define and measure clinically meaningful "arousal", that the lack of complete clarity is not FDA's intention – in fact, we think recent history shows that FDA's goal is to facilitate industry's development of novel drugs to treat women's sexual function disorders – and part of that is working with companies like DARE to design feasible clinical trials (including defining and measuring endpoints). We think this is a critical point and is one of the reasons why we have provided additional detail on this topic in prior reports.

BACKGROUND

DARE is a pre-revenue, clinical-stage company engaged in the development of novel therapeutic technologies targeting unmet needs in women's health. The company, which went public through a reverse-merger in July 2017**,**

currently has two core programs in phase 2 development; **Ovaprene**®, a novel non-hormonal monthly intravaginal ring contraceptive, and **Topical Sildenafil**, a proprietary cream incorporating the active ingredient in Viagra, for the treatment of female sexual arousal disorder.

Looking to further expand their women's reproductive health pipeline, DARE recently added a number of earlier-stage opportunities. Recent additions to their pipeline include;

- VVA1 (fka PT-101): DARE added VVA1 through their May acquisition of Pear Tree Pharmaceuticals. VVA1 is a proprietary formula of the drug tamoxifen, one of the most widely used treatments for hormone-receptor positive (HRP) breast cancer. DARE intends to develop VVA1 for the treatment of vaginal atrophy in women with, or at risk of developing, HRP breast cancer – an indication for which it has shown early promise
- Novel intravaginal ring technology: in April DARE secured exclusive rights (from Juniper Pharmaceuticals) to a novel intravaginal ring drug-delivery platform technology, including its use in three pre-clinical candidates for; overactive bladder, hormone replacement therapy and for the prevention of preterm birth
- Novel long-acting injectable contraceptives: in March DARE penned an agreement with Orbis Biosciences which gives them the option to license rights to two (pre-clinical stage) novel long-acting injectable contraceptives
- CatSper contraceptive for men/women: In mid-July DARE acquired rights to Hydra Biosciences' CatSper ion channel intellectual property. As Cation Channel of Sperm (CatSper) is unique to sperm, a drug that could temporarily block or disable it could serve as a novel contraceptive option for both men and women

Ovaprene

SOURCE: Dare Bioscience

Core Programs

In July 2017 DARE obtained worldwide rights (licensed from ADVA-Tec) to **Ovaprene**, the company's lead development program. Ovaprene, a monthly non-hormonal intravaginal ring, represents a new class of women's contraception. Unlike all other current non-coital methods, Ovaprene is hormone-free. Instead of hormones it uses a mesh barrier to physically block sperm while non-hormonal ingredients (ferrous gluconate), which are released from the silicone ring, induce spermiostasis. While certain features of vaginal rings (including effectiveness, reversibility and convenience of monthly use) score high in consumer surveys and studies, hormone-related side-effects (including risk of serious cardiovascular events) are an oft-cited drawback of currently available options, such as NuvaRing (etonogestrel/ethinyl estradiol). Hormonal contraceptive methods, which (in addition to the vaginal ring) also come in the form of the pill, implant, patch, IUD and injection, account for approximately 74% of U.S. contraceptive product use (condoms account for another 25%). But while hormonal contraceptives remain popular, 50% of women that try them discontinue use and of those that do, side effects are the overwhelming reason why.

Approximately 40M women in the U.S. currently use some form of birth control, 23M of which use one or more contraceptive products, including ~17M which use hormonal methods. The unmet need for an effective monthly contraceptive option which is free of hormone-related side effects (and related concerns) has created an opportunity for DARE. Development of new and alternative methods of contraception is also recognized as a means to reduce the number of unintended pregnancies, which account for 45% (or 2.8M) of all pregnancies in the U.S. every year. Of the unintended pregnancies, 41% (~1.2M) are attributed to inconsistent or incorrect use of contraception and 54% (~1.5M) result from the lack of contraceptive use (or month+ gap of use). Reducing unwanted pregnancies and increasing contraceptive access and use are the subject of grants from the National Institute of Health (NIH), the Bill & Melinda Gates Foundation, FHI 360 and other agencies and organizations which have provided funding

for the development of novel modes of contraception. In April DARE received (an initial) $225k of an anticipated $1.9M grant from a division of NIH - this provides DARE with non-dilutive funding for development of Ovaprene.

