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COMPANY UPDATE

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Daré Biosciences, Inc. (Nasdaq/DARE)

BUY **Price Target $8.00**

Daré is a women's health company with 2 beginning Phase 2b studies: Ovaprene™ a non-hormonal contraceptive and topical 5% sildenafil cream for FSAD.

September 6, 2018

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Daré Clarifies Topical 5% Sildenafil Citrate Cream Phase 2b Trial Clinical Endpoints with the FDA

Yesterday, Daré updated its expectations for its primary programs that are beginning Phase 2b studies in 2018: Ovaprene®, a non-hormonal monthly contraceptive and topical 5% sildenafil cream for Female Sexual Arousal Disorder (FSAD) uses localized action, with minimal systemic uptake of the active drug.

Topical 5% sildenafil cream: There are no approved treatments for FSAD. After meeting with the FDA the next steps are: 1) to begin a Phase 2b validity Patient Reported Outcomes (PRO) study; 2) conduct additional clinical and non-clinical work that may be required to support the anticipated design of the next Phase 2b; and 3) another Type C meeting with the FDA to determine the adequacy of these data prior to beginning the Phase 2b "at home" study (early 2019)**.** We have modeled worldwide sales beginning in 2024 of $175M reaching $2B in 2028. (see Exhibit. 1 Daré Upcoming Events)

Ovaprene® on track: An open label trial was successful, and the Phase 2b postcoital (PTC) program with 50 couples may begin imminently. Results are expected in 2H:19. We expect worldwide Ovaprene® sales of $91M in 2023 that may reach $1.3B in 2028.

DARE-HRT1 Intervaginal ring (IVR): This ring is to provide estradiol and progesterone replacement. A Phase 1 PK and safety study in 60 subjects to start in early 2019 in Australia.

DARE-VVA1 Vaginally delivered Tamoxifen: This product is to treat Vulvar and Vaginal atrophy (VVA) in HR+ breast cancer patients. Currently, Daré is conducting formulation work to get ready for an IND. No timeline is available.

Current Price	**$1.11**
Price Target	**$8.00**

Estimates	F2016A	F2017A	F2018E
Revenue($000s)	**$0**	**$0**	**$225 A**
1Q March	0	0	0 A
2Q June	0	0	0 A
3Q September	0	0	101 E
4Q December	0	0	124 E
EPS	**($0.81)**	**($3.56)**	**($1.67) E**
1Q March	N/A	N/A	(0.87) A
2Q June	N/A	N/A	(0.31) A
3Q September	N/A	N/A	(0.23) E
4Q December	N/A	N/A	(0.25) E
P/E (x)	N/A	N/A	N/A
EBITDA/Share	NM	NM	NM
EV/EBITDAx	NM	NM	NM
Stock Data			
52-Week Range			$0.74-$3.60
Shares Outstanding (mil.)			11.4
Market Capitalization (mil.)			$12.7
Enterprise Value (mil.)			$0.3
Cash (mil.)			$12.4
Debt (mil.)			$0.0
Book Value/Share (6/18)			$1.07
Price/Book			$1.03 X
Average Trading Volume (3-month) (000s)			386.2
Insider Ownership			29.1%
Institutional Ownership			14.9%
Short interest (000s)			669.1

Price target and ratings changes over the past 3 years:
Initiation - July 18, 2018 - Buy - Price Target $8.00

2Q:18 EPS uneventful. The company ended the June 30th quarter with $12.4M in cash, at least a 1-year runway. There was no revenue booked in the quarter, and R&D spending was higher than we expected due to a 1x charge of $452K related to the merger. The net loss was $3.6M and EPS $(0.31). The Company has 11.4 shares and 3.7M warrants and no debt. During the quarter Daré received a notice of award for the first $224,665 of a $1.9M grant from the NIH SBIR Award. The revenue will be booked as the work is completed, we have modeled the initial award in 2H:18E.

