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## Dare Bioscience (NASDAQ/DARE)

### BUY: December PDUFA Set for BV-1

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Dare announced that the FDA has accepted for filing the company's New Drug Application (NDA) for DARE-BV1 for the treatment of bacterial vaginosis. The FDA granted this application Priority Review and set a Prescription Drug User Fee Act (PDUFA) date of December 7, 2021 for the target completion of its review of the NDA.

### Investment Highlights

**BV1 "One & Done."** DARE-BV1 is in development for bacterial vaginosis (BV). Differentiating characteristics include a gel technology (w/Clindamycin) that allows for local delivery and a one-time application. The pivotal trial delivered a high cure rate, at 76% just 7-14 days after a single administration; the product appears superior to the standard of care treatments that average 50%.

The NDA is supported by positive results from the DARE-BVFREE Phase 3 randomized, multi-center, double-blinded, placebo-controlled clinical trial evaluating DARE-BV1 in women diagnosed with bacterial vaginosis. The results from the study demonstrated DARE-BV1's potential to provide improved clinical cure rates in a convenient, one-time dose compared to those of currently branded FDA-approved products indicated for the treatment of bacterial vaginosis.

Patients in the study were evaluated during three clinic visits: Day 1 (screening and randomization visit), Day 7-14 (assessment visit), and Day 21-30 (test-of-cure visit). The study met its primary endpoint, demonstrating that as a primary therapeutic intervention, a single vaginal dose of DARE-BV1 was statistically superior to placebo at Day 21-30 in the modified intent-to-treat population (70% compared to 36% of subjects clinically cured). Additionally, DARE-BV1 demonstrated clinical cure rates of 77% at Day 21-30 and 81% at Day 7-14 in the per protocol population, compared to 43% and 30% for placebo cream, respectively. Current FDA-approved products have clinical cure rates in the range of only 37-68%.

**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.

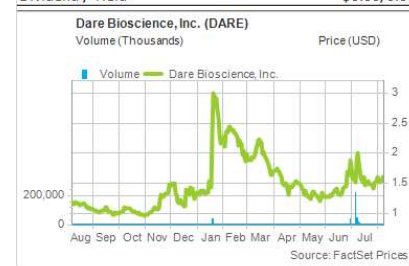
**Risks to our thesis include:** (1) commercial; (2) clinical and regulatory; (3) partnership; (4) financial; and (5) legal and intellectual property.

 Current Price \$1.75  
 Price Target \$3.00

DARE-BV1: Potential for Improved Clinical Cure Rates vs. Current Branded Rx				
Product	Frequency, Dose, and Route of Administration	Study Description	Clinical Cure Rates	
DARE-BV1 (Clindamycin gel)	1 dose, 1x application, applied vaginally	Phase 3 randomized, double-blind, placebo-controlled trial	76% (per protocol)	
Clindamycin cream	1 dose, 1x application, applied vaginally	Phase 3 randomized, double-blind, placebo-controlled trial	43% (per protocol)	
Clindamycin tablets	1 dose, 1x application, applied orally	Phase 3 randomized, double-blind, placebo-controlled trial	30% (per protocol)	
Metronidazole gel	1 dose, 1x application, applied vaginally	Phase 3 randomized, double-blind, placebo-controlled trial	43% (per protocol)	
Metronidazole tablets	1 dose, 1x application, applied orally	Phase 3 randomized, double-blind, placebo-controlled trial	30% (per protocol)	

Source: Dare Bioscience

Stock Data			
52-Week Range	\$0.94	-\$	\$3.85
Shares Outstanding (mil.)	49.4		
Market Capitalization (mil.)	\$86		
Enterprise Value (mil.)	\$82		
Debt to Capital	0%		
Book Value/Share	\$2.20		
Price/Book	-		
Average Three Months Trading Volume (K)	691		
Insider Ownership	6.4%		
Institutional Ownership	6.7%		
Short interest (mil.)	10.6%		
Dividend / Yield	\$0.00/0.0%		



