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Zacks Small-Cap Research

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MIRA Pharmaceuticals (MIRA-NASDAQ)

MIRA: IND Application Submitted to FDA

MIRA is creating a THC analog that has the same benefits as THC without the negative side effects. We value MIRA at $17.75 using discounted cash flow analysis and a 20% discount rate.

Current Price (12/18/24)	$1.05
Valuation	**$17.75**

OUTLOOK

MIRA Pharmaceuticals is a preclinical-stage pharmaceutical company focused on the development and commercialization of new molecular synthetic cannabinoid analog for the treatment of adult patients with neuropathic pain as well as anxiety and cognitive decline typically associated with early-stage dementia.

The company announced that it has submitted an IND with the FDA for Ketamir-2—a major step forward and setting up for Phase 1 trials.

SUMMARY DATA

52-Week High	**$5.01**
52-Week Low	**$0.54**
One-Year Return (%)	**0.96**
Beta	**1.93**
Average Daily Volume (sh)	**449,557**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**35**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**

Risk Level	**High**
Type of Stock	**Small Growth**
Industry	**Biotech**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 A	0 E	0 E	0 E
2025	0 E	0 E	0 E	0 E	0 E

Earnings per share*

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	N/A	N/A	N/A	N/A	(0.48) A
2023	(0.09) A	(0.10) A	(0.26) A	(0.37) A	(0.64) A
2024	(0.12) A	(0.11) A	(0.14) A	(0.29) E	(0.66) E
2025	(0.15) E	(0.10) E	(0.16) E	(0.13) E	(0.54) E

*numbers may not add to yearly total due to share issuance.

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Update

MIRA Pharmaceuticals is a preclinical-stage pharmaceutical company that is about to be a clinical-stage company focused on the development and commercialization of a new molecular synthetic cannabinoid analog for the treatment of adult patients with neuropathic pain as well as anxiety and cognitive decline typically associated with early-stage dementia. The company also acquired the rights to Ketamir, which, in layman's terms, is a potential derivative of the antidepressant ketamine that has shown indications of having fewer side effects, working more rapidly, and having the opportunity to impact millions of patients that have not responded to other, existing treatments. We have written about the exciting preclinical results for Ketamir-2, the company's novel oral ketamine analog, and the company just released further study results that, in our view, boost the potential for the treatment.

Ketamir-2 took a major step forward with the company announcing that it has submitted an Investigational New Drug (IND) for the treatment of neuropathic pain. With this advancement, the company plans to initiate Phase 1 trials in 1Q 2025, and we look forward to seeing the results.

As previously discussed, Ketamir-2 is under investigation for its potential in treating neurological and neuropsychiatric disorders, including depression, treatment-resistant depression (TRD), and post-traumatic stress disorder (PTSD). We were pleased to see the company's announcement several weeks ago to focus its attention on neuropathic pain to begin with, which we believe will allow for a quicker and more efficient approval process.

Supporting that belief is the announcement by MIRA that a preclinical study, which was conducted using a nerve ligation-induced neuropathy model in female rats, showed that low doses of Ketamir-2 provided "significant pain relief" by day 15. Even more encouraging for the potential approval and commercialization of the drug was the announcement that by day 22 of the study, Ketamir-2 provided up to 112% and 70% greater relief than two leading neuropathic pain relief drugs—Pregabalin and Gabapentin, respectively. Sales of these two approved treatments are expected, according to research cited by the company, to reach a combined $7 billion in annual sales by 2033.

As a reminder, the existing treatments also have side effects such as drowsiness, dizziness, cognitive impairment, and weight gain, along with the potential for misuse and withdrawal upon discontinuation. In previous tests, Ketamir-2 has shown none of these side effects and is a non-opioid and has no known risk of dependence.

We remain extremely positive on MIRA, and this announcement is yet further confirmation that the potential for MIRA's treatments is large and growing. The company has two potential groundbreaking therapies and is rightly focusing on the one with the potential to get to market the fastest—Ketamir-2, but also continuing to advance MIRA-55, which we have written extensively about, in the background. We urge investors to look at MIRA and suggest those with a modestly higher risk tolerance consider investing before MIRA announces more positive results or collaborations the stock really starts to move higher.