Information summary. In our opinion, the details of the topical 5% sildenafil citrate cream for FSAD clinical plan is solid. It also fits with our estimated time lines discussed in our July Initiation report. The DARE-HRT1 Intervaginal ring (IVR) Phase 1 to begin in 2019 is new and not in our model. To us, there was nothing notably new with Ovaprene or DARE-VVA1 (also not in our model).

Rating and Valuation. We reiterate our Buy rating. Daré's shares that trade at ~1x cash, in our opinion assigning zero value to its 2 lead programs and its pipeline which it intends to fund through partnerships and/or out licensing. Our $8 price target based on an average of a 20x multiple of 2027 EPS of $2.65 discounted back at 30% and a 10x multiple of 2027 adjusted royalties of $162M discounted back at 25%. We have forecasted a 5-year revenue compounded growth rate of 25% annually and a 4-year EPS compounded growth rate of 20%.

Risks include: 1) successful clinical trial results; 2) regulatory approval; 3) the need for additional capital; 4) competition; 5) reimbursement; 6) IP; 7) share illiquidity; and 8) formulation/manufacturing.

Exhibit 1. Daré Upcoming Events

Milestone	Timing
Begin Ovaprene postcoital (PCT) Phase 2b clinical trial	2H:18
Begin validation study for topical sildenafil in FSAD	2H18
Begin IVR estrodial + progesterone Phase 1 trial (Austrailia)	1H:19
TYPE C mtg w/ FDA prior to start of Phase 2b topical sildenafil study	H1:19
Phase 2b topical sildenafil for FSAD to begin (at home study)	H1:19
Receive grants, use ATM to raise cash	**2019**
Results of Ovaprene postcoital test (PCT)	**2H:19**
File an IDE prior to Ovaprene pivotal trial	2H:19
IVR estrodial + progesterone Phase 1 top-line results	2H:19
Pipeline updates, in-license/out-liscense new products	2019
Begin Ovaprene single contraception pivotal trial	2020
Phase 2b topical sildenafil for FSAD results	**YE:20-1Q:21**
2 Phase 3 topical sildenafil FSAD trials in pre- and post menapausal women begin	2021
Ovaprene pivotal trial results	**YE:21**
Ovaprene worldwide partner and regulatory filing	2022
2 Phase 3 topical sildenafil FSAD trials in pre- and post menapausal women results	YE:22-1Q:23
Topical 5% sidenafil cream partner is signed	2023
Ovaprene US & EU approval and launch	**2023**
Topical 5% sidenafil cream launched US & EU	**2024**

Source: Company reports and Dawson James Securities Estimates.

Results of FDA TYPE C meeting for Topical 5% Sildenafil Citrate Cream for Female Sexual Arousal Disorder (FSAD)

Primary Endpoints for the Phase 2b trial

- The 2016 Draft Guidance on arousal disorder discusses the use of the Female Sexual Function Index (FSFI) arousal questions as a possible PRO instrument for evaluating arousal improvement and suggest for FSAD as co-primary endpoint of improvement in satisfactory sexual events and arousal. Since this is uncharted waters with no other drugs approved for this indication, the FDA is open to considering an alternative approach.
- The agency was receptive to Daré's proposal that the co-primary endpoints assess the most important and relevant symptoms of the disorder. Specifically, 1) lack of genital sensation of arousal indicating inadequate lubrication-swelling response to sexual excitement; and 2) the distress that results. There are several good distress tools that have been validated. If symptoms improve, clearly distress is likely to fall.
- The agency and Daré agreed that the Phase 2b study should start with a validity study to demonstrate that the symptoms assessed are the most important and relevant to the target population.
- As a result, Daré plans to conduct a small trial with a Patient Reported Outcomes (PRO) instrument to determine the best questions to assess arousal symptoms. One goal is to assure that the PRO instrument questions asked are understood by the FSAD patients. The questions used may be from the some of the FSFI plus or minus others. Patients will not receive drug. This trial is necessary as no drugs have been approved for FSAD and the company plans to use the 2nd part of the Phase 2b, the at-home study, to validate the clinical endpoints for the two pivotal trials.
- Since Daré plans to use the same endpoint, just at a different timepoint, the company plans to meet with the FDA for a Type C meeting after the qualitative Patient Reported Outcomes (PRO) instrument portion of the Phase 2b is done and before the Phase 2b-at home study begins. The goal would be to ensure that the FDA agrees that the PRO instruments are content valid for the target population. The FDA also expects both pre- and post-menopausal women to be included in these studies.

