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Dare Bioscience (NASDAQ/DARE)

BUY: XACIATO (BV1) Approved!

December 8, 2021

Dare announced that the FDA has approved XACIATO (clindamycin phosphate vaginal gel, 2%, formerly known as DARE-BV1) for the treatment of bacterial vaginosis in females 12 years of age and older.

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Investment Highlights

BV1: A thermosetting bio-adhesive hydrogel formulated with clindamycin phosphate 2% as a first-line, single-administration treatment for bacterial vaginosis.

Market Opportunity? Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women in the United States. Several therapeutic options for women exist but have insufficient clinical cure rates, require sequential daily administrations or can be otherwise inconvenient for women to use. It is estimated that as many as 50% of women treated for bacterial vaginosis will experience a recurrence within 12 months of their treatment.

Our Model – We Assume a Partnership

	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total BV Population ('000)	21,000	21,630	22,279	22,947	23,636	24,345	25,075	25,827	26,602
15% unsatisfied/Target patient population ('000)	3990	4110	4233	4360	4491	4626	4764	4907	5054
Market share	3%	5%	7%	10%	11%	12%	12%	12%	12%
Patients treated	119,700	205,485	296,309	435,998	493,986	555,060	571,712	588,864	606,530
Price	\$202	\$204	\$206	\$208	\$210	\$212	\$214	\$217	\$219
Price Change	1%	1%	1%	1%	1%	1%	1%	1%	1%
Revenues ('000)	\$ 24,179	\$ 41,923	\$ 61,058	\$ 90,740	\$ 103,837	\$ 117,842	\$ 122,591	\$ 127,531	\$ 132,670
Probability of Success	100%	100%	100%	100%	100%	100%	100%	100%	100%
Adjusted Revenues (M)	\$ 24,179	\$ 41,923	\$ 61,058	\$ 90,740	\$ 103,837	\$ 117,842	\$ 122,591	\$ 127,531	\$ 132,670
Assume Royalty Model 25%	\$ 6,045	\$ 10,481	\$ 15,264	\$ 22,685	\$ 25,959	\$ 29,460	\$ 30,648	\$ 31,883	\$ 33,168
Revenue to Dare	\$ 6,045	\$ 10,481	\$ 15,264	\$ 22,685	\$ 25,959	\$ 29,460	\$ 30,648	\$ 31,883	\$ 33,168

Price Target- No change. We have eliminated our therapeutic risk rate in our BV model but otherwise our model and assumptions are unchanged. The effect on our valuation is de minimis.

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.

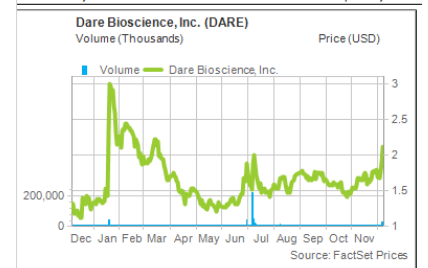
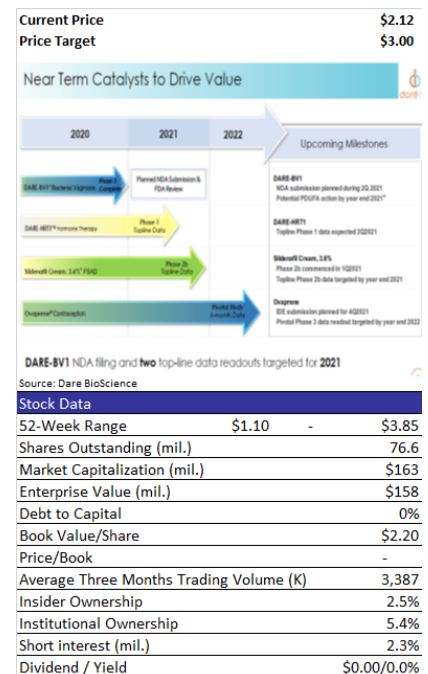