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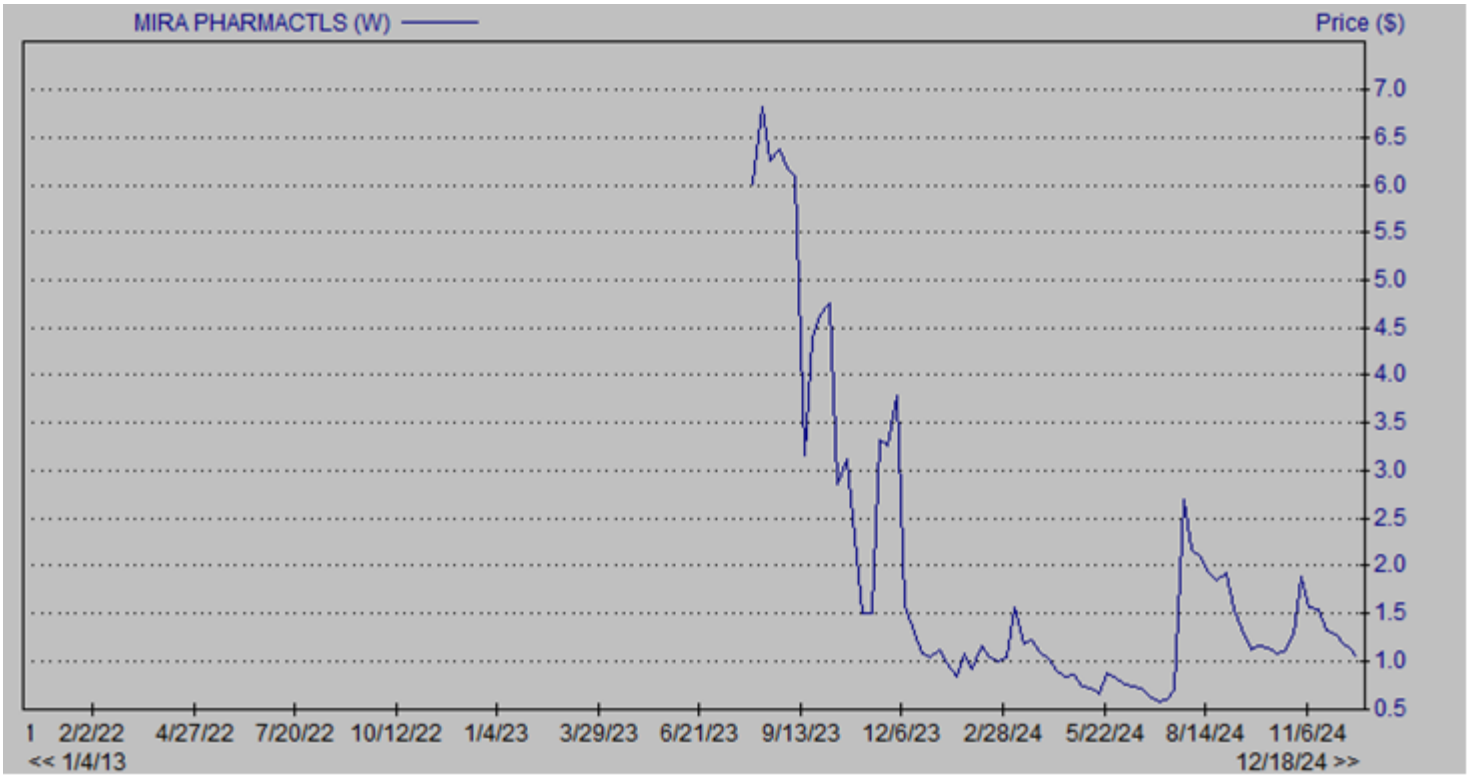
INCOME STATEMENT AND BALANCE SHEET

MIRA Pharmaceuticals Income Statement and Balance Sheet							
	2023A	1Q2024A	2Q2024A	3Q2024A	4Q2024E	2025E	2026E
Revenue	0	0	0	0	0	0	0
Operating Costs:							
General and Admin.	6,499,537	1,005,911	1,116,260	1,014,223	3,363,143	6,824,514	6,824,515
Travel Costs	453,550	0	0	0	0	0	0
Research and Dev.	1,572,962	762,276	614,462	1,067,396	1,088,744	1,651,610	1,734,191
Total Operating Costs	8,526,049	1,768,187	1,730,722	2,081,619	4,451,887	8,476,124	8,558,706
Interest Income/(Expense)	(3,456,294)	(50,416)	39,397	37,752	0	0	0
Net Gain/(Loss)	(11,982,343)	(1,818,603)	(1,691,325)	(2,043,867)	(4,451,887)	(8,476,124)	(8,558,706)
Basic and diluted loss per share	(0.64)	(0.12)	(0.11)	(0.14)	(0.29)	(0.54)	(0.54)
Common Shares Outstanding	18,566,158	19,707,847	14,780,885	15,071,915	15,373,353	15,680,820	15,994,437
Assets							
Current Assets							
Cash	4,602,566	3,528,695	2,823,781	4,144,560	4,602,566	4,142,309	3,728,078
Deferred Offering Costs	0	0	0	0	0	0	0
Prepaid Expenses	243,802	185,336	108,622	86,572	243,802	246,240	248,702
Total Current Assets	4,846,368	3,714,031	2,932,403	4,231,132	4,846,368	4,388,549	3,976,781
Other Assets	86,075	94,760	83,175	35,439	86,075	87,797	89,552
Total Assets	4,932,443	3,808,791	3,015,578	4,266,571	4,932,443	4,476,346	4,066,333
Liabilities and SH deficit (equity)							
Current Liabilities							
Trade accts payable	538,564	636,261	782,140	692,833	699,761	706,759	713,827
Other current liablities	19,533	15,745	14,472	0	0	0	0
Total Current Liabilities	558,097	652,006	796,612	692,833	699,761	706,759	713,827
Non-current operating lease	0	0	0	0	0	0	0
Total Liabilities	558,097	652,006	796,612	692,833	699,761	706,759	713,827
Common Stock	1,478	1,478	1,478	1,627	1,478	1,478	1,478
Additional Paid-in Capital	25,657,930	26,158,140	26,911,646	30,310,136	30,613,237	30,919,370	31,228,563
Accumulated Deficit	(21,285,062)	(23,002,833)	(24,694,158)	(26,738,025)	(26,382,034)	(27,151,261)	(27,877,535)
Total SH deficit/(equity)	4,374,346	3,156,785	2,218,966	3,573,738	4,232,681	3,769,587	3,352,507
Total Liabilities and SH deficit/(equity)	4,932,443	3,808,791	3,015,578	4,266,571	4,932,443	4,476,346	4,066,333

HISTORICAL STOCK PRICE



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