Human proof-of-concept of Ovaprene was demonstrated in a small (n=20) post-coital test (PCT) study which showed no viable sperm in the cervical mucus and that the device was well tolerated. Ovaprene is a combination product (device/drug), U.S. regulatory oversight of which will be the responsibility of FDA's (CDRH) medical device branch and which will follow a PMA pathway. DARE's U.S. regulatory strategy and anticipated timelines are similar to that followed by other approved barrier methods including the Caya diaphragm. Specifically, DARE plans to use results (assuming positive) of their recently-initiated post-coital trial (n=25) to petition FDA for IDE approval of a pivotal randomized controlled study. DARE's anticipated timelines are to complete the PCT (data expected H2 2019). If all goes well they could IDE approval in late-2019 or 1H 2020 and start/finish a pivotal study (n=~250) in 2020/2021. Assuming success, an FDA PMA filing could happen in 2021/2022 and it is possible that Ovaprene could launch in the U.S. by sometime in 2022/2023.

In February 2018 DARE in-licensed rights to **Topical Sildenafil** (SST-6007) for any indications related to female sexual dysfunction and female reproductive health. DARE plans to develop Topical Sildenafil for Female Sexual Arousal Disorder (FSAD), a condition characterized by the inability to attain and/or maintain sufficient physical sexual arousal. While FSAD is estimated to affect approximately 13M women in the U.S., no products currently exist that are indicated to treat the condition (importantly, FDA does recognize FSAD as a distinct condition). Topical Sildenafil has already been evaluated in a phase 1 (n=21) and phase 2b study (n=31), which demonstrated that it was well tolerated and resulted in increased blood flow to the vaginal tissue in both pre- and post-menopausal women. IP includes six issued U.S. patents related to topical delivery. Given sildenafil's (i.e. Viagra's) known safety profile, a 505(b)(2) FDA NDA pathway may apply. A content validity study commenced in late-November 2018 as did a thermographic feasibility study. DARE's current timeline is to complete a content validity study – essentially a market research study which – followed by another FDA meeting prior to commencing an at-home portion of the Ph2b study.

Strategic Pipeline: *VVA therapy, intravaginal ring technology, longer-acting injectable contraceptive, men/women contraceptive …*

In May DARE announced a merger agreement with (privately-held) Pear Tree Pharmaceuticals that added a **novel, vaginally-delivered treatment for VVA in women with hormone-receptor-positive (including ER-positive and PR-positive) breast cancer**. PT-101 is a proprietary vaginal formulation of oral tamoxifen, a selective estrogen-receptor modulator (SERM) which, along with aromatase inhibitors (AIs), are the most widely used drugs to treat hormone-receptor-positive (HRP) breast cancer. VVA, characterized by vaginal dryness and pain during intercourse (i.e. dyspareunia), is caused by low estrogen levels associated with menopause. Localized estrogen therapy is typically used to treat VVA but, since it can interfere with action of AIs/oral tamoxifen and increase the risk of cancer recurrence, it is often contraindicated for women with (or at risk of) HRP breast cancer as well as those taking AIs, the use of which has been shown to further exacerbate VVA symptoms. Approximately 600k post-menopausal women in the U.S. take AIs to treat or mitigate risk of HRP breast cancer and an estimated 2M women in the U.S. with breast cancer suffer from VVA, the majority of which do not receive treatment. DARE intends to develop PT-101 for the treatment of VVA in women with (or at risk of recurrence of) hormone-receptor positive breast cancer, including those undergoing therapy – an indication for which there is no currently approved treatment.

