

## Daré Bioscience (NASDAQ/DARE)

## BUY: Daré Provides an Update on the Launch of XACIATO

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*Organon will pay Daré \$1.0 million in July 2023 and will pay Daré \$1.8 million upon the first commercial sale of XACIATO. In 2022, Daré received a \$10.0 million upfront payment from Organon when the license agreement became effective. In addition to the upfront payment and the \$2.8 million described above, Daré is also eligible to receive additional potential future milestone payments of up to \$180.0 million and tiered double-digit royalties based on net sales.*

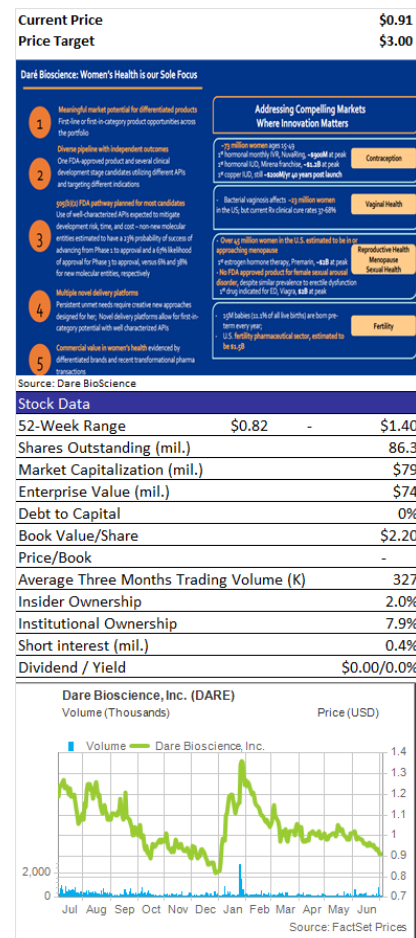
### Investment Highlights:

**What is it?** The first FDA-approved product, XACIATO (clindamycin phosphate) vaginal gel, 2% is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older. XACIATO is now licensed (globally) to Organon (OGN – Not Rated). XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. About bacterial vaginosis: This can be a recurring infection that often is difficult to treat effectively. It is the most common vaginal condition in women ages 15-44 and is estimated to affect ~23 million women in the US. Bacterial Vaginosis increases health risks, including increased risk of preterm birth, sexually transmitted infections, post-surgical infection, and pelvic inflammatory disease that can increase the risk of infertility.

**Standard of Care Limitations:** Bacterial vaginosis is a disruption in the optimal vaginal microbiome and therefore recurrent in many women. Women experiencing recurrence have three or more episodes in the same year and may not prefer multiple doses of systemic antibiotics. Rx suboptimal: clinical cure rates of 37-68% (excluding XACIATOTM). XACIATO Offers a single self-administered dose, any time of day. Vaginal delivery of the antibiotic, with minimal systemic exposure. It is colorless, odorless gel. It has demonstrated equivalent cure rates in both women having her first occurrence of bacterial vaginosis as well as those with a history of multiple prior episodes. Clear labeling for special populations such as pregnant and lactating women. Is Organon the Right Partner? Organon believes there is roughly a 90% overlap of those healthcare providers who prescribe NEXPLANON (birth control implant) and who diagnose and treat BV. Organon's sales force relationships with these providers should position them well to promote XACIATO. Double Digit Royalties.

