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## Daré Bioscience (NASDAQ/DARE)

### BUY: The Phase 1/2 study of DARE-HRT1

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*Daré announced the initiation of a Phase 1/2 clinical study of DARE-HRT1. Recall that this is a intravaginal ring (IVR) designed to deliver bio-identical 17β-estradiol and bio-identical progesterone continuously over a 28-day period as part of a hormone therapy (HT) regimen to treat the vasomotor symptoms (VMS) and genitourinary syndrome associated with menopause.*

### Investment Highlights

**HRT-1:** Topline data reported in 2021 from a Phase 1 study evaluating pharmacokinetics (PK) of two different dose versions of DARE-HRT1 over 28 days support DARE-HRT1's potential to be the first FDA-approved product to offer vaginal delivery of combination bio-identical estradiol and bio-identical progesterone hormone therapy in a convenient monthly format to treat both VMS as well as vaginal symptoms of menopause. The open-label Phase 1/2 study that has been initiated will evaluate the PK of the same two dose versions of DARE-HRT1 (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) in approximately 20 healthy, post-menopausal women over approximately three consecutive months of use. The study will also collect safety, usability, acceptability and symptom-relief data. The study is being conducted by the company's wholly owned subsidiary in Australia.

### Why is the Stock Down? Dare' has fallen from a recent peak of \$1.84 to \$1.34.

**Why?** Management announced a deal for BV1. An exclusive global license agreement with Organon to commercialize XACIATO. The license includes a \$10M cash payment upon effective U.S. commercial launch of XACIATO, expected in 4Q-2022. In addition, milestones could total \$182M plus double-digit royalties on sales. Daré also reported full-year 2021 results closing the year with \$52M in cash. While some might be disappointed with this news we are not. The company has a strong cash position and solid pipeline.