A four-subject proof-of-concept study indicated PT-101 was associated with improvement in vaginal dryness and decreased vaginal pH. Interestingly, Ospemifene (marketed as Osphena), also a SERM, acts as an estrogen agonist in the endometrium and works similar to the way that estrogen does in reducing VVA symptoms. Osphena (taken orally) is the only FDA-approved (since February 2013) product for the treatment of VVA that can claim it does not raise estrogen levels. It, however, is not indicated specifically for women with (or at risk of) HRP breast cancer (i.e. the claim that DARE expects to pursue). Presumably the method-of-action of PT-101 would prove similar to that of Osphena. Next steps in development of PT-101, per DARE's May 7th press release announcing the merger, are to optimize the vaginal formulation before moving to larger clinical trials.

In April DARE secured exclusive worldwide rights to a **novel intravaginal ring (IVR) drug-delivery platform technology** from Juniper Pharmaceuticals. DARE obtained rights to three pre-clinical candidates; OAB1 (fka JNP-101) oxybutynin for overactive bladder, HRT1 (fka JNP-201) natural progesterone and estradiol hormone replacement therapy (for menopause) and FRT1 (fka JNP-301) natural progesterone for the prevention of preterm birth. By using a solid ethylene vinyl acetate (EVA) polymer matrix to release drugs, the novel drug-delivery technology is expected to allow for delivery of multiple drugs at multiple release rates and provide longer duration of

efficacy as compared to current methods. Initial human proof-of-concept was established in a six-subject clinical trial whereby their IVR delivered leuprolide (a hormone which is used for the treatment of prostate and breast cancers as well as endometriosis and other conditions). Development for all indications is expected to follow 505(b)(2) pathways which would include a phase 2 bioavailability and dose-finding study followed by a pivotal phase 3 clinical trial. DARE noted in September that a phase 1 (PK/safety) study is starting for HRT1 which will evaluate two doses to determine steady-state over 28 days.

In March DARE announced an agreement with (privately-held) Orbis Biosciences related to the development of **two long-acting injectable contraceptives**. Development work to-date (pre-clinical) has been through a subcontracted program funded by FHI 360, which was sponsored by the Bill & Melinda Gates Foundation. Built on Orbis' controlled-release technology, ORB-204 and ORB-214 are pre-clinical stage etonogestrel injectable contraceptives being developed for (relatively long) pregnancy-protection durations of six and twelve months, respectively. Currently available injectables have a duration of only three months. While specifics were not publicly disclosed, per terms of the agreement with Orbis, if "upcoming development efforts [are] successful" DARE has the option to license rights to ORB-204 and ORB-214. Etonogestrel is currently used in FDA-approved contraceptive implants as well as in vaginal rings including NuvaRing. We expect we will hear development-related status updates in the near-future.

DARE Adds Novel Preclinical Contraceptive Candidate for Men and Women
In mid-July DARE announced an asset transfer agreement with Hydra Biosciences for their CatSper ion channel intellectual property. Ion channels are membrane proteins that allow for the flow of ions, and therefore the transmission of information, into cells. Backed by some of the largest global life sciences-focused venture capital funds, Hydra's main focus is the Transient Receptor Potential (TRP) ion channel and the development of drugs for diseases that may respond to modulation of the TRP channel.

While CatSper, or Cation Channel of Sperm, is distantly related to TRP, it is unique to sperm. The CatSper channel is essential for male fertility, controlling entry of calcium (Ca2+) into the sperm cells, which is necessary for hyperactivation (i.e. swimming) to occur. Significant preclinical work has already been done that indicates CatSper may be a viable target for contraception. The CatSper family consists of four members, CatSper1 through CatSper 4, all of which are required for fertility. CatSper 1 and 2 have been established as critical for hyperactivity and motility while CatSper 3 and 4 are believed to play a role in the acrosome reaction (i.e. a process as the sperm approaches the egg). Studies on mice have shown that disruption of one or more of these channels resulted in immotile sperm but did not affect sperm production.

