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Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

## Daré Bioscience (NASDAQ/DARE)

### BUY: Daré Bioscience announces first shipment of XACIATO

*Daré Bioscience announced the first shipment of XACIATO (clindamycin phosphate) vaginal gel, 2% in connection with the first commercial sale of the product in the United States, triggering a \$1.8M milestone payment to Daré under its global license agreement with Organon.*

### Investment Highlights:

The NDA for XACIATO was supported by positive results from the DARE-BVFREE Phase 3 randomized, multi-center, double-blinded, placebo-controlled clinical trial evaluating XACIATO for the treatment of bacterial vaginosis. Recall that Daré and Organon entered into a global exclusive license agreement for XACIATO in March 2022. Daré received a \$10.0M upfront payment after the license agreement became effective and a \$1.0M payment in July 2023. In addition to the \$1.8M milestone payment, Daré is eligible to receive potential future milestone payments of up to \$180M and tiered double-digit royalties based on net sales.

Recent - Second Quarter Results: Dare spent \$2.9M in G&A and \$6.0M in R&D. Overall the company reported a net loss of \$8.7M in the quarter. Management highlighted anticipated milestones ahead in the quarter's press release:

1. "We are on track to begin patient enrollment in what we believe will be the single pivotal Phase 3 study for Dare's late-stage portfolio candidate, *Ovaprene*, an investigational, hormone-free, monthly intravaginal contraceptive designed to be an easy-to-use monthly option with effectiveness approaching hormonal methods and whose U.S. commercial rights are under a license agreement with Bayer."
2. "Later this year we expect to announce the topline findings from our DARE-PDM1 Phase 1 trial, a multi-center, randomized, placebo-controlled, double-blind, 3-arm parallel group study of approximately 36 healthy, premenopausal women with primary dysmenorrhea, also referred to as menstrual cramps and pain. Prevalence rates of dysmenorrhea vary but range from 50% to 90%. Recent market research suggests that the global market for dysmenorrhea treatment was valued at \$13 billion in 2022 and is expected to increase to \$28.5 billion 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 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 \$2.00 price target.

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

October 20, 2023

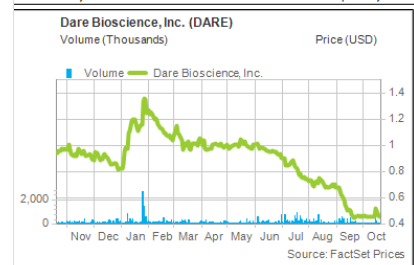
Jason Kolbert

Managing Director & Senior Analyst  
jkolbert@dawsonjames.com

Current Price \$0.46  
Price Target \$2.00



Stock Data		
52-Week Range	\$0.45 -	\$1.40
Shares Outstanding (mil.)	88.3	
Market Capitalization (mil.)	\$41	
Enterprise Value (mil.)	\$36	
Debt to Capital	0%	
Book Value/Share	\$2.20	
Price/Book	-	
Average Three Months Trading Volume (K)	993	
Insider Ownership	2.0%	
Institutional Ownership	7.3%	
Short Interest (mil.)	0.7%	
Dividend / Yield	\$0.00/0.0%	



