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Miravo Healthcare (TSX:MRV; C\$0.96)

Another Shoe Drops Unexpectedly – Reversal Possible, but More Likely Not.

Yesterday, Miravo announced that Apotex (private) received FDA approval for its generic version of Pennsaid 2%. Sales of the product in the U.S. account for about 13% of Miravo’s annual revenues (approximately C\$9.0M) and approximately \$4.3M of EBITDA.

The approval is unusual because Teva (NYSE:TEVA; unrated) was first to file an ANDA for the product; a launch date in October 2027 had been negotiated; and FDA would not typically grant full approval of another ANDA until 180 days after the Teva launch.

As such, FDA may have made a mistake, which could result in reversal of the Apotex approval. However, we find it hard to believe the Agency would fumble with such simple and clear rules, so we think there may have been a reason.

Miravo’s U.S. partner, Horizon Therapeutics (NASDAQ:HZNP; unrated), is likely to challenge the Apotex approval as Pennsaid 2% still contributes materially to revenues (US\$35.4M in 1Q-2022), although it is in decline (-23% Y/Y).

We are taking the conservative approach and removing U.S. Pennsaid 2% sales from our model starting in 2Q-2022 (changes shown in accompanying table, middle right).

The effect on our valuation goes beyond the revenue (-\$4.5M [-6.0%]; -\$9.0M [-11.8%]) and adjusted EBITDA (-\$2.2M [-9.0%]; -\$4.4M [-18.2%]) impacts in 2022 and 2023. Cash flows from U.S. Pennsaid 2% sales between 2024 and 2027 carried more weight after expected loss of exclusivity of Blexten in October 2024 and expiry of the Cambia patent in mid-2026. Pennsaid 2% U.S. sales also largely supported operation of the company’s manufacturing business, accounting for approximately 75% of \$12.1M revenues generated by the Production and Service division.

We believe the news may also serve as a distraction and financial barrier as management endeavors to in-license and/or acquire new products.

Taken together, the removal of U.S. Pennsaid 2% from our base case model has the impact of reducing our DCF-based target price (20% rate) to C\$1.00 (was \$2.60). Rating becomes HOLD (Speculative risk).

If Miravo/Horizon prevail on this issue, we would revisit our previous target and rating. We also note that if a 10% discount rate is used in our current Miravo model, the DCF value would be C\$3.60 per share, even with near term loss of U.S. sales of Pennsaid 2% in the base forecast.

We continue to use a 20% discount rate due to Miravo’s high debt load and patent/exclusivity terminations for Blexten and Cambia in the current decade. We had anticipated lowering the discount rate over time as the company deleveraged – this will be more challenging now if Pennsaid 2% faces a near-term generic competitor.

We also note that equity valuation swings with MRV stock can be extreme due to the tiny proportion of enterprise value contributed by equity value (C\$11.0M) vs net debt (C\$84.9M at December 31).

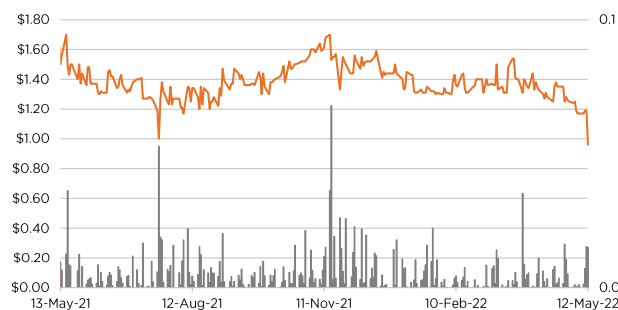
| | |
|------------------------|---------------------|
| Rating: | HOLD (was BUY) |
| Risk: | Speculative |
| 12 Month Price Target: | \$1.00 (was \$2.60) |

| | |
|------------------------|---------------|
| Price | \$0.96 |
| Implied Return | 4.2% |
| Fiscal Year End | 31-Dec |
| 52 Week Range | \$0.95-\$1.75 |
| Shares Outstanding (M) | 11.4 |
| Market Cap. (M) | \$10.9 |
| Net debt (M) | \$84.9 |
| Avg. Daily Volume (M) | 0.004 |

| (C\$M, except EPS) | 2020A | 2021A | 2022E* | 2023E |
|--------------------|----------|----------|--------|--------|
| Revenues | \$73.8 | \$68.9 | \$70.7 | \$67.1 |
| Revenues (adj.) | \$71.0 | \$69.4 | \$71.1 | \$67.4 |
| <i>Previous</i> | nc | nc | \$75.6 | \$76.4 |
| EBITDA (adj.) | \$28.4 | \$22.2 | \$21.7 | \$19.7 |
| <i>Previous</i> | nc | nc | \$23.8 | \$24.1 |
| EPS (f.d.) | (\$0.36) | (\$2.83) | \$0.37 | \$0.24 |
| EV/EBITDA (adj.) | 3.4 | 4.3 | 4.4 | 4.9 |

*includes expected US\$2M milestone from Takeda

| 2022E | 1Q | 2Q | 3Q | 4Q |
|-----------------|--------|--------|--------|--------|
| Revenues | \$14.7 | \$21.6 | \$17.3 | \$17.1 |
| Revenues (adj.) | \$14.8 | \$21.7 | \$17.4 | \$17.2 |
| EBITDA (adj.) | \$4.7 | \$6.8 | \$5.1 | \$5.0 |



This report is priced as of recent trading. All values in C\$ unless otherwise noted.

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|---------------------------|--|
| Buy | Expected to materially outperform the sector average over the next 12 months. |
| Accumulate | Expected to outperform the sector average over the next 12 months or longer. |
| Hold | Expected to perform similar to the sector average over the next 12 months. |
| Sell | Expected to materially underperform the sector average over the next 12 months |

Risk Rankings

Average – Volatility and risk expected to be comparable to the broader market; revenue and earnings have predictability; no significant cash flow and/or financing concerns over next 12 months Expected to outperform the sector average over the next 12 months or longer.

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Speculative – High volatility and risk expected; potential for balance sheet concerns, low public float. Stock may be suitable for only a small subset of equity investors willing to take on the risks of a high risk investment of equity investors.

Distribution of Ratings as of May 2022

| Rating | Number | Percentage |
|--------------|-----------|-------------|
| Buy | 17 | 71% |
| Accumulate | 4 | 17% |
| Hold | 2 | 8% |
| Sell | 1 | 4% |
| Total | 24 | 100% |