**Exhibit 1. Income Statement**

DARE: Income Statement (\$000)																					
12-Month Period Ending	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20A	2020A	1Q21A	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:																					
DARE-BV1								-	-	-	-	-	13,737	23,817	34,688	51,551	58,991	66,947	69,645	72,452	75,372
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	2,947,017	3,446,180	3,715,473	3,865,579	
Total Product Sales								-	-	-	-	-	13,737	213,581	882,989	2,044,151	3,051,688	4,007,888	4,770,977	5,319,177	5,763,834
DARE-BV1 Royalty Revenue (US)									-	-	-	-	3,434	5,954	8,672	12,888	14,748	16,737	17,411	18,113	18,843
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	
Total royalties, collaborative revenue								-	-	-	-	-	3,434	53,395	220,747	511,038	762,922	1,001,972	1,192,744	1,329,794	1,440,959
Total Revenue Received by Dare		-	-	-	-	-	-	-	-	-	-	-	3,434	53,395	220,747	511,038	762,922	1,001,972	1,192,744	1,329,794	1,440,959
Expenses:																					
Costs of Goods Sold								-	-	-	-	-	584	9,077	37,527	86,876	129,697	170,335	202,767	226,065	244,963
%COGS		17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%
General & Administrative	4,656	5,266	1,862	1,558	1,353	1,777	6,550	1,940	1,657	1,873	1,734	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	2,380	5,547	6,204	6,638	20,769	5,728	5,255	5,940	5,923	22,846	29,700	32,670	35,937	35,219	34,514	33,824	32,471	31,172	30,549
License Expense	625	533	13	21	25	25	83	25	22	20	17	85	89	94	98	103	108	114	120	126	132
Impairment of Goodwill	5,188																				
Total Expenses	16,882	14,345	4,254	7,126	7,582	8,441	27,402	7,694	6,934	7,834	7,675	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)	(4,254)	(7,126)	(7,582)	(8,441)	(27,402)	(7,694)	(6,934)	(7,834)	(7,675)	(30,136)	(34,280)	11,914	36,358	95,409	155,255	218,517	284,569	354,185	426,896
Other income (expense)	143	81	2	2	(1)	(1)	2	3	0	0	(2)	2	2	2	2	2	2	2	2	2	2
Trigger Down Dvd		(790)				(7)	(7)	370				370									
						(7)	(7)	(7)				(7)									
Pre-tax Income	(16,739)	(15,054)	(4,252)	(7,124)	(7,580)	(8,441)	(27,408)	(7,330)	(6,933)	(7,833)	(7,677)	(29,774)	(34,279)	11,916	36,359	95,411	155,257	218,519	284,571	354,187	426,898
Income Taxes																14,312	31,051	65,556	93,909	131,049	157,952
Tax Rate															0%	15%	20%	30%	33%	37%	37%
GAAP Net Income (Loss)	(16,817)	(15,061)	(4,274)	(7,124)	(7,589)	(8,420)	(27,408)	(7,330)	(6,933)	(7,833)	(7,677)	(29,774)	(34,279)	11,916	36,359	95,411	155,257	218,519	284,571	354,187	426,898
Fx Translation	(79)		(22)	12		21	11														
GAAP Total Comprehensive Income (Loss)	-	(15,061)	(4,296)	(7,112)	(7,589)	(8,399)	(27,397)	(7,330)	(6,933)	(7,833)	(7,677)	(29,774)	(34,279)	11,916	36,359	95,411	155,257	218,519	284,571	354,187	426,898
GAAP EPS	(1.57)	(0.97)	(0.18)	(0.27)	(0.24)	(0.22)	(0.91)	(0.16)	(0.15)	(0.17)	(0.17)	(0.66)	(0.73)	0.24	0.71	1.80	2.82	3.81	4.77	5.70	6.60
Fully Diluted EPS	(1.69)	(0.90)	(0.18)	(0.27)	(0.24)	(0.22)	(0.91)	(0.16)	(0.15)	(0.17)	(0.17)	(0.66)	(0.73)	0.24	0.71	1.80	2.82	3.81	4.77	5.70	6.60
Wtd Avg Shrs (Bas) - '000s	10,732	15,799	23,799	26,711	31,588	38,518	30,091	44,503	44,948	45,397	45,851	45,175	47,009	48,918	50,904	52,971	55,122	57,360	59,689	62,112	64,634
Wtd Avg Shrs (Dil) - '000s	11,422	16,736	23,799	26,711	31,588	38,518	30,091	44,503	44,948	45,397	45,851	45,175	47,009	48,918	50,904	52,971	55,122	57,360	59,689	62,112	64,634

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.

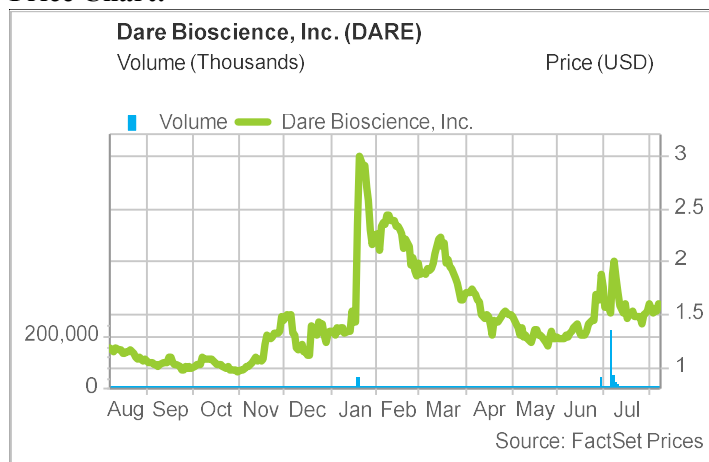
**Commercial risk.** There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

**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

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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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	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	<b># of Companies</b>	<b>% of Total</b>	<b># of Companies</b>	<b>% of Totals</b>
Market Outperform (Buy)	25	71%	4	16%
Market Perform (Neutral)	10	29%	0	0%
Market Underperform (Sell)	0	0%	0	0%
<b>Total</b>	<b>35</b>	<b>100%</b>	<b>4</b>	<b>11%</b>

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