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Daré Bioscience (NASDAQ/DARE)

BUY: Female Viagra – FSAD Trial Data Provides a Signal

Daré Bioscience announced additional positive data from the exploratory Phase 2B RESPOND study evaluating topical Sildenafil Cream, 3.6% (Sildenafil Cream) as a treatment for female sexual arousal disorder (FSAD). The data reported supports the continued clinical development of Sildenafil Cream.

Investment Highlights:

FSAD Data: The exploratory endpoint for sexual desire demonstrated a statistically significant improvement from baseline to the 8-week mark after randomization in women in the intent to treat (ITT) population who used Sildenafil Cream compared to placebo, at P value = 0.022. The improvement in sexual desire at the 8-week mark compared to baseline in the Sildenafil Cream ITT group persisted through 12 weeks post-randomization (end of study). Based on data from the exploratory Phase 2B RESPOND study, demonstrating improvement in multiple facets of female sexual dysfunction, and because there is no FDA-approved product for FSAD, as described in the fourth edition of the Diagnostic and Statistical Manual (DSM-IV), or for FSIAD, as described in the fifth edition of the Diagnostic and Statistical Manual (DSM-5), Sildenafil Cream has the potential to be a first-in-category product.

What is it? Female sexual arousal disorder (FSAD) is the inability to reach or maintain a sufficient physical response to sexual stimulation. Market research suggests that 16% of women ages 21 to 60, or approximately 10 million women in the U.S., are distressed from experiencing symptoms associated with FSAD, including low or no sexual arousal, and are seeking a solution to improve their condition. To put the market opportunity for an FDA-approved FSAD treatment in context, the prevalence of complete erectile dysfunction (ED) in men is estimated to be about 5% of men at age 40, increasing to about 15% at age 70.

Female Viagra? Sildenafil Cream, 3.6% is an investigational proprietary topical formulation of sildenafil being developed as a first-in-category option for women for the treatment of FSAD. Unlike the oral formulations of PDE-5 inhibitors, Sildenafil Cream is applied locally to the vaginal tissue and is designed to facilitate vasodilation and increased blood flow directly to the genital tissue to improve the physical arousal response symptoms commonly associated with FSAD while avoiding systemic side effects observed with oral formulations of sildenafil.

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 \$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.

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| | |
|---------------|--------|
| Current Price | \$0.89 |
| Price Target | \$3.00 |



| Stock Data | | |
|---|-------------|--------|
| 52-Week Range | \$0.82 | \$1.40 |
| Shares Outstanding (mil.) | 86.3 | |
| Market Capitalization (mil.) | \$76 | |
| Enterprise Value (mil.) | \$72 | |
| Debt to Capital | 0% | |
| Book Value/Share | \$2.20 | |
| Price/Book | - | |
| Average Three Months Trading Volume (K) | 245 | |
| Insider Ownership | 2.0% | |
| Institutional Ownership | 7.9% | |
| Short interest (mil.) | 0.6% | |
| Dividend / Yield | \$0.00/0.0% | |

