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Dare Bioscience (NASDAQ/DARE)

BUY: Ovaprene Hormone-Free Contraception

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Dare announced that data from the Company's postcoital test (PCT) clinical study of its novel investigational hormone-free monthly intravaginal contraceptive, Ovaprene, will be presented at the 2021 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting. The meeting will be conducted virtually from April 30 to May 2, 2021.

Investment Highlights

Ovaprene. The poster will present topline results from the Ovaprene PCT clinical study, a pre-pivotal, multi-center, open-label, non-significant risk device trial. In the PCT study, Ovaprene prevented essentially all progressively motile sperm from entering the cervical canal (mean 0.48, median 0.00, per high powered field), a surrogate marker for contraceptive effectiveness. In PCT studies of similar size, products (diaphragms) that demonstrated no motile sperm in the cervical mucus during PCT assessments later demonstrated "typical use" contraceptive effectiveness of 86-91% in pivotal contraceptive studies evaluating pregnancy rates over six-month periods. Dare plans to file an Investigational Device Exemption (IDE) for Ovaprene (a once monthly product). Upon FDA acceptance, the company would then initiate a pivotal contraceptive effectiveness and safety clinical study of Ovaprene with data expected by year-end 2022.

BV1 "One & Done." Daré announced that data from the DARE-BVFREE Phase 3 study of DARE-BV1, will be presented at the 2021 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting. The meeting will be conducted virtually from 30-Apr - 2-May-21. DARE-BV1 is in development for bacterial vaginosis (BV). Differentiating characteristics include a gel technology (w/Clindamycin) that allows for local delivery and a one-time application. The pivotal trial delivered a high cure rate, at 76% just 7-14 days after a single administration; the product appears superior to the standard of care treatments that average 50%. Based on the data set, we expect the company to be engaged in a business development deal that should bring in a combination of cash and resources. NDA submission is expected in 2Q21.

Female Viagra. Yes, It's 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 is currently living with the disorder. Although FSAD affects more women than erectile dysfunction affects men, there are currently no approved products on the market. Phase 2b trial top-line data is expected by YE 2021.

Valuation: We assume that DARE-BV1 can be commercialized in 2022 and that Ovaprene can follow 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 risks associated with each product. This results in models that are equally weighted and rounded to the nearest whole number, for a \$3.00 price target.

Risk to our thesis, include the following: (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property.

Current Price	\$1.53
Price Target	\$3.00

Estimates	F2019A	F2020A	F2021E
Expenses (\$000s)	\$ 14,345	\$ 27,402	\$ 30,136
1Q March	\$ 3,083	\$ 4,254	\$ 7,233
2Q June	\$ 3,982	\$ 7,126	\$ 6,934
3Q September	\$ 3,419	\$ 7,582	\$ 7,834
4Q December	\$ 3,861	\$ 8,441	\$ 8,136

	F2019A	F2020A	F2021E
EPS (diluted)	\$ (0.97)	\$ (0.91)	\$ (0.63)
1Q March	\$ (0.27)	\$ (0.18)	\$ (0.15)
2Q June	\$ (0.29)	\$ (0.27)	\$ (0.15)
3Q September	\$ (0.20)	\$ (0.24)	\$ (0.16)
4Q December	\$ (0.20)	\$ (0.22)	\$ (0.17)

EBITDA/Share	(\$0.90)	(\$0.91)	(\$0.63)
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EV/EBITDA (x)	0.0	0.0	0.0
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Stock Data			
52-Week Range	\$0.91	-	\$3.85
Shares Outstanding (mil.)	47.5		
Market Capitalization (mil.)	\$73		
Enterprise Value (mil.)	\$68		
Debt to Capital	0%		
Book Value/Share	\$2.20		
Price/Book	-		
Average Three Months Trading Volume (K)	2,352		
Insider Ownership	7.5%		
Institutional Ownership	11.1%		
Short interest (mil.)	2.4%		
Dividend / Yield	\$0.00/0.0%		