**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 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	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Revenue:</b>																	
DARE-BV1				-	5,803	6,045	5,561	6,770	24,179	41,923	61,058	90,740	103,837	117,842	122,591	127,531	132,670
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
<b>Total Product Sales</b>				-	5,803	6,045	5,561	6,770	24,179	231,887	909,359	2,083,340	3,096,533	4,058,782	4,823,922	5,374,256	5,821,133
DARE-BV1 Royalty Revenue (US)				-	1,451	1,511	1,390	1,693	6,045	10,481	15,264	22,685	25,959	29,460	30,648	31,883	33,168
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
<b>Total royalties, collaborative revenue</b>				-	1,451	1,511	1,390	1,693	6,045	57,922	227,340	520,835	774,133	1,014,695	1,205,980	1,343,564	1,455,283
<b>Total Revenue Received by Dare</b>				-	1,451	1,511	1,390	1,693	6,045	57,922	227,340	520,835	774,133	1,014,695	1,205,980	1,343,564	1,455,283
<b>Expenses:</b>																	
Costs of Goods Sold				-	247	257	236	288	1,028	9,847	38,648	88,542	131,603	172,498	205,017	228,406	247,398
%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	2,205	2,113	2,388	2,480	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	9,553	9,155	10,349	10,747	39,803	43,783	48,161	47,198	46,254	45,329	43,516	41,775	40,940
License Expense	625	533	83	100	25	27	25	27	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>11,783</b>	<b>11,295</b>	<b>12,762</b>	<b>13,254</b>	<b>49,094</b>	<b>53,998</b>	<b>59,392</b>	<b>59,546</b>	<b>59,831</b>	<b>60,257</b>	<b>59,930</b>	<b>59,824</b>	<b>60,786</b>
Operating Income (Loss)	(16,882)	(14,345)	(27,402)	(39,069)	(10,332)	(9,784)	(11,372)	(11,562)	(43,049)	3,924	29,183	91,530	152,861	217,684	284,505	354,874	428,103
Other income (expense)	143	81	2	2	0	0	0	0	2	2	2	2	2	2	2	2	2
Trigger Down Dvd		(790)	(7)	370													
<b>Pretax Income</b>	<b>(16,739)</b>	<b>(15,054)</b>	<b>(27,408)</b>	<b>(38,696)</b>	<b>(10,331)</b>	<b>(9,783)</b>	<b>(11,372)</b>	<b>(11,561)</b>	<b>(43,047)</b>	<b>3,925</b>	<b>29,184</b>	<b>91,532</b>	<b>152,863</b>	<b>217,686</b>	<b>284,507</b>	<b>354,874</b>	<b>428,105</b>
Income Taxes												13,730	30,573	65,306	93,887	131,303	158,399
Tax Rate											0%	15%	20%	30%	33%	37%	37%
<b>GAAP Net Income (Loss)</b>	<b>(16,817)</b>	<b>(15,061)</b>	<b>(27,408)</b>	<b>(38,696)</b>	<b>(10,331)</b>	<b>(9,783)</b>	<b>(11,372)</b>	<b>(11,561)</b>	<b>(43,047)</b>	<b>3,925</b>	<b>29,184</b>	<b>91,532</b>	<b>152,863</b>	<b>217,686</b>	<b>284,507</b>	<b>354,874</b>	<b>428,105</b>
Fx Translation	(79)		11	63													
<b>GAAP Total Comprehensive Income (Loss)</b>	<b>-</b>	<b>(15,061)</b>	<b>(27,397)</b>	<b>(38,759)</b>	<b>(10,331)</b>	<b>(9,783)</b>	<b>(11,372)</b>	<b>(11,561)</b>	<b>(43,047)</b>	<b>3,925</b>	<b>29,184</b>	<b>91,532</b>	<b>152,863</b>	<b>217,686</b>	<b>284,507</b>	<b>354,874</b>	<b>428,105</b>
<b>GAAP-EPS</b>	<b>(1.57)</b>	<b>(0.97)</b>	<b>(0.91)</b>	<b>(0.63)</b>	<b>(0.14)</b>	<b>(0.13)</b>	<b>(0.15)</b>	<b>(0.16)</b>	<b>(0.59)</b>	<b>0.05</b>	<b>0.37</b>	<b>1.11</b>	<b>1.78</b>	<b>2.43</b>	<b>3.06</b>	<b>3.66</b>	<b>4.25</b>
Fully Diluted EPS	(1.69)	(0.90)	(0.91)	(0.63)	(0.14)	(0.13)	(0.15)	(0.16)	(0.59)	0.05	0.37	1.11	1.78	2.43	3.06	3.66	4.25
Wgtd Avg Shrs (Bas) - '000s	10,732	15,799	30,091	61,154	72,198	72,920	73,649	74,385	73,288	76,264	79,360	82,583	85,936	89,425	93,056	96,834	100,766
Wgtd Avg Shrs (Dil) - '000s	11,422	16,736	30,091	61,154	72,198	72,920	73,649	74,385	73,288	76,264	79,360	82,583	85,936	89,425	93,056	96,834	100,766

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.

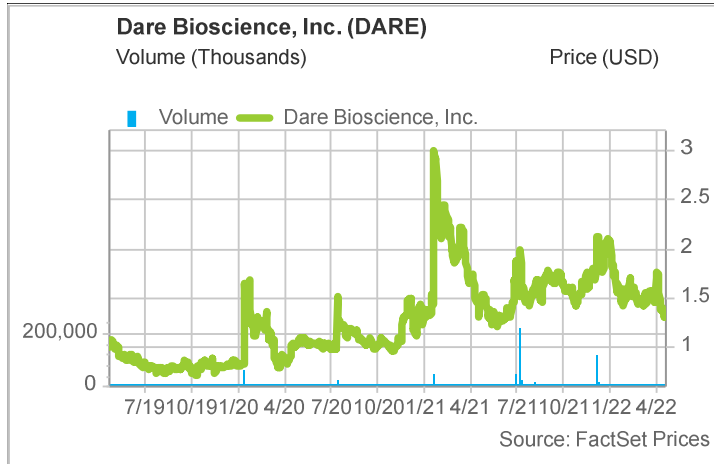
**Commercial risk.** There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

**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

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Current as of... 7-Apr-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
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Market Perform (Neutral)	11	26%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	42	100%	4	10%

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