A drug that could temporarily block or disable CatSper could serve as a novel contraceptive option and could, at least theoretically, be taken by men and women. And, given that CatSper is unique only to sperm presents the possibility that a highly CatSper-targeted therapy could be virtually side-effect free.

The novelty of the target, non-hormonal nature and the potential that a CatSper-targeted contraceptive could be side-effect free and used by both men and women would put it in a class of its own. It also lends itself to increasing contraceptive use and, therefore, fits perfectly within the mandates of the NIH, the Bill & Melinda Gates Foundation, FHI 360 and other agencies and organizations which have provided funding for the development of novel modes of contraception which can help to reduce the rates of unintended pregnancies.

Valuation

Ovaprene
Based on our estimates and assumptions (below), Ovaprene represents more than 70% of DARE's current total value. We believe, if successfully developed and eventually approved for sale, that Ovaprene's attributes could position it as competitive to most contraceptive products – both hormonal and non-hormonal. And while overall use of contraception in the U.S. has remained largely steady (at ~62% of women of reproductive age) over the last two decades, it is possible that perceived advantages of Ovaprene (and the fact that it would represent a new class of contraception) could attract (previous) non-users of contraception and effectively result in expansion of the overall U.S. market. Market expansion may also be facilitated by public and non-profit initiatives aimed at increasing contraceptive use as a whole, as well as by the (relatively recent) mandated insurance coverage. And while the original mandate has recently been slightly watered down and is potentially at-risk of partial or complete repeal, we think at least a portion of any total market size expansion is likely to be sustained over time (regardless of reimbursement status).

However, we feel that Ovaprene is too early in development to reasonably estimate how demand may differ based on individual segments within the larger women's contraceptive market. For example, while we think Ovaprene may provide an attractive alternative to users of short-acting hormonal contraceptives, estimating proportional switching-based demand from users of the pill versus that of the patch or vaginal rings is too granular of an exercise at this stage. Similarly, we have little confidence in accurately forecasting potential differences in the rate or level of uptake as a result of switching (or supplemental use) from condom users versus that from couples that primarily practice withdrawal.

Instead, we think (at this stage) that given the similarity in class (i.e. monthly vaginal rings), that NuvaRing's commercial history provides a better basis for estimating what potential demand for Ovaprene may look like. To be clear, we acknowledge that significant differences exist between NuvaRing and Ovaprene (as envisioned). Similarly, we think that by the time that Ovaprene would potentially launch, the competitive landscape of the U.S. contraceptives market may be meaningfully different as compared to during much of NuvaRing's commercial history (for context, NuvaRing launched in the U.S. in 2002). Some of the differences between Ovaprene and NuvaRing and the dynamics of the markets during the respective periods of commercialization should play in Ovaprene's favor, while others, we think, are/were likely to have been more a benefit to NuvaRing. While not an exhaustive list, some of the more significant factors (favorable and unfavorable) that have been incorporated into our modeling methodology include;

