MIRA Pharmaceuticals, Inc. (Nasdaq: MIRA)

Rating: Hold

Price Target: N/A
Share Price: $0.93

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Company Data	
Average Daily Volume (M)	0.35
52-Week Range	0.51-5.01
Shares Outstanding (M)	16.56
Market Cap (M)	15.07
Enterprise Value (M)	11.54
Total Cash (M), mrq	4.14
Total Debt (M)	0
Total Debt to Cap	0

Estimates			
FYE: Dec		2024E	2025E
EPS	Q1	(0.09)	(0.14)
	Q2	(0.11)	(0.15)
	Q3	(0.14)	(0.15)
	Q4	(0.18)	(0.22)
	FY	(0.52)	(0.66)
P/E		NM	NM
Rev	Q1	0.0	0.0
	Q2	0.0	0.0
	Q3	0.0	0.0
	Q4	0.0	0.0
	FY	0.0	0.0
EV/Sales		N/A	N/A

One-Year Performance Chart

As of March 4, 2025. Source: E*Trade.

MIRA Pharmaceuticals Announces Upcoming Start of Phase 1 Clinical Trial for Ketamir-2 in Neuropathic Pain

Milestone marks MIRA's transition from pre-clinical to clinical-stage company. Downgrade from BUY to HOLD based on delays in MIRA's clinical development timeline and a more challenging competitive landscape

On March 4, 2025, MIRA Pharmaceuticals announced the upcoming initiation of its first Phase 1 clinical trial testing Ketamir-2, its oral ketamine analog, for the treatment of neuropathic pain. The study will be conducted at Hadassah Medical Center in Jerusalem, Israel, with subject recruitment scheduled to commence this month.

The study, designed to evaluate the safety, tolerability, and pharmacokinetics of Ketamir-2 in healthy adults, will proceed in two parts: a single ascending dose portion enrolling 32 healthy volunteers and a multiple ascending dose portion enrolling an additional 24 participants. Areas of assessment will include severity of adverse and serious adverse events, ketamine-related behavioral side effects, as well as Ketamir-2's pharmacological profile.

Mira expects to complete the Phase 1 study by Q4 2025, giving investors an initial indication whether the safety, tolerability, pharmacokinetics, and pharmacodynamics signals observed in animals may translate to humans. The company expects to initiate a follow-on Phase 2a study by year-end 2025.

Beyond the neuropathic pain indication, MIRA is targeting post-traumatic stress disorder (PTSD) as a potential additional indication for Ketamir-2. The company is also exploring a topical formulation of Ketamir-2 for localized pain relief.

We believe that while the advancement of MIRA's lead product candidate into the clinic represents an important milestone for the company, its competitive landscape has become more challenging with the January 2025 FDA approval and market entry of Vertex Pharmaceutical's JOURNAVX (suzetrigine), a first-in-class, non-opioid, oral therapy to treat moderate to severe acute pain in adults.

Vertex's pivotal program assessing suzetrigine in painful diabetic peripheral neuropathy, a type of peripheral neuropathic pain, is ongoing. In Phase 2 development, suzetrigine demonstrated significant pain reduction in various neuropathic pain populations, and Vertex is said to be aiming for a broad label covering a wide range of neuropathic pain conditions when the company applies for FDA approval. We anticipate that even prior to FDA evaluation and potential approval of suzetrigine for chronic pain indications, we can expect off-label use of the new therapy outside of acute pain.

Other companies with non-opioid pain drugs in mid-to-late-stage development include Tris Pharma, Algiax Pharmaceuticals, Levicept, and Latigo Biotherapeutics, among others. In this dynamic environment, MIRA is lagging behind a number of larger players with deeper pockets and is highly unlikely to be able to capitalize on a first-mover advantage in bringing its product candidates to market or to a stage of development that would support a lucrative asset sale.

We also note that MIRA has continued to stretch previously announced development timelines for both of its current product candidates, pointing to greater than anticipated challenges or unrealistic expectations regarding developmental execution. As a result, we believe that the expectation of an asset sale in 2026, post Phase 2 proof-of-concept, which formed the basis of our initial valuation model, is no longer realistic.

Finally, with MIRA's stock price having dropped below $1.00 per share, the risk of delisting from the Nasdaq once again rears its ugly head and warrants investor concern.