Exhibit 1. Income Statement

DARE: Income Statement (\$'000)																	
YE December	2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:																	
DARE-BV1				-	-	-	-	-	24,179	41,923	61,058	90,740	103,837	117,842	122,591	127,531	132,670
Opavrene										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
Total Product Sales				-	-	-	-	-	24,179	231,687	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)				-	-	-	-	-	6,045	10,481	15,264	22,685	25,959	29,460	30,648	31,883	33,168
Opavrene Royalty Revenue (US)										47,441	73,311	100,699	129,676	160,310	192,677	226,852	262,916
Opavrene 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	492,765
Total royalties, collaborative revenue				-	-	-	-	-	6,045	57,922	227,340	520,835	774,133	1,014,695	1,205,980	1,343,564	1,455,283
Total Revenue Received by Dare				-	-	-	-	-	6,045	57,922	227,340	520,835	774,133	1,014,695	1,205,980	1,343,564	1,455,283
Expenses:																	
Costs of Goods Sold				-	-	-	-	-	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	1,940	1,798	2,211	1,255	7,204	7,925	8,717	9,589	10,548	11,603	12,763	14,039	15,443	16,988
Research & Development	6,414	8,546	20,769	5,728	7,340	10,432	(654)	22,846	29,700	32,670	35,937	35,219	34,514	33,824	32,471	31,172	30,549
License Expense	625	533	83	25	25	25	10	85	89	94	98	103	108	114	120	126	132
Impairment of Goodwill	5,188																
Total Expenses	16,882	14,345	27,402	7,694	9,163	12,668	611	30,136	37,714	41,481	45,625	45,870	46,226	46,701	46,630	46,741	47,668
Operating Income (Loss)	(16,882)	(14,345)	(27,402)	(7,694)	(9,163)	(12,668)	(611)	(30,136)	(31,670)	16,442	42,950	105,209	166,467	231,242	297,806	367,955	441,220
Other income (expense)	143	81	2	3	(9)	2	6	2	2	2	2	2	2	2	2	2	2
Trigger Down Dvd		(790)	(7)	370				370									
				(7)				(7)									
Pretax Income	(16,739)	(15,054)	(27,408)	(7,330)	(9,172)	(12,667)	(605)	(29,774)	(31,668)	16,442	42,952	105,209	166,469	231,242	297,808	367,957	441,223
Income Taxes												15,781	33,294	69,373	98,277	136,144	163,252
Tax Rate											0%	15%	20%	30%	33%	37%	37%
GAAP Net Income (Loss)	(16,817)	(15,061)	(27,408)	(7,330)	(9,172)	(12,604)	(605)	(29,711)	(31,668)	16,442	42,952	105,209	166,469	231,242	297,808	367,957	441,223
Fx Translation	(79)		11			63											
GAAP Total Comprehensive Income (Loss)	-	(15,061)	(27,397)	(7,330)	(9,172)	(12,667)	(605)	(29,711)	(31,668)	16,442	42,952	105,209	166,469	231,242	297,808	367,957	441,223
GAAP-EPS	(1.57)	(0.97)	(0.91)	(0.16)	(0.18)	(0.18)	(0.01)	(0.53)	(0.43)	0.22	0.54	1.27	1.94	2.58	3.20	3.80	4.38
Fully Diluted EPS	(1.69)	(0.90)	(0.91)	(0.16)	(0.18)	(0.18)	(0.01)	(0.53)	(0.43)	0.22	0.54	1.27	1.94	2.58	3.20	3.80	4.38
Wgtd Avg Shrs (Bas) - '000s	10,732	15,799	30,091	44,503	50,437	70,775	71,483	59,299	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	44,503	50,437	70,775	71,483	59,299	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 Dare 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. Dare 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.

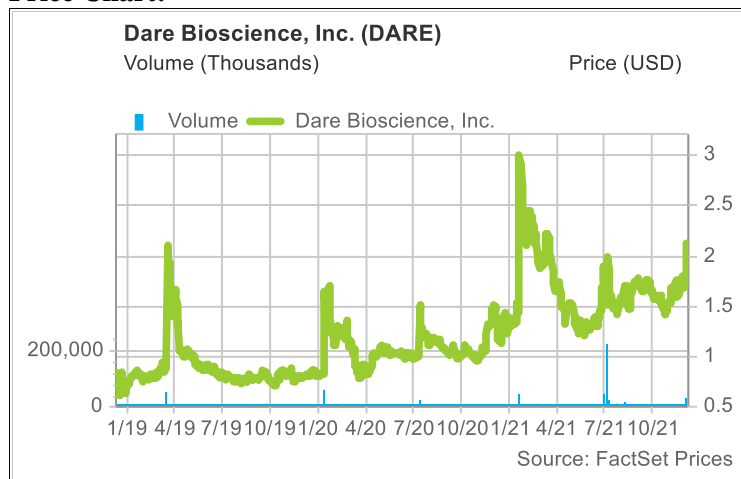
Commercial risk. There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

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

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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... 1-Dec-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	67%	5	21%
Market Perform (Neutral)	12	33%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	5	14%

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