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Daré Bioscience (NASDAQ/DARE)

BUY: IDE Approval for a Single-Arm, Open-Label Pivotal Contraceptive Efficacy Study of Ovaprene

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The FDA has granted an Investigational Device Exemption (IDE) setting the stage for Daré to conduct a single-arm, open-label pivotal contraceptive efficacy study of Ovaprene. The IDE submission includes the results of the postcoital test (PCT) clinical study of Ovaprene, in which Ovaprene prevented essentially all sperm from entering the cervical canal across all women and all cycles evaluated. PCT clinical trials have been used as a surrogate marker for contraceptive effectiveness.

Investment Highlights

Management Commented: (press release): “The FDA communication confirms our alignment on a number of key aspects of the clinical study, including the adequacy of a 12-month (13 menstrual cycles) duration. The additional study design considerations provided by the FDA are considered by the FDA to be recommendations that do not need to be addressed in order for us to initiate and conduct this study. However, implementing the guidance that we received from the FDA will further position this pivotal study to collect safety and effectiveness data that will support the submission of a Premarket Approval (PMA) application. Therefore, we look forward to working with our collaborators at the NIH and at Bayer to review and implement the recommendations and **we are targeting mid-year 2023 study recruitment initiation.**”

The multi-center, single arm, non-comparative, pivotal Phase 3 contraceptive study of Ovaprene is designed to evaluate the effectiveness as a contraceptive device along with its safety and usability. If successful, Daré expects the pivotal study to support marketing approvals of Ovaprene in the U.S. and other countries.

Valuation: We assume that DARE-BV1 can be commercialized in 2023 and that Ovaprene can follow in the U.S. (2023) and in the EU in 2025. For Sildenafil cream, we expect commercialization in the U.S. in 2024 and in the EU in 2025. 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.

Risks to our thesis include: (1) commercial; (2) clinical and regulatory; (3) partnership; (4) financial; and (5) legal and intellectual property.