Company Description

MIRA Pharmaceuticals, Inc. is a preclinical development-stage life sciences company with two neuroscience programs targeting a broad range of neurologic diseases and neuropsychiatric disorders:

1. Ketamir-2, a novel oral ketamine analog, is under investigation in various neuropathic pain indications and to potentially deliver ultra-rapid antidepressant effects for patients suffering from major depressive disorder (MDD).

2. MIRA-55, a novel oral synthetic tetrahydrocannabinol (THC) pharmaceutical, is currently in IND-enabling studies to treat anxiety and cognitive decline typically associated with early-stage dementia in the elderly, as well as the chronic neuropathic pain frequently experienced by this patient population.

Both Ketamir-2 and MIRA-55 are classified as unscheduled drugs by the DEA and are therefore not considered controlled substances or listed chemicals.

MIRA Pharmaceuticals was incorporated in September 2020 and is headquartered in Baltimore, Maryland. The company completed its initial public offering on August 3rd, 2023, and its common stock began trading on the Nasdaq Capital Market under the symbol “MIRA.”

Risks to Valuation

- **High Failure Rate in Drug Development**. Conclusions based on preclinical data or early clinical trials may prove inaccurate and are not necessarily predictive of future results in later stage clinical trials. There is a high rate of failure for drug candidates proceeding through clinical trials. MIRA Pharmaceuticals’ long-term viability depends on the success of its product candidates, some or all of which may fail to receive regulatory approval.

- **Future Market Traction Remains Uncertain**. Even upon receiving FDA marketing approval, MIRA’s product candidates may fail to achieve the degree of market penetration required for commercial success. Reimbursement by third-party payors will be instrumental in gaining market traction.

- **Competition From Companies with Greater Resources**. The emerging market for synthetic cannabinoids as well as development and commercialization of drugs is and will remain competitive. For some of MIRA’s areas of therapeutic interest, various treatment options are already available, and new treatments are under development by competitors with greater financial and technical resources than MIRA’s. Achieving market traction will require superior safety and efficacy profiles compared to existing options, at competitive price points.

- **Outsourcing Clinical Development and Manufacturing Creates Vulnerabilities**. Any problems in MIRA Pharmaceuticals’ anticipated outsourcing of clinical trials and manufacturing processes and capabilities could have a material adverse effect on its business and financial condition.

- **No Patent Protection Exists for MIRA-55**. MIRA Pharmaceuticals has no issued patents relating to MIRA-55, and its patent application for MIRA-55 may not result in the issuance of such patents. This would significantly impact MIRA-55's potential competitive position and likely result in diminished market share, price levels, and third-party reimbursement.

- **Strength of Intellectual Property Remains Untested**. If the scope of MIRA's intellectual property portfolio is not broad enough, competitors could design comparable products around MIRA's technology or patent rights and hamper its ability to successfully commercialize its products. In addition, patent protection for naturally occurring compounds is difficult to obtain, defend, and enforce. Patent litigation is expensive and would siphon off limited resources.

- **Uncertain Ability to Continue as a Going Concern**. Because MIRA Pharmaceuticals is not currently generating revenue and operates at a loss, the company is dependent on the continued availability of additional financing to continue business operations. Clinical trials are expensive, time-consuming, uncertain, and susceptible to change, delay, or termination. The FDA regulatory approval process is lengthy and inherently unpredictable. MIRA's IPO proceeds should fund preclinical development and provide runway through Q4 2024, but there is no assurance that additional financing will be available on reasonable terms.

- **Ability to Maintain Nasdaq Listing Requirements in Question**. MIRA stock has seen a sharp decline from its IPO price of $7.00 to its current price below $1.00. In light of the need to raise additional capital, if MIRA fails to remain in compliance with the Nasdaq requirements the company's shares could be delisted. As a result, liquidity would drop, MIRA's ability to raise future rounds of external capital via equity or debt financing would be impaired, the terms and conditions of future financings could be punitive, and current shareholders might experience significant dilution.

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BUY	3	60.00	1	33.33
HOLD	1	20.00	0	0.00
SELL	0	0.00	0	0.00
NOT RATED	1	20.00	1	100.00

As of February 2025.

MIRA Pharmaceuticals Rating History as of March 4, 2025

Source: E*Trade.

Other Disclosures

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