**Exhibit 1. Income Statement**

DARE Income Statement (\$'000)																	
YE December	2018A	2019A	2020A	2021A	2022A	1Q23A	2Q23A	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											29,581	44,915	58,940	68,924	74,309	77,312	
<b>Total Product Sales</b>				-	-	-	-	-	-	-	158,805	432,489	716,522	996,238	1,308,191	1,612,516	1,931,833
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)											-	4,620	6,609	8,126	9,105	9,473	9,855
Sildenafil Cream Royalty Revenue (EU)												2,775	4,620	6,609	8,126	9,105	9,473
<b>Total royalties, collaborative revenue</b>				-	10,000	-	-	-	-	-	39,701	108,122	179,130	249,060	327,048	403,129	482,958
<b>Total Revenue Received by Dare</b>		-	-	-	10,000	-	-	-	-	-	39,701	108,122	179,130	249,060	327,048	403,129	482,958
<b>Expenses:</b>																	
Costs of Goods Sold				-		-	-	-	-	-	6,749	18,381	30,452	42,340	55,598	68,532	82,103
%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	2,921	3,215	2,894	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	6,044	8,202	12,279	31,544	34,699	34,005	33,325	32,658	31,352	30,098	29,496
License Expense	625	533	83	100	100	25	25	25	30	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>8,989</b>	<b>11,442</b>	<b>15,203</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>
Operating Income (Loss)	(16,882)	(14,345)	(27,402)	(39,069)	(31,385)	(8,382)	(8,989)	(11,442)	(15,203)	(44,017)	(8,712)	51,642	117,994	183,432	258,413	332,404	409,886
Other income (expense)	143	81	2	2	438	340	227	115	(222)	460	483	507	532	559	587	616	647
Trigger Down Dvd & Fx		(790)	(7)	2,520	(196)	(22)	(31)										
			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>(8,793)</b>	<b>(11,327)</b>	<b>(15,425)</b>	<b>(43,610)</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>											<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>(31,376)</b>	<b>(8,064)</b>	<b>(8,793)</b>	<b>(11,327)</b>	<b>(15,425)</b>	<b>(43,610)</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>(8,793)</b>	<b>(11,327)</b>	<b>(15,425)</b>	<b>(43,610)</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>(0.10)</b>	<b>(0.12)</b>	<b>(0.16)</b>	<b>(0.47)</b>	<b>(0.08)</b>	<b>0.50</b>	<b>1.09</b>	<b>1.62</b>	<b>2.19</b>	<b>2.71</b>	<b>3.21</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>(0.10)</b>	<b>(0.11)</b>	<b>(0.14)</b>	<b>(0.44)</b>	<b>(0.07)</b>	<b>0.45</b>	<b>0.99</b>	<b>1.47</b>	<b>1.99</b>	<b>2.46</b>	<b>2.91</b>
Wgtd Avg Shrs (Bas) - '000s	10,732	15,799	30,091	61,154	84,571	85,517	86,403	97,267	98,240	91,857	100,720	104,810	109,066	113,494	118,103	122,898	127,888
Wgtd Avg Shrs (Dil) - '000s	11,422	16,736	30,091	61,154	84,571	85,517	86,403	107,267	108,340	96,882	111,075	115,586	120,279	125,163	130,245	135,533	141,036

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.

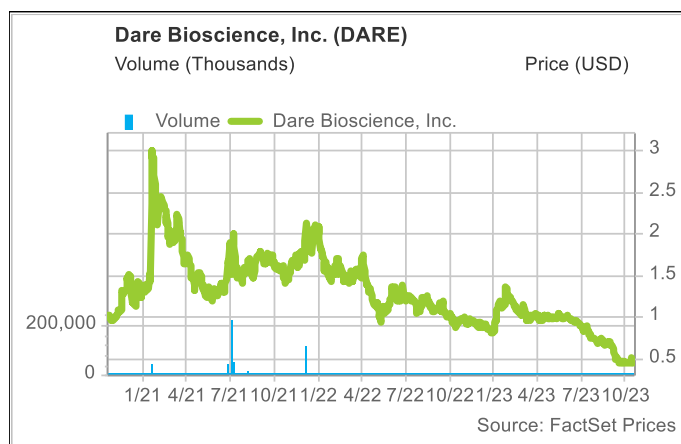
**Commercial risk.** There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

**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  
Update Report – Buy – 7/13/2023 - Price Target \$3.00  
Price Target Change – Buy – 8/30/2023 - Price Target changed from \$3.00 to \$2.00  
Update Report – Buy – 10/20/2023 – Price Target \$2.00

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- 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.

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Current as of 27-Sep-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	64.70%	3	8.80%
Market Perform (Neutral)	12	35.30%	3	8.80%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	6	17.60%

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