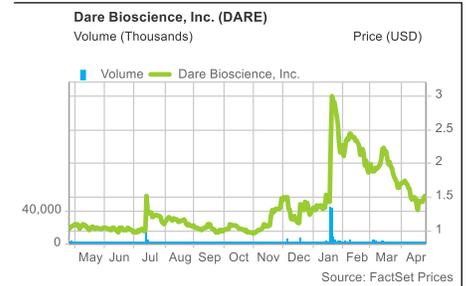


Exhibit 1. Income Statement

DARE: Income Statement (\$'000)																	
∴ YE December	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20A	2020A	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2Q28E	2Q29E	2Q30E
Revenue:																	
DARE-BV1								-	13,737	23,817	34,688	51,551	58,991	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	2,245,765	2,947,017	3,446,180	3,715,473	3,865,579
Total Product Sales								-	13,737	213,581	882,989	2,044,151	3,051,688	4,007,888	4,770,977	5,319,177	5,763,834
DARE-BV1 Royalty Revenue (US)								-	3,434	5,954	8,672	12,888	14,748	16,737	17,411	18,113	18,843
Ovaprene Royalty Revenue (US)										47,441	73,311	100,699	129,676	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
Total royalties, collaborative revenue								-	3,434	53,395	220,747	511,038	762,922	1,001,972	1,192,744	1,329,794	1,440,959
Total Revenue Received by Dare								-	3,434	53,395	220,747	511,038	762,922	1,001,972	1,192,744	1,329,794	1,440,959
Expenses:																	
Costs of Goods Sold								-	584	9,077	37,527	86,876	129,697	170,335	202,767	226,065	244,963
%COGS		17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%
General & Administrative	4,656	5,266	1,862	1,558	1,353	1,777	6,550	7,204	7,925	8,717	9,589	10,548	11,603	12,763	14,039	15,443	16,988
Research & Development	6,414	8,546	2,380	5,547	6,204	6,638	20,769	22,846	29,700	32,670	35,937	35,219	34,514	33,824	32,471	31,172	30,549
License Expense	625	533	13	21	25	25	83	85	89	94	98	103	108	114	120	126	132
Impairment of Goodwill	5,188																
Total Expenses	16,882	14,345	4,254	7,126	7,582	8,441	27,402	30,136	37,714	41,481	45,625	45,870	46,226	46,701	46,630	46,741	47,668
Operating Income (Loss)	(16,882)	(14,345)	(4,254)	(7,126)	(7,582)	(8,441)	(27,402)	(30,136)	(34,280)	11,914	36,358	95,409	155,255	218,517	284,569	354,185	426,896
Other income (expense)	143	81	2	2	(1)	(1)	2	2	2	2	2	2	2	2	2	2	2
Trigger Down Dvd		(790)			(7)		(7)										
Pretax Income	(16,739)	(15,054)	(4,252)	(7,124)	(7,589)	(8,441)	(27,408)	(30,134)	(34,279)	11,916	36,359	95,411	155,257	218,519	284,571	354,187	426,898
Income Taxes																	
Tax Rate											0%	15%	20%	30%	33%	37%	37%
GAAP Net Income (Loss)	(16,817)	(15,061)	(4,274)	(7,124)	(7,589)	(8,420)	(27,408)	(30,134)	(34,279)	11,916	36,359	95,411	155,257	218,519	284,571	354,187	426,898
Fx Translation	(79)		(22)	12		21	11										
GAAP Total Comprehensive Income (Loss)	-	(15,061)	(4,296)	(7,112)	(7,589)	(8,399)	(27,397)	(30,134)	(34,279)	11,916	36,359	95,411	155,257	218,519	284,571	354,187	426,898
GAAP-EPS	(1.57)	(0.97)	(0.18)	(0.27)	(0.24)	(0.22)	(0.91)	(0.63)	(0.69)	0.23	0.68	1.71	2.67	3.61	4.52	5.41	6.26
Fully Diluted EPS	(1.69)	(0.90)	(0.18)	(0.27)	(0.24)	(0.22)	(0.91)	(0.74)	(0.81)	0.27	0.79	2.00	3.12	4.23	5.29	6.33	7.33
Wgtd Avg Shrs (Bas) - '000s	10,732	15,799	23,799	26,711	31,588	38,518	30,091	47,611	49,545	51,556	53,650	55,828	58,095	60,454	62,909	65,463	68,121
Wgtd Avg Shrs (Dil) - '000s	11,422	16,736	23,799	26,711	31,588	38,518	30,091	40,709	42,362	44,082	45,872	47,734	49,672	51,689	53,788	55,972	58,245

Source: Dawson James estimates, company reports

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 its 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.

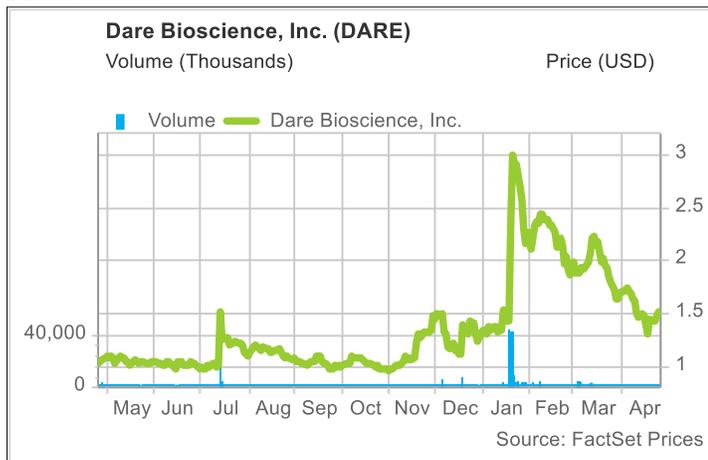
Commercial risk. There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

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 parties' patents.

Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiation – Buy – 7/18/2018 – Price Target \$8.00
- Update Report – Buy – 9/6/2018 – Price Target \$8.00
- Transfer of Coverage – Buy – 7/18/2019 – Price Target \$4.00
- Update Report – Buy – 8/13/2019 – Price Target \$4.00
- Update Report – Buy – 8/15/2019 – Price Target \$4.00
- Update Report – Buy – 9/10/2019 – Price Target \$4.00
- Update Report – Buy – 11/11/2019 – Price Target \$4.00
- Update Report – Buy – 11/12/2019 – Price Target \$4.00
- Update Report – Buy – 12/11/2019 – Price Target \$4.00
- Update Report – Buy – 1/13/2020 – Price Target \$4.00
- Update Report – Buy – 1/27/2020 - Price Target \$4.00
- Price Target Change – Buy – 3/31/2020 – Price Target changed from \$4.00 to \$3.00
- Update Report – Buy – 5/15/2020 - Price Target \$3.00
- Update Report – Buy – 9/1/2020 - Price Target \$3.00
- Update Report – Buy – 11/13/2020 - Price Target \$3.00
- Price Target Change – Buy – 12/7/2020 - Price Target changed from \$3.00 to \$4.00
- Price Target Change – Buy – 3/30/2021 - Price Target changed from \$4.00 to \$3.00
- Update Report – Buy – 4/27/2021 - Price Target \$3.00

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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) **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.

As of: 19-Apr-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	67%	5	25%
Market Perform (Neutral)	10	33%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	30	100%	5	17%

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