Study Length: The FDA is agreeable with a 12-week Phase 2b trial to assess reasonable safety and preliminary efficacy. The 2016 Draft Guidance specifies 24 weeks for the two pivotal trials.

Target Population: The FDA confirmed that the 2016 Draft Guidance is that menopause status and concomitant conditions is the group to be studied. The inclusion/exclusion criteria should reflect the population anticipated to use the drug is approved. The FDA reiterated its position that efficacy should be established separately in pre- and post-menopausal women to enable an adequate benefit/risk determination. The guidance indicated that pre- and post-menopausal women can be studied in separate trials or within the same trial, however efficacy needs to be demonstrated for each group.

DARE-HRT1 Intervaginal ring (IVR) Phase 1 to Start in 2019

One of the assets gained in the Juniper merger was the HRT1 Intervaginal ring (IVR) technology platform originally developed at MIT and Mass General Hospital and Harvard Medical School by Dr. Robert Langer and Dr. William Crowley, respectively. The features of the IVR technology include: 1) sustained drug delivery; 2) variable dosing and duration; and 3) 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.

DARE-HRT1 is designed to treat the vasomotor symptoms due to menopause. Specifically, it is hormone replacement therapy (HRT) composed of 80 ug and 160 ug estradiol/ 5 mg and 10 mg of progesterone in an intervaginal ring (IVR).

The company is planning a Phase 1, open-label, 3-arm parallel group study to evaluate the pharmacokinetics and safety of DARE-HR1. The trial will evaluate the PK over 28 days using 2 doses: Estradiol 80 ug with Progesterone 5 mg IVR and Estradiol 160 ug with Progesterone 10 mg IVR. The goal is to identify the steady-state PK after 28 days of each dose. The study includes 60 patients.

HRT is the most effective way to treat vasomotor symptom, genitourinary syndrome of menopause, and has been shown to prevent bone loss and fracture. The US HRT market is estimated to be $2.2B, with $660M FDA-approved medications and ~$1.5B compounded. There are 45M women in the US approaching or in menopause. We have not included DARE-HRT1 in our model.

DARE-VVA1 Vaginally delivered Tamoxifen to treat Vulvar and Vaginal atrophy (VVA) in HR+ Breast Cancer Patients

DARE-VVA1 is a proprietary vaginal formulation of tamoxifen that has the potential to be a first-in-class treatment. VVA is a chronic condition characterized by pain during intercourse, vaginal dryness and irritation. Most women use localized estrogen therapy which is contradicted for more than 2M women diagnosed with or at risk of recurrence of ER-positive and PR-positive breast cancer. Daré plans 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. This will include women receiving anti-cancer therapy. Since the introduction of aromatase inhibitors for the treatment of HR+ breast cancer, the prevalence of VVA in postmenopausal breast cancer patients is reported to be between 42-70%. Currently, Daré is conducting formulation work to get ready for an IND. No timeline is available.