Contextual product-specific considerations

- Women like features of vaginal rings, just not necessarily all the hormones:
    - 50% of women that try hormonal methods discontinue use and of those that do, side effects are the overwhelming reason why
    - most commonly cited specific reasons for discontinuation were; side effects, worried about side effects and did not like changes to menstrual cycle
    - a recent study found a potential association between use of hormonal contraception and depression
- NuvaRing risks (almost all of which are relate to hormones):
    - NuvaRing is contraindicated for women at risk of arterial or venous thrombotic diseases. Study of 1.6M women found users of NuvaRing had a greater than 6x times increased risk of blood clots as compared to non-users
    - FDA's Adverse Events Reporting System (FAERS) lists 8,281 reports of 'serious' events attributable to NuvaRing, including 233 deaths. Of the serious events, 38% related to blood clots (in either the lung or the leg)
    - $100M judgement: in 2014 Merck paid $100M to settle a liability lawsuit which claimed NuvaRing caused blood clots
- Interestingly, despite the negative publicity of the lawsuit, NuvaRing's revenue continued to grow. By contrast, liability-related lawsuits against the makers of certain other hormonal contraceptives such as Yaz (oral progestin), Norplant (levonorgestrel implant) and Depo-Provera (norelgestromin/ethinyl estradiol injection) negatively affected sales. This may suggest that many NuvaRing users believe the convenience-related benefits of vaginal rings (i.e. effectiveness, reversibility and convenience of monthly use) outweigh the risks – which may also suggest that a non-hormonal vaginal ring (i.e. Ovaprene) would be a particularly appealing option
- For much of its commercial life, NuvaRing has had significant sales/marketing support, which undoubtedly aided uptake and sales. Schering-Plough acquired it via its purchase of Organon in 2007 then in 2009, SGP and Merck merged
- NuvaRing patent expiration: NuvaRing's patent expired in April 2018. Mithra Pharma/Mayne Pharma and Dr. Reddy's Labs both expect to launch a generic version of NuvaRing in 2019. Others could follow. Lower generic pricing and tier 1 formulary coverage could catalyze uptake of that contraceptive method and take share of others. This, in our opinion, will be an interesting dynamic to keep an eye on as while, intuitively, we might expect NuvaRing generics to represent direct competition to Ovaprene, they may in fact prove a (net) catalyst to driving demand for it. Our reasoning is that friendlier pricing of the generics may promote switching from other methods and result in sustainably-higher market share of vaginal rings (as a class). If that happens, by the time Ovaprene could come to market, more women would be vaginal ring-experienced and looking for a non-hormonal option.
- New vaginal ring: the competitive landscape could soon include a one-year Nestorone (a progestin) /ethinyl estradiol vaginal ring, an NDA for which Population Council filed in January 2018. Pre-marketing studies (per Pop Council) indicated 89% of women surveyed were 'satisfied' with the ring as a contraceptive method

Contextual market considerations

- Women want more contraceptive options, which is evidenced by one survey (n=2k) that showed 70% of women have quit or are considering quitting use of the pill. Top reasons for quitting the pill include that they want a more convenient method that does not require daily administration and one with no hormones
- Contraceptive reimbursement: the Affordable Care Act of 2010 mandated that all health insurance plans (aside from self-insured employer plans or grandfathered plans) provide no-out-of-pocket coverage of contraceptives. Specifically, the ACA requires coverage of 18 distinct methods of contraception (reimbursement is subject to updating, revision and potentially, complete repeal)
- Recent public and non-profit initiatives aimed at increasing contraceptive use

Sum-of-the-Parts

Given the likelihood that initial commercialization related to any of DARE's various development programs is at least four years away, we think price-to-sales, based on sum-of-the-parts, is the most appropriate valuation methodology. Additionally, while we think the earlier-stage programs currently represent option-like value, based on our background work, their intrinsic worth (at this point) is too difficult to quantify within a reasonable-enough range to warrant inclusion in our (risk-adjusted) valuation model.

Our forecasts and assumptions are based solely on our research and experience and should not be interpreted to reflect those of management. We model Ovaprene, Topical Sildenafil and VVA1 based on commercialization histories of NuvaRing, Addyi and Osphena, respectively, as proxy-like guides. While we are not suggesting that commercialization experience of DARE's candidates will necessarily mirror that of these three products, we do think this is an appropriate and reasonable approach given indication-based and (in some cases,) other similarities and, simply, due to the fact that there is just not enough information (at this point) to confidently model uptake-curves using an alternative method.