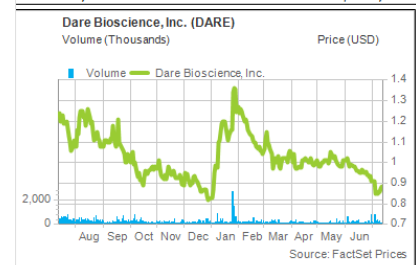


Exhibit 1. Income Statement

| DARE Income Statement (\$'000) | | | | | | | | | | | | | | | | | |
|---|-----------------|-----------------|-----------------|-----------------|-----------------|----------------|-----------------|-----------------|-----------------|-----------------|----------------|---------------|----------------|----------------|----------------|----------------|----------------|
| YE December | 2018A | 2019A | 2020A | 2021A | 2022A | 1Q23A | 2Q23E | 3Q23E | 4Q23E | 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 | | | | | | | | | | | - | 29,581 | 44,915 | 58,940 | 68,924 | 74,309 | 77,312 |
| Total Product Sales | | | | - | - | - | - | - | - | - | 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 |
| Total royalties, collaborative revenue | | | | - | 10,000 | - | - | - | - | - | 39,701 | 108,122 | 179,130 | 249,060 | 327,048 | 403,129 | 482,958 |
| Total Revenue Received by Dare | | - | - | - | 10,000 | - | - | - | - | - | 39,701 | 108,122 | 179,130 | 249,060 | 327,048 | 403,129 | 482,958 |
| Expenses: | | | | | | | | | | | | | | | | | |
| 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 | 2,844 | 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 | | | | | | | | | | | | | | | | |
| Total Expenses | 16,882 | 14,345 | 27,402 | 39,069 | 41,385 | 8,382 | 10,127 | 11,442 | 14,065 | 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) | (31,385) | (8,382) | (10,127) | (11,442) | (14,065) | (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 | 124 | 115 | (119) | 460 | 483 | 507 | 532 | 559 | 587 | 616 | 647 |
| Trigger Down Dvd & Fx | | (790) | (7) | 2,520 | (196) | (22) | | | | | | | | | | | |
| Pretax Income | (16,739) | (15,054) | (27,408) | (38,696) | (31,144) | (8,064) | (10,003) | (11,327) | (14,185) | (43,579) | (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) | (31,376) | (8,064) | (10,003) | (11,327) | (14,185) | (43,579) | (8,229) | 52,149 | 118,527 | 183,990 | 259,000 | 333,020 | 410,533 |
| Fx Translation | (79) | | 11 | 64 | | | | | | | | | | | | | |
| GAAP Total Comprehensive Income (Loss) | - | (15,061) | (27,397) | (38,759) | (31,376) | (8,064) | (10,003) | (11,327) | (14,185) | (43,579) | (8,229) | 52,149 | 118,527 | 183,990 | 259,000 | 333,020 | 410,533 |
| GAAP-EPS | (1.57) | (0.97) | (0.91) | (0.63) | (0.37) | (0.09) | (0.12) | (0.13) | (0.16) | (0.50) | (0.09) | 0.55 | 1.21 | 1.81 | 2.44 | 3.02 | 3.58 |
| Fully Diluted EPS | (1.69) | (0.90) | (0.91) | (0.63) | (0.37) | (0.09) | (0.12) | (0.13) | (0.16) | (0.50) | (0.09) | 0.55 | 1.21 | 1.81 | 2.44 | 3.02 | 3.58 |
| 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.

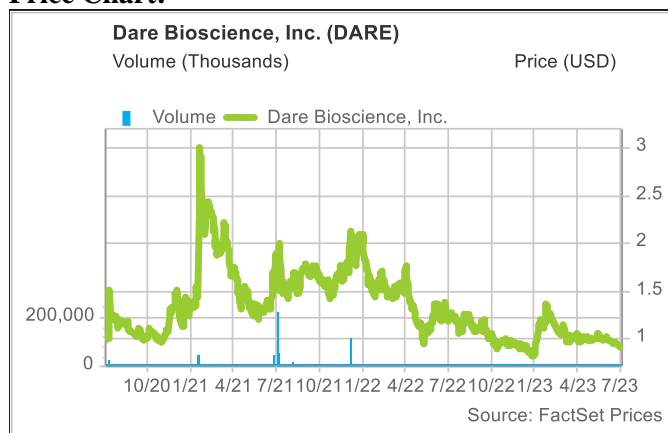
Commercial risk. There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

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
Update Report – Buy – 7/13/2023 - 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 22-Jun-23

| | Company Coverage | | Investment Banking | |
|-----------------------------|-------------------------|-------------|---------------------------|---------------|
| Ratings Distribution | # 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% |
| Total | 36 | 100% | 4 | 11.00% |

Analyst Certification:

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