**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	2022A	1Q23A	2Q23E	3Q23E	4Q23E	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
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
<b>Total Product Sales</b>				-	-	-	-	-	-	-	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
<b>Total royalties, collaborative revenue</b>				-	10,000	-	-	-	-	-	39,701	470,485	729,343	971,079	1,171,362	1,313,420	1,430,025
<b>Total Revenue Received by Dare</b>		-	-	-	10,000	-	-	-	-	-	39,701	470,485	729,343	971,079	1,171,362	1,313,420	1,430,025
<b>Expenses:</b>																	
Costs of Goods Sold				-		-	-	-	-	-	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	11,243	3,337	2,844	3,215	2,970	12,367	13,604	14,964	16,461	18,107	19,918	21,909	24,100
Research & Development	6,414	8,546	20,769	30,618	30,042	5,020	7,255	8,202	11,068	31,544	34,699	34,005	33,325	32,658	31,352	30,098	29,496
License Expense	625	533	83	100	100	25	27	25	27	105	110	116	122	128	134	141	148
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>41,385</b>	<b>8,382</b>	<b>10,127</b>	<b>11,442</b>	<b>14,065</b>	<b>44,017</b>	<b>48,413</b>	<b>49,085</b>	<b>49,907</b>	<b>50,893</b>	<b>51,404</b>	<b>52,148</b>	<b>53,744</b>
<b>Operating Income (Loss)</b>	<b>(16,882)</b>	<b>(14,345)</b>	<b>(27,402)</b>	<b>(39,069)</b>	<b>(31,385)</b>	<b>(8,382)</b>	<b>(10,127)</b>	<b>(11,442)</b>	<b>(14,065)</b>	<b>(44,017)</b>	<b>(8,712)</b>	<b>51,642</b>	<b>117,994</b>	<b>183,432</b>	<b>258,413</b>	<b>332,404</b>	<b>409,886</b>
Other income (expense)	143	81	2	2	438	340	124	115	(119)	460	483	507	532	559	587	616	647
Trigger Down Dvd & Fx		(790)	(7)	2,520	(196)	(22)											
			397														
<b>Pretax Income</b>	<b>(16,739)</b>	<b>(15,054)</b>	<b>(27,408)</b>	<b>(38,696)</b>	<b>(31,144)</b>	<b>(8,064)</b>	<b>(10,003)</b>	<b>(11,327)</b>	<b>(14,185)</b>	<b>(43,579)</b>	<b>(8,229)</b>	<b>52,149</b>	<b>118,527</b>	<b>183,990</b>	<b>259,000</b>	<b>333,020</b>	<b>410,533</b>
Income Taxes											-	7,822	23,705	55,197	85,470	123,217	151,897
<b>Tax Rate</b>											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>(38,645)</b>	<b>(31,376)</b>	<b>(8,064)</b>	<b>(10,003)</b>	<b>(11,327)</b>	<b>(14,185)</b>	<b>(43,579)</b>	<b>(8,229)</b>	<b>52,149</b>	<b>118,527</b>	<b>183,990</b>	<b>259,000</b>	<b>333,020</b>	<b>410,533</b>
Fx Translation	(79)		11	64													
<b>GAAP Total Comprehensive Income (Loss)</b>	<b>-</b>	<b>(15,061)</b>	<b>(27,397)</b>	<b>(38,759)</b>	<b>(31,376)</b>	<b>(8,064)</b>	<b>(10,003)</b>	<b>(11,327)</b>	<b>(14,185)</b>	<b>(43,579)</b>	<b>(8,229)</b>	<b>52,149</b>	<b>118,527</b>	<b>183,990</b>	<b>259,000</b>	<b>333,020</b>	<b>410,533</b>
<b>GAAP-EPS</b>	<b>(1.57)</b>	<b>(0.97)</b>	<b>(0.91)</b>	<b>(0.63)</b>	<b>(0.37)</b>	<b>(0.09)</b>	<b>(0.12)</b>	<b>(0.13)</b>	<b>(0.16)</b>	<b>(0.50)</b>	<b>(0.09)</b>	<b>0.55</b>	<b>1.21</b>	<b>1.81</b>	<b>2.44</b>	<b>3.02</b>	<b>3.58</b>
<b>Fully Diluted EPS</b>	<b>(1.69)</b>	<b>(0.90)</b>	<b>(0.91)</b>	<b>(0.63)</b>	<b>(0.37)</b>	<b>(0.09)</b>	<b>(0.12)</b>	<b>(0.13)</b>	<b>(0.16)</b>	<b>(0.50)</b>	<b>(0.09)</b>	<b>0.55</b>	<b>1.21</b>	<b>1.81</b>	<b>2.44</b>	<b>3.02</b>	<b>3.58</b>
Wgtd Avg Shrs (Bas) - '000s	10,732	15,799	30,091	61,154	84,571	85,517	86,372	87,236	88,108	86,808	90,333	94,001	97,818	101,790	105,923	110,224	114,699
Wgtd Avg Shrs (Dil) - '000s	11,422	16,736	30,091	61,154	84,571	85,517	86,372	87,236	88,108	86,808	90,333	94,001	97,818	101,790	105,923	110,224	114,699

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.

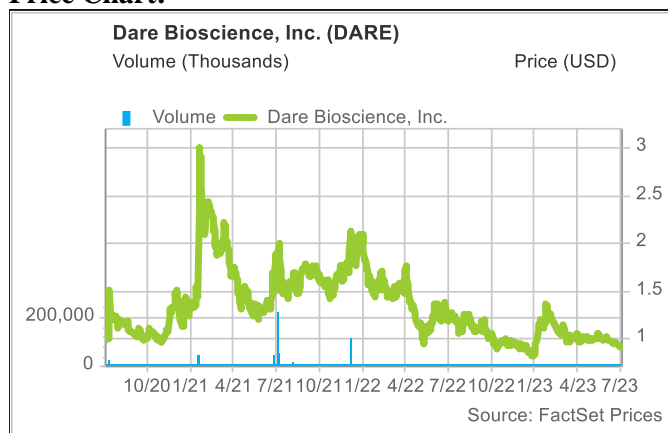
**Commercial risk.** There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

**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  
Update Report – Buy – 4/13/2023 - Price Target \$3.00  
Update Report – Buy – 6/20/2023 - Price Target \$3.00  
Update Report – Buy – 7/5/2023 - Price Target \$3.00

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Current as of 22-Jun-23

	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	72%	2	5.50%
Market Perform (Neutral)	10	28%	2	5.50%
Market Underperform (Sell)	0	0%	0	0.00%
<b>Total</b>	<b>36</b>	<b>100%</b>	<b>4</b>	<b>11.00%</b>

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