Some of the key assumptions in our model include:

Ovaprene
- launches late-2023
- achieves nearly 25% share of NuvaRing's peak penetration by 2026 and 30% by 2028. These equate to ~1.9% and 2.6%, respectively, penetration of the estimated total U.S. contraceptive market
- U.S. annual revenue per user averages $300 initially and grows with inflation (for context NuvaRing averaged ~$424 from 2011 through 2017)
- OUS revenue equal to 85% of U.S. (similar to NuvaRing)
- royalties average 12%
- additional 5% OUS haircut
- 60% risk-adjustment haircut reflects risk of regulatory failure. Clinical trial successes would likely positively influence (i.e. reduce) our risk adjustment

Topical Sildenafil
- launches 2022
- achieves 25% share of Addyi's peak penetration by 2025 and 70% by 2028. These equate to less than 1% penetration of the estimated total U.S. FSAD market in those years
- U.S. revenue per user averages ~$1.5k initially and grows with inflation. This assumes $30/dose and 52 doses per year
- OUS revenue equals 30% of U.S.
- royalties average 12%
- additional 5% OUS haircut
- 70% risk-adjustment haircut reflects risk of regulatory failure – a significant portion of this risk-adjustment reflects current ambiguity over regulatory "FSAD definition" in the context of designing and successfully executing a clinical program for Topical Sildenafil – depending on outcomes of meetings with FDA, our risk-adjustment could come down

PT-101
- launches 2023
- achieves 27% share of Osphena's peak penetration by 2026 and 30% by 2028 (which we also assume represents PT-101 peak). These equate to less than 1% penetration of the estimated U.S. hormone receptor positive breast cancer VVA+ market in those years
- U.S. revenue per user averages $2.2k initially (similar to Osphena historical) and grows with inflation
- OUS revenue equals 30% of U.S.
- royalties average 12%
- additional 5% OUS haircut

- 35% risk-adjustment haircut reflects risk of regulatory failure – we base our risk adjustment on Osphena's history and regulatory successes in U.S. and OUS

P/S Values DARE at $6.75/share

We use 5.0x sales and discount revenue at 20%, 15% and 10% reflecting bear, base and bull cases, respectively. Given assumed commercial acceleration for each of the therapies not occurring until at least 2025, we think 2025, 2026 and 2027 are 'usable' out-years in the valuation waterfall (see below) and still reflect growth potential implied by a 5x sales multiple. Based on a current fully-diluted share count of approximately 15.7M, base case puts fair value of DARE at approximately $6.75/share.

VALUATION WATERFALL

Risk-Adjusted Forecasted Revenue

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Ovaprene	$0	$0	$0	$5,187	$22,220	$49,323	$72,041	$83,411	$97,531	$125,465
%of total		-	*0%*	*59%*	*74%*	*76%*	*73%*	*72%*	*71%*	*74%*
PT-101 (VVA)	$0	$0	$0	$1,430	$3,484	$8,840	$16,150	$18,214	$18,487	$18,764
%of total		-	*0%*	*16%*	*12%*	*14%*	*16%*	*16%*	*14%*	*11%*
Topical Sildenafil (FSAD)	$0	$0	$814	$2,203	$4,192	$7,092	$10,941	$14,612	$20,763	$25,591
%of total		-	*100%*	*25%*	*14%*	*11%*	*11%*	*13%*	*15%*	*15%*
TOTAL Risk-adj Revenue	**$0**	**$0**	**$814**	**$8,820**	**$29,896**	**$65,255**	**$99,132**	**$116,237**	**$136,781**	**$169,819**

