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Daré Bioscience (NASDAQ/DARE)

BUY: Reports Full Year (2022) Results

April 13, 2023

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Daré Bioscience reported full-year 2022 results. The company spent \$31M last year and closed the period with \$34.6M in cash and equivalents. From the company's press release: "During 2022, we received \$24.1 million in non-dilutive funding, which included a \$10.0 million cash payment upon the license agreement with Organon for XACIATO becoming effective, \$13.3 million received under grants".

Investment Highlights (adapted from the press release):

XACIATO: Bacterial Vaginosis

- 3Q-2022: \$10.0 million cash payment received under license agreement with Organon to commercialize XACIATO
- 4Q-2022: Organon market access team began meeting with customers and preparing for a U.S. launch
- 2Q-2023: First commercial sale expected, triggering a \$2.5 million milestone to Daré

Ovaprene: A hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer HealthCare.

- 4Q-2022: FDA approved an Investigational Device Exemption (IDE) application for a single arm, open-label pivotal contraceptive efficacy study over 12-months (13 menstrual cycles) and provided additional study design considerations
- 4Q-2022: Investigator meeting held (with the NICHD) for the pivotal Phase 3 clinical study
- Mid-2023: Anticipated initiation of subject recruitment for the pivotal Phase 3 clinical study

Sildenafil Cream, 3.6%: A proprietary, investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical administration to treat female sexual arousal disorder.

- 4Q-2022: Completed subject screening for exploratory Phase 2b RESPOND clinical study
- 2Q-2023: Topline data announcement targeted for Phase 2b RESPOND clinical study

DARE-HRT1: A unique, investigational intravaginal ring (IVR) designed to deliver bio-identical estradiol and progesterone continuously over a 28-day period for the treatment of menopausal symptoms, including moderate to severe vasomotor symptoms, as part of a menopausal hormone therapy regimen.

- 4Q-2022: Positive topline efficacy data reported from Phase 1/2 clinical study
- 1Q-2023: Positive topline PK data reported from Phase 1/2 clinical study, and anticipated plans to progress to a single Phase 3 study announced.

DARE-VVA1: A proprietary, investigational formulation of tamoxifen for intravaginal administration to treat vulvar and vaginal atrophy in women without the use of hormones.

- 3Q-2021: Phase 1/2 clinical study initiated in Australia
- 4Q-2022: Positive topline safety, tolerability, PK and pharmacodynamics data reported from Phase 1/2 clinical study

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.

Current Price \$0.97
Price Target \$3.00

Daré Bioscience: Women's Health is our Sole Focus

Addressing Compelling Markets Where Innovation Matters

- Meaningful market potential for differentiated products. First line of first-in-category product opportunities across the portfolio.
- Diverse pipeline with independent outcomes. One FDA-approved product and several critical development stage candidates utilizing different APIs and targeting different indications.
- Highly differentiated pathways planned for most candidates. Use of well-characterized APIs expected to mitigate development risk, time, and cost - non-molecular entities estimated to have a 30% probability of success of advancing from Phase 1 to approval and a 60% likelihood of approval. Phase 3 approval, success the end goal for new molecular entities, respectively.
- Multiple novel delivery platforms. Persistent unmet needs require creative new approaches designed for her. Novel delivery platforms allow for first-in-category potential with well-characterized APIs.
- Commercial value in women's health evidenced by differentiated brands and recent transformational plasma transactions.

Source: Daré Bioscience

Stock Data		
52-Week Range	\$0.82 -	\$1.47
Shares Outstanding (mil.)	86.2	
Market Capitalization (mil.)	\$84	
Enterprise Value (mil.)	\$79	
Debt to Capital	0%	
Book Value/Share	\$2.20	
Price/Book	-	
Average Three Months Trading Volume (K)	257	
Insider Ownership	2.0%	
Institutional Ownership	8.2%	
Short interest (mil.)	0.6%	
Dividend / Yield	\$0.00/0.0%	