Exhibit 2. Historical and Projected Income Statement

Dare Biosciences, Inc.
Income Statement
(in $000 except per share values)

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	2016	2017	Mar Q1:18A	Jun Q2:18A	Sep Q3:18E	Dec Q4:18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Ovaprene																	
US sales (risk adj. 50%)												23,965	124,666	181,583	242,896	322,906	379,771
EU sales (risk adj. 50%)												21,728	66,488	113,030	161,407	211,674	263,887
Topical 5% Sidinafil (SST-6007)																	
US sales (risk adj. 50%)													77,601	242,208	419,988	524,347	636,452
Royalty Revenue												6,854	41,058	82,043	125,969	162,001	196,048
Licensing/Milestone Revenue	-	-	-	-	101	124	225	500	6,000	6,000	6,000	6,000	6,000	6,000	6,000	6,000	6,000
Total Revenue (000s)	**$ -**	**$ -**	**$ -**	**$ -**	**$ 101**	**$ 124**	$ 225	$ 500	$ 6,000	$ 6,000	$ 6,000	$ 12,854	$ 47,058	$ 88,043	$ 131,969	$ 168,001	$ 202,048
COGS	-	-	-	-	-	-	-	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Gross Profit	-	-	-	-	***101***	***124***	***225***	***$ 500***	***$ 6,000***	***$ 6,000***	***$ 6,000***	***$ 12,854***	***$ 47,058***	***$ 88,043***	***$ 131,969***	***$ 168,001***	***$ 202,048***
Operating Expenses																	
General and administrative	(158)	(2,705)	(1,303)	(1,157)	(1,250)	(1,450)	$ (5,160)	$ (6,400)	$ (7,040)	$ (7,744)	$ (8,518)	$ (9,370)	$ (10,307)	$ (11,338)	$ (12,472)	$ (13,719)	$ (15,091)
R&D	(73)	(985)	(1,087)	(2,218)	(1,500)	(1,500)	$ (6,304)	$ (5,750)	$ (6,325)	$ (6,958)	$ (7,653)	$ (8,419)	$ (9,260)	$ (10,186)	$ (11,205)	$ (12,326)	$ (13,558)
License expenses	(400)	-	(25)	(250)	(25)	(25)	$ (325)	$ (100)	$ (100)	$ (100)	$ (100)						
Impairment of goodwill	-	(7,491)	(5,188)	-	-	-	$ (5,188)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total Operating Expenses	(631)	(11,180)	(7,602)	(3,625)	(2,775)	(2,975)	(16,977)	(12,250)	(13,465)	(14,802)	(16,272)	(17,789)	(19,568)	(21,524)	(23,677)	(26,045)	(28,649)
Operating Income (loss)	**(631)**	**(11,180)**	**(7,602)**	**(3,625)**	**(2,674)**	**(2,851)**	**(16,752)**	**(11,750)**	**(7,465)**	**(8,802)**	**(10,272)**	**(4,935)**	**27,491**	**66,518**	**108,292**	**141,957**	**173,399**
Interest expense	(42)	(323)	(12)	(43)			$ (54)										
Pre-tax Income	(673)	(11,503)	(7,591)	(3,582)	(2,674)	(2,851)	(16,698)	(11,750)	(7,465)	(8,802)	(10,272)	(4,935)	27,491	66,518	108,292	141,957	173,399
Taxes	-	-	-	-	-	-	$ -	$ -	$ -	-	-	-	7,697	18,625	30,322	39,748	48,552
Tax rate 28%	-	-	-	-	-	-	-	-					*28%*	*28%*	*28%*	*28%*	*28%*
Net Income	(673)	$ (11,503)	(7,591)	(3,582)	(2,674)	(2,851)	$ (16,698)	$ (11,750)	$ (7,465)	$ (8,802)	$ (10,272)	$ (4,935)	$ 19,793	$ 47,893	$ 77,970	$ 102,209	$ 124,848
Foreign curency translation adj ne	$ -	$ (18)	$ 14	$ 27	$ 30	$ 25	$ 96	$ (13)	$ (25)	$ (25)	$ (25)	$ (25)	$ (25)	$ (25)	$ (25)	$ (25)	$ (25)
Comprehensive loss	$ (672.7)	$ (11,485)	$ (7,604)	$ (3,610)	$ (2,704)	$ (2,876)	$ (16,794)	$ (11,737)	$ (7,440)	$ (8,777)	$ (10,247)	$ (4,910)	$ 19,818	$ 47,918	$ 77,995	$ 102,234	$ 124,873
GAAP EPS - basic and diluted	**$ (0.81)**	**$ (3.56)**	**$ (0.87)**	**$ (0.31)**	**$ (0.23)**	**$ (0.25)**	**$ (1.67)**	**$ (0.76)**	**$ (0.37)**	**$ (0.36)**	**$ (0.41)**	**$ (0.18)**	**$ 0.59**	**$ 1.36**	**$ 2.11**	**$ 2.65**	**$ 3.09**
Basic Shares	835	3,232	8,685	11,422	11,445	11,468	10,755	15,537	19,896	24,294	24,779	27,275	27,821	28,377	28,944	29,523	30,114
Diluted Shares	31,645	3,232	45,674	15,122	15,152	15,183	22,783	19,629	24,081	29,021	29,601	31,897	33,535	35,206	36,910	38,648	40,421