Risk-Adjusted Market Value

Present Value based on 2029 out-year:	Per-share value	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
20% discount rate	$3.23	$50,783	$63,479	$79,349	$99,186	$123,982	$154,978	$193,722	$242,152	$302,691	$378,363	$472,954	$591,192
15% discount rate	$7.10	$111,685	$131,394	$154,581	$181,860	$213,953	$251,710	$296,129	$348,387	$409,868	$482,197	$567,291	$667,401
10% discount rate	$14.93	$234,802	$260,891	$289,879	$322,088	$357,875	$397,639	$441,821	$490,912	$545,458	$606,065	$673,405	$748,228
Present Value based on 2028 out-year:													
20% discount rate	$3.74	$58,747	$73,434	$91,792	$114,740	$143,425	$179,281	$224,102	$280,127	$350,159	$437,699	$547,124	
15% discount rate	$7.28	$114,447	$134,643	$158,404	$186,357	$219,244	$257,934	$303,452	$357,002	$420,003	$494,121	$581,319	
10% discount rate	$13.65	$214,616	$238,463	$264,959	$294,398	$327,109	$363,455	$403,839	$448,710	$498,566	$553,963	$615,514	
Present Value based on 2027 out-year:													
20% discount rate	$3.97	$62,404	$78,005	$97,506	$121,883	$152,354	$190,442	$238,053	$297,566	$371,957	$464,946		
15% discount rate	**$7.28**	$114,420	$134,612	$158,367	$186,314	$219,193	$257,874	$303,381	$356,919	$419,905	$494,006		
10% discount rate	$12.89	$202,646	$225,162	$250,180	$277,978	$308,865	$343,183	$381,314	$423,682	$470,758	$523,065		
Present Value based on 2026 out-year:													
20% discount rate	$4.23	$66,526	$83,158	$103,948	$129,934	$162,418	$203,022	$253,778	$317,223	$396,528			
15% discount rate	**$7.30**	$114,803	$135,063	$158,897	$186,938	$219,927	$258,738	$304,397	$358,115	$421,311			
10% discount rate	$12.21	$192,029	$213,366	$237,073	$263,414	$292,682	$325,203	$361,336	$401,485	$446,094			
Present Value based on 2025 out-year:													
20% discount rate	$3.48	$54,739	$68,424	$85,530	$106,913	$133,641	$167,052	$208,815	$261,018				
15% discount rate	**$5.65**	$88,906	$104,596	$123,054	$144,769	$170,316	$200,372	$235,732	$277,332				
10% discount rate	$8.93	$140,450	$156,055	$173,395	$192,661	$214,067	$237,853	$264,281	$293,645				
Present Value based on 2024 out-year:													
20% discount rate	$1.99	$31,348	$39,185	$48,981	$61,226	$76,533	$95,666	$119,583					
15% discount rate	$3.05	$47,919	$56,376	$66,324	$78,029	$91,798	$107,998	$127,057					
10% discount rate	$4.55	$71,495	$79,439	$88,265	$98,073	$108,970	$121,078	$134,531					
Present Value based on 2023 out-year:													
20% discount rate	$0.74	$11,560	$14,450	$18,062	$22,578	$28,222	$35,278						
15% discount rate	$1.06	$16,631	$19,566	$23,019	$27,081	$31,860	$37,483						
10% discount rate	$1.49	$23,435	$26,039	$28,932	$32,147	$35,719	$39,688						

