

## Daré Bioscience (NASDAQ/DARE)

### BUY: Daré Announces the Start – P1 Study for Primary Dysmenorrhea

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*Daré Bioscience announced the start of a Phase 1 study evaluating its development program targeted at treating primary dysmenorrhea by delivering the active pharmaceutical ingredient diclofenac, a nonsteroidal anti-inflammatory drug (NSAID), in a novel way.*

### Investment Highlights

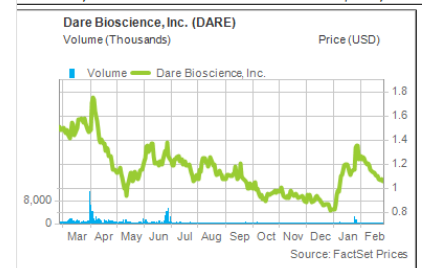
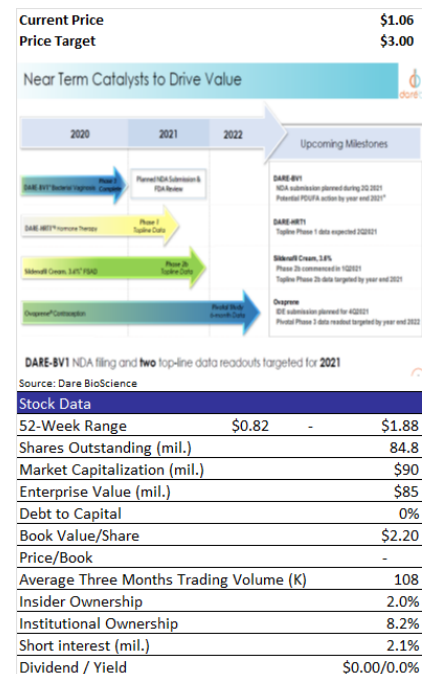
**Dare' PDM1:** A Phase 1 study of DARE-PDM1 has begun. The plan is to leverage existing safety/efficacy data for diclofenac to utilize the FDA's (FDA) 505(b)(2) pathway to obtain marketing approval of DARE-PDM1 in the U.S. PDM1 will deliver diclofenac vaginally via the company's proprietary hydrogel.

**The Trial Details:** The DARE-PDM1 Phase 1 study, DARE-PDM1-001, is a multi-center, randomized, placebo-controlled, double-blind, 3 arm parallel group study of approximately 36 healthy, premenopausal women with primary dysmenorrhea. This study is designed to assess the systemic (plasma) and local mucosal (vaginal fluid) diclofenac pharmacokinetics (PK) and safety after a single dose and during three daily doses of vaginally administered DARE-PDM1, given in two different strengths (1% or 3% diclofenac in 2.5 mL of hydrogel) versus placebo. The study will also assess, as an exploratory endpoint, the preliminary dysmenorrhea treatment efficacy of DARE-PDM1, when dosed in three daily doses at the onset of dysmenorrhea symptoms, compared to a no-treatment, baseline, control cycle. The study observation period will encompass approximately three menstrual cycles. The DARE-PDM1-001 study will be conducted in Australia by the company's subsidiary, DARE Bioscience Australia Pty Ltd.

**What is Primary dysmenorrhea?** It is defined as painful menstruation in women with normal pelvic anatomy, typically described as cramping pain in the lower abdomen before or during the menstrual period. Recent market research suggests that the global market for dysmenorrhea treatment was estimated to be valued at USD \$13B in 2022 and that the size of this market is expected to increase to USD \$28.5B by 2029.