Source: Company reports, Factset, Dawson James estimates

Exhibit 3. Historical Balance Sheet

Dare Biosciences, Inc.
Balance Sheet
(in $000s except per share values)

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	Mar Q1:17	Jun Q2:17	Sep Q3:17	Dec Q4:17	Mar Q1:18	Jun Q2:18 d
Current Assets						
Cash and cash equivalents	12,028	7,244	8,529	7,560	15,625	12,447
Other receivables	1,139	890	711	284	29	25
Prepaid expenses	1,069	0	1,143	312	291	347
Other current assets	1,373	0	0	193	0	0
Total current assets	**15,609**	**8,134**	**10,383**	**8,349**	**15,945**	**12,819**
Property and equipment, net	114	17	-	-	-	-
Goodwill	-	0	12,881	5,188	-	8
Other non-current assets	230	-	3	723	686	657
Total Assets	**15,953**	**8,151**	**23,267**	**14,260**	**16,631**	**13,484**
Current liabilities						
Accounts payable and accrued expenses	644	660	839	967	808	1,265
Acurred expenses	3,538	189	-	-	-	-
Convertible promissary notes	0	0	-	-	-	-
Curremt portion of deferred revenue	2,500	2,500	-	-	-	-
Current portion of loan payable	-	-	-	-	-	-
Interest payable	0	0	-	-	-	-
Total current liabilities	**6,682**	**3,349**	**839**	**967**	**808**	**1,265**
Loan payable, net of curent position	-	-	0	0	3	0
Deferred revenue	1,368	743	-	-	-	-
Other long-term liabitities	162	-	-	-	-	0
Total long-term liabilities	**1,530**	**743**	**0**	**0**	**3**	**0**
Total Liabilities	**8,212**	**4,092**	**840**	**967**	**810**	**1,266**
Stockholders' equity:						
Common stock	3		1	1	1	1
Accumlated other comprehensive loss			(10)	(18)	(32)	(59)
Additional paid in captial	214,757	215,213	25,536	25,541	35,748	35,755
Accumulated deficit	(207,019)	(211,154)	(3,100)	(12,231)	(19,897)	(23,479)
Total stockholders' equity (deficit)	**7,741**	**4,059**	**22,427**	**13,293**	**15,820**	**12,218**
Total liabilites and stockholders' equity	**15,953**	**8,151**	**23,267**	**14,260**	**16,631**	**13,484**

Source: Company Reports, Factset.

Important Disclosures:

Exhibit 4. Daré's Stock Performance

Source: Stockcharts.com

Price target and ratings changes over the past 3 years:
Initiated – Buy – July 18, 2018 – Price Target $8.00

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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) **Neutra**l: 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 in the last twelve months.

Exhibit 21. Dawson James Ratings Distributions

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 in the last twelve months.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	90%	8	31%
Market Perform (Neutral)	3	10%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	8	28%

Analyst Certification:

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