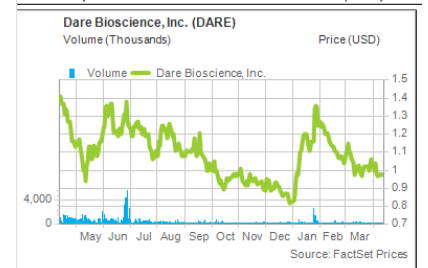


Exhibit 1. Income Statement

DARE: Income Statement (\$'000)																	
: YE December	2018A	2019A	2020A	2021A	1Q22A	2Q22A	3Q22A	4Q22A	2022A	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:																	
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
Total Product Sales											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
Total royalties, collaborative revenue						10,000			10,000		39,701	470,485	729,343	971,079	1,171,362	1,313,420	1,430,025
Total Revenue Received by Dare						10,000			10,000		39,701	470,485	729,343	971,079	1,171,362	1,313,420	1,430,025
Expenses:																	
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	2,570	2,793	2,652	3,229	11,243	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	5,805	6,798	4,462	12,977	30,042	31,544	34,699	34,005	33,325	32,658	31,352	30,098	29,496
License Expense	625	533	83	100	24	25	24	25	100	105	110	116	122	128	134	141	148
Impairment of Goodwill	5,188																
Total Expenses	16,882	14,345	27,402	39,069	8,399	9,616	7,138	16,232	41,385	44,017	48,413	49,085	49,907	50,893	51,404	52,148	53,744
Operating Income (Loss)	(16,882)	(14,345)	(27,402)	(39,069)	(8,399)	384	(7,138)	(16,232)	(31,385)	(44,017)	(8,712)	51,642	117,994	183,432	258,413	332,404	409,886
Other income (expense)	143	81	2	2	2	30	119	287	438	460	483	507	532	559	587	616	647
Trigger Down Dvd & Fx		(790)	(7)	2,520		(136)		(60)	(196)								
Pretax Income	(16,739)	(15,054)	(27,408)	(38,696)	(8,398)	278	(7,019)	(16,006)	(31,144)	(43,557)	(8,229)	52,149	118,527	183,990	259,000	333,020	410,533
Income Taxes												7,822	23,705	55,197	85,470	123,217	151,897
Tax Rate											0%	15%	20%	30%	33%	37%	37%
GAAP Net Income (Loss)	(16,817)	(15,061)	(27,408)	(38,645)	(8,399)	278	(7,250)	(16,006)	(31,376)	(43,557)	(8,229)	52,149	118,527	183,990	259,000	333,020	410,533
Fx Translation	(79)		11	64	(9)		(231)										
GAAP Total Comprehensive Income (Loss)	-	(15,061)	(27,397)	(38,759)	(8,408)	278	(7,250)	(16,006)	(31,376)	(43,557)	(8,229)	52,149	118,527	183,990	259,000	333,020	410,533
GAAP-EPS	(1.57)	(0.97)	(0.91)	(0.63)	(0.10)	0.00	(0.08)	(0.19)	(0.37)	(0.50)	(0.09)	0.55	1.20	1.79	2.42	2.98	3.54
Fully Diluted EPS	(1.69)	(0.90)	(0.91)	(0.63)	(0.10)	0.00	(0.08)	(0.19)	(0.37)	(0.50)	(0.09)	0.55	1.20	1.79	2.42	2.98	3.54
Wgtd Avg Shrs (Bas) - '000s	10,732	15,799	30,091	61,154	83,944	84,683	84,823	85,671	84,571	87,834	91,400	95,112	98,974	102,992	107,174	111,526	116,054
Wgtd Avg Shrs (Dil) - '000s	11,422	16,736	30,091	61,154	83,944	84,683	84,823	85,671	84,571	87,834	91,400	95,112	98,974	102,992	107,174	111,526	116,054

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.

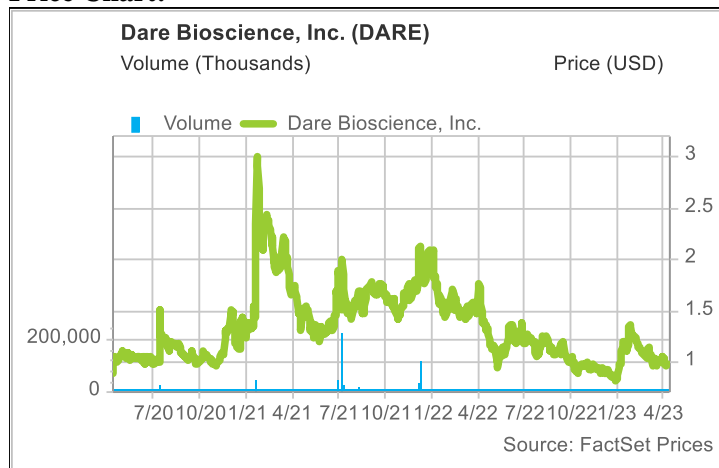
Commercial risk. There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

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

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Rating Definitions:

- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return 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.

The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 17-Mar-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	1	3%
Market Perform (Neutral)	11	31%	2	6%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	3	9%

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