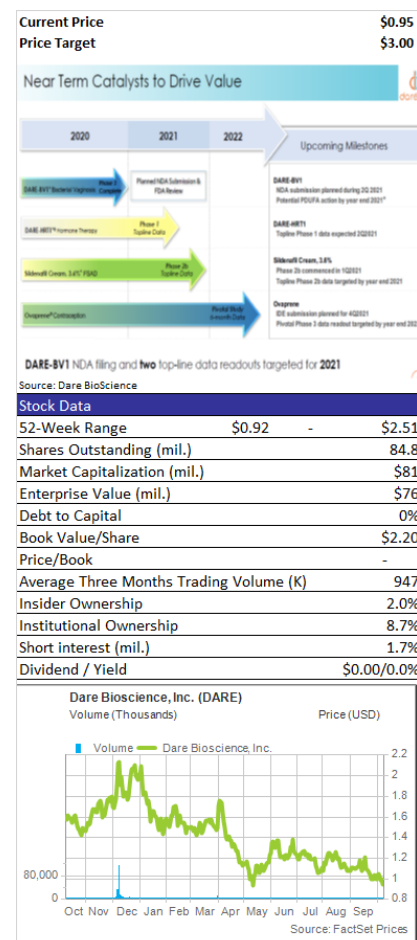


Exhibit 1. Income Statement

DARE Income Statement (\$'000)																	
YE December	2018A	2019A	2020A	2021A	1Q22A	2Q22A	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:																	
DARE-BV1				-						-	61,058	90,740	132,156	157,122	204,318	233,807	265,341
Opavrene										-	97,747	312,168	539,450	780,176	1,034,949	1,304,400	1,589,181
Sildenafil Cream											-	1,479,033	2,245,765	2,947,017	3,446,180	3,715,473	3,865,579
Total Product Sales				-	-	-	-	-	-	-	158,805	1,881,942	2,917,371	3,884,315	4,685,447	5,253,680	5,720,100
DARE-BV1 Royalty Revenue (US)				-						-	15,264	22,685	33,039	39,281	51,079	58,452	66,335
Opavrene Royalty Revenue (US)										-	24,437	50,350	77,805	106,873	137,626	170,139	204,490
Opavrene Royalty Revenue (EU)												27,692	57,057	88,171	121,111	155,961	192,805
Sildenafil Cream Royalty Revenue (US)												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
Total royalties, collaborative revenue				-	-	10,000	-	-	10,000	-	39,701	470,485	729,343	971,079	1,171,362	1,313,420	1,430,025
Total Revenue Received by Dare		-	-	-	-	10,000	-	-	10,000	-	39,701	470,485	729,343	971,079	1,171,362	1,313,420	1,430,025
Expenses:																	
Costs of Goods Sold				-	-		-	-	1,700	-	6,749	79,983	123,988	165,083	199,131	223,281	243,104
%COGS		17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%
General & Administrative	4,656	5,266	6,550	8,351	2,570	2,793	2,388	1,435	9,186	10,105	11,115	12,227	13,449	14,794	16,274	17,901	19,691
Research & Development	6,414	8,546	20,769	30,618	5,805	6,798	8,359	11,187	32,148	33,756	37,131	36,389	35,661	34,948	33,550	32,208	31,564
License Expense	625	533	83	100	25	25	25	30	105	110	116	122	128	134	141	148	155
Impairment of Goodwill	5,188																
Total Expenses	16,882	14,345	27,402	39,069	8,401	9,616	10,772	12,651	41,439	43,971	48,362	48,737	49,238	49,876	49,964	50,257	51,410
Operating Income (Loss)	(16,882)	(14,345)	(27,402)	(39,069)	(8,401)	384	(10,772)	(12,651)	(31,439)	(43,971)	(8,661)	51,990	118,664	184,448	259,853	334,295	412,220
Other income (expense)	143	81	2	2	2	30	0	(30)	2	2	2	2	2	2	2	2	2
Trigger Down Dvd & Fx		(790)	(7)	2,520		(136)											
			397														
Pretax Income	(16,739)	(15,054)	(27,408)	(38,696)	(8,399)	278	(10,772)	(12,681)	(31,574)	(43,969)	(8,659)	51,992	118,666	184,451	259,855	334,297	412,223
Income Taxes												7,799	23,733	55,335	85,752	123,690	152,522
Tax Rate											0%	15%	20%	30%	33%	37%	37%
GAAP Net Income (Loss)	(16,817)	(15,061)	(27,408)	(38,645)	(8,399)	278	(10,772)	(12,681)	(31,574)	(43,969)	(8,659)	51,992	118,666	184,451	259,855	334,297	412,223
Fx Translation	(79)		11	64	(9)												
GAAP Total Comprehensive Income (Loss)	-	(15,061)	(27,397)	(38,759)	(8,408)	278	(10,772)	(12,681)	(31,574)	(43,969)	(8,659)	51,992	118,666	184,451	259,855	334,297	412,223
GAAP-EPS	(1.57)	(0.97)	(0.91)	(0.63)	(0.10)	0.00	(0.13)	(0.15)	(0.37)	(0.50)	(0.09)	0.54	1.19	1.78	2.40	2.97	3.52
Fully Diluted EPS	(1.69)	(0.90)	(0.91)	(0.63)	(0.10)	0.00	(0.13)	(0.15)	(0.37)	(0.50)	(0.09)	0.54	1.19	1.78	2.40	2.97	3.52
Wgtd Avg Shrs (Bas) - '000s	10,732	15,799	30,091	61,154	83,944	84,683	85,530	86,385	85,135	88,566	92,162	95,905	99,799	103,851	108,068	112,456	117,022
Wgtd Avg Shrs (Dil) - '000s	11,422	16,736	30,091	61,154	83,944	84,683	85,530	86,385	85,135	88,566	92,162	95,905	99,799	103,851	108,068	112,456	117,022

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 Daré 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. Daré 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.

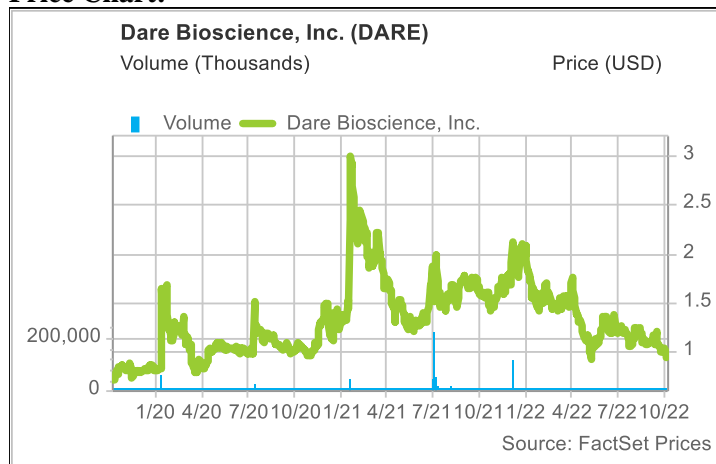
Commercial risk. There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

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

Update Report – Buy – 5/13/2021 - Price Target \$3.00

Update Report – Buy – 6/29/2021 - Price Target \$3.00

Update Report – Buy – 8/9/2021 - Price Target \$3.00

Update Report – Buy – 8/12/2021 - Price Target \$3.00

Update Report – Buy – 11/23/2021 - Price Target \$3.00

Update Report – Buy – 12/8/2021 - Price Target \$3.00

Update Report – Buy – 2/28/2022 - Price Target \$3.00

Update Report – Buy – 3/31/2022 - Price Target \$3.00

Update Report – Buy – 4/20/2022 - Price Target \$3.00

Update Report – Buy – 5/12/2022 - Price Target \$3.00

Update Report – Buy – 7/1/2022 - Price Target \$3.00

Update Report – Buy – 8/10/2022 - Price Target \$3.00

Update Report – Buy – 8/24/2022 - Price Target \$3.00

Update Report – Buy – 8/30/2022 - Price Target \$3.00

Update Report – Buy – 10/10/2022 - Price Target \$3.00

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- 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.

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Current as of 20-Sep-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	83%	3	12%
Market Perform (Neutral)	4	13%	1	25%
Market Underperform (Sell)	1	3%	0	0%
Total	30	100%	4	13%

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