FINANCIAL MODEL

DARE	2017 A	Q1A	Q2A	Q3A	Q4E	2018 E	2019 E	2020 E
Ovaprene U.S. Mkt Assumptions								
Net annual revenue per patient	$200					$300	$300	$300
NuvaRing Avg Annual Patients	1,106,000					1,106,000	1,117,060	1,128,231
NuvaRing Peak US Revenue	$564,000,000					564,000,000	$572,460,000	$581,046,900
U.S. Contracep Product Patient Mkt	23,000,000					$23,000,000	23,000,000	23,460,000
U.S. Contraceptives Mkt Value	$5,500,000,000					$5,500,000,000	5,500,000,000	$5,610,000,000
Ovaprene U.S. Penetration Assmptions								
Penetration of US contraceptives $ value								
Penetration of NuvaRing's Peak US patients								
Number of Annual U.S. Ovaprene patients								
OVAPRENE U.S. REVENUE ($'000)						$0		
OVAPRENE OUS REVENUE						$0	$0	$0
Ovaprene OUS as % of U.S.	-					85.0%	85.0%	85.0%
TOTAL OVAPRENE REVENUE						$0	$0	$0
yoy growth							-	-
PT-101 U.S. Mkt Assumptions								
Net annual revenue per patient	$2,160					$2,160	$2,182	$2,203
PT-101 Total Patient Market	1,400,000					1,400,000	1,414,000	1,428,140
Osphena Peak US Revenue	$43,000,000					$43,000,000	$43,645,000	$44,299,675
PT-101 Patient Market Value	$3,024,000,000					$3,024,000,000	$3,084,782,400	$3,146,786,526
PT-101 U.S. Penetration Assumptions								
Penetration' of Osphena's Peak Revenue								
Penetration of US HRP+ VVA						0.00%	0.00%	0.00%
U.S. PT-101 REVENUE ($000s)						$0	$0	$0
PT-101 OUS REVENUE						$0	$0	$0
PT -101 OUS as % of U.S.	-					30.0%	30.0%	30.0%
TOTAL PT-101 REVENUE						$0	$0	$0
yoy growth							-	-
Topical Sildenafil US Mkt Assumptions								
TS Net Annual revenue per patient	$1,560					$1,560	$1,576	$1,591
TS Total US Patient Market	13,000,000					$13,000,000	13,195,000	13,392,925
Addyi Peak Revenue	$78,000,000					$78,000,000	$79,170,000	$80,357,550
TS Patient Market Value	20,280,000,000					20,280,000,000	20,790,042,000	21,312,911,556
TS U.S. Penetration Assumptions								
Penetration' of Addyi's Peak Revenue						0.00%	0.00%	0.00%
Penetration' of FSAD						0.00%	0.00%	0.00%
Total TS REVENUE ($000s)						$0	$0	$0
TS OUS REVENUE						$0	$0	$0
TS OUS as % of U.S.	-					30.0%	30.0%	30.0%
TOTAL TS REVENUE						$0	$0	$0
yoy growth						-	-	-
Total Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-
SG&A	$2,704.9	$1,303.2	$1,157.2	$1,175.0	$1,551.0	$5,186.4	$6,450.0	$6,856.0
% SG&A	-	-	-	-	-	-	-	-
R&D	$984.7	$1,186.7	$2,467.6	$1,446.5	$1,542.0	$6,642.8	$7,455.0	$8,142.0

%R&D	-	-	-	-	-	-	-	-
Impairment of Goodwill	$7,490.9	$5,187.5	$0.0	$0.0	$0.0	$5,187.5	$0.0	$0.0
TOTAL OpEx	$11,180.5	$7,677.4	$3,624.8	$2,621.6	$3,093.0	$17,016.8	$13,905.0	$14,998.0
% Total OpEx	-	-	-	-	-	-	-	-
Operating Income	($11,180.5)	($7,677.4)	($3,624.8)	($2,621.6)	($3,093.0)	($17,016.8)	($13,905.0)	($14,998.0)
Operating Margin	-	-	-	-	-	-	-	-
Total Other Income (Expense)	($340.7)	($2.0)	$15.1	$28.4	$5.1	$106.6	$28.2	$16.7
Pre-Tax Income	($11,521.2)	($7,679.3)	($3,609.7)	($2,593.2)	($3,087.9)	($16,910.1)	($13,876.8)	($14,981.3)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income	($11,521.2)	($7,679.3)	($3,609.7)	($2,593.2)	($3,087.9)	($16,910.1)	($13,876.8)	($14,981.3)
YOY Growth	1612.7%	3049.0%	624.5%	58.2%	-69.7%	46.8%	-17.9%	8.0%
Net Margin	-	-	-	-	-	-	-	-
EPS (GAAP)	($3.56)	($0.88)	($0.32)	($0.23)	($0.27)	($1.57)	($0.91)	($0.74)
YOY Growth	342.4%	230.0%	-42.3%	-31.0%	-89.0%	-55.8%	-42.2%	-18.9%
Shares O/S	3,232	8,685	11,422	11,422	11,422	10,738	15,250	20,300

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