MIRA Pharmaceuticals, Inc. (Nasdaq: MIRA)

Rating: Buy

Price Target: $7.50
Share Price: $1.00

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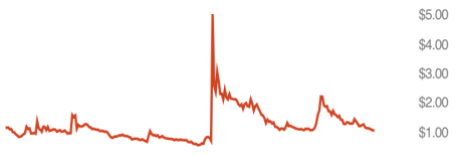
December 20, 2024

Company Data	
Average Daily Volume (M)	1.46
52-Week Range	0.51-5.01
Shares Outstanding (M)	16.56
Market Cap (M)	16.56
Enterprise Value (M)	13.03
Total Cash (M), mrq	4.15
Total Debt (M)	0
Total Debt to Cap	0

Estimates				
FYE: Dec		2023A	2024E	2025E
EPS	Q1	(0.10)	(0.12)	(0.13)
	Q2	(0.10)	(0.11)	(0.10)
	Q3	(0.26)	(0.14)	(0.10)
	Q4	(0.20)	(0.15)	(0.12)
	FY	(0.64)	(0.52)	(0.44)
P/E		NM	NM	NM
Rev	Q1	0.0	0.0	0.0
	Q2	0.0	0.0	0.0
	Q3	0.0	0.0	0.0
	Q4	0.0	0.0	0.0
	FY	0.0	0.0	0.0
EV/Sales		N/A	N/A	N/A

One-Year Performance Chart



As of December 19, 2024. Source: E*Trade.

MIRA Pharmaceuticals Files Investigational New Drug Application for Ketamir-2 with FDA

Achieving a long-awaited milestone, MIRA prepares to become a clinical-stage company in early 2025

On December 19, 2024, MIRA Pharmaceuticals announced the filing of its first investigational new drug (IND) application with the FDA for Ketamir-2, its oral ketamine analog, for the treatment of neuropathic pain.

The IND application includes data from preclinical pharmacology, pharmacokinetics, and toxicology studies of Ketamir-2 along with results from *in vitro* and *in vivo* studies, including neuropathic pain models. In parallel with the submission, MIRA is preparing to conduct a complementary neurotoxicity study, as required by the FDA