**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	3Q22A	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Revenue:</b>																	
DARE-BV1				-						-	61,058	90,740	132,156	157,122	204,318	233,807	265,341
Ovaprene										-	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
<b>Total Product Sales</b>											<b>158,805</b>	<b>1,881,942</b>	<b>2,917,371</b>	<b>3,884,315</b>	<b>4,685,447</b>	<b>5,253,680</b>	<b>5,720,100</b>
DARE-BV1 Royalty Revenue (US)				-						-	15,264	22,685	33,039	39,281	51,079	58,452	66,335
Ovaprene Royalty Revenue (US)										-	24,437	50,350	77,805	106,873	137,626	170,139	204,490
Ovaprene 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
<b>Total royalties, collaborative revenue</b>						10,000			<b>10,000</b>		<b>39,701</b>	<b>470,485</b>	<b>729,343</b>	<b>971,079</b>	<b>1,171,362</b>	<b>1,313,420</b>	<b>1,430,025</b>
<b>Total Revenue Received by Dare</b>						<b>10,000</b>			<b>10,000</b>		<b>39,701</b>	<b>470,485</b>	<b>729,343</b>	<b>971,079</b>	<b>1,171,362</b>	<b>1,313,420</b>	<b>1,430,025</b>
<b>Expenses:</b>																	
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	2,652	1,172	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	4,462	15,083	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																
<b>Total Expenses</b>	<b>16,882</b>	<b>14,345</b>	<b>27,402</b>	<b>39,069</b>	<b>8,401</b>	<b>9,616</b>	<b>7,139</b>	<b>16,284</b>	<b>41,439</b>	<b>43,971</b>	<b>48,362</b>	<b>48,737</b>	<b>49,238</b>	<b>49,876</b>	<b>49,964</b>	<b>50,257</b>	<b>51,410</b>
Operating Income (Loss)	(16,882)	(14,345)	(27,402)	(39,069)	(8,401)	384	(7,139)	(16,284)	(31,439)	(43,971)	(8,661)	51,990	118,664	184,448	259,853	334,297	412,223
Other income (expense)	143	81	2	2	2	30	119	(149)	2	2	2	2	2	2	2	2	2
Trigger Down Dvd & Fx		(790)	(7)	2,520		(136)		397									
<b>Pretax Income</b>	<b>(16,739)</b>	<b>(15,054)</b>	<b>(27,408)</b>	<b>(38,696)</b>	<b>(8,399)</b>	<b>278</b>	<b>(7,020)</b>	<b>(16,433)</b>	<b>(31,574)</b>	<b>(43,969)</b>	<b>(8,659)</b>	<b>51,992</b>	<b>118,666</b>	<b>184,451</b>	<b>259,855</b>	<b>334,297</b>	<b>412,223</b>
Income Taxes												7,799	23,733	55,335	85,752	123,690	152,522
<b>Tax Rate</b>											<b>0%</b>	<b>15%</b>	<b>20%</b>	<b>30%</b>	<b>33%</b>	<b>37%</b>	<b>37%</b>
<b>GAAP Net Income (Loss)</b>	<b>(16,817)</b>	<b>(15,061)</b>	<b>(27,408)</b>	<b>(38,645)</b>	<b>(8,399)</b>	<b>278</b>	<b>(7,251)</b>	<b>(16,433)</b>	<b>(31,804)</b>	<b>(43,969)</b>	<b>(8,659)</b>	<b>51,992</b>	<b>118,666</b>	<b>184,451</b>	<b>259,855</b>	<b>334,297</b>	<b>412,223</b>
Fx Translation	(79)		11	64	(9)		(231)										
<b>GAAP Total Comprehensive Income (Loss)</b>	<b>-</b>	<b>(15,061)</b>	<b>(27,397)</b>	<b>(38,759)</b>	<b>(8,408)</b>	<b>278</b>	<b>(7,251)</b>	<b>(16,433)</b>	<b>(31,804)</b>	<b>(43,969)</b>	<b>(8,659)</b>	<b>51,992</b>	<b>118,666</b>	<b>184,451</b>	<b>259,855</b>	<b>334,297</b>	<b>412,223</b>
<b>GAAP-EPS</b>	<b>(1.57)</b>	<b>(0.97)</b>	<b>(0.91)</b>	<b>(0.63)</b>	<b>(0.10)</b>	<b>0.00</b>	<b>(0.08)</b>	<b>(0.19)</b>	<b>(0.37)</b>	<b>(0.50)</b>	<b>(0.09)</b>	<b>0.55</b>	<b>1.20</b>	<b>1.79</b>	<b>2.42</b>	<b>3.00</b>	<b>3.55</b>
<b>Fully Diluted EPS</b>	<b>(1.69)</b>	<b>(0.90)</b>	<b>(0.91)</b>	<b>(0.63)</b>	<b>(0.10)</b>	<b>0.00</b>	<b>(0.08)</b>	<b>(0.19)</b>	<b>(0.37)</b>	<b>(0.50)</b>	<b>(0.09)</b>	<b>0.55</b>	<b>1.20</b>	<b>1.79</b>	<b>2.42</b>	<b>3.00</b>	<b>3.55</b>
Wgtd Avg Shrs (Bas) - '000s	10,732	15,799	30,091	61,154	83,944	84,683	84,823	85,671	84,780	87,834	91,400	95,112	98,974	102,992	107,174	111,526	116,054
Wgtd Avg Shrs (Dil) - '000s	11,422	16,736	30,091	61,154	83,944	84,683	84,823	85,671	84,780	87,834	91,400	95,112	98,974	102,992	107,174	111,526	116,054

Source: Company reports and Dawson James

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.

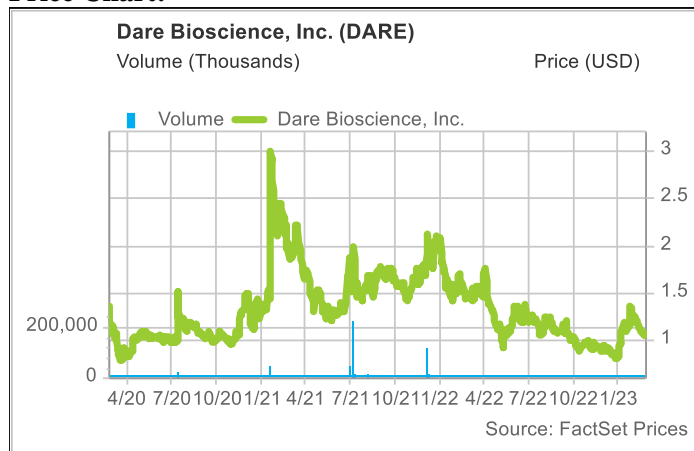
**Commercial risk.** There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

**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  
Update Report – Buy – 10/17/2022 - Price Target \$3.00  
Update Report – Buy – 11/1/2022 - Price Target \$3.00  
Update Report – Buy – 11/14/2022 - Price Target \$3.00  
Update Report – Buy – 12/14/2022 - Price Target \$3.00  
Update Report – Buy – 2/27/2023 - 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 22-Feb-23

	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	68%	1	4%
Market Perform (Neutral)	11	32%	2	18%
Market Underperform (Sell)	0	0%	0	0%
<b>Total</b>	<b>34</b>	<b>100%</b>	<b>3</b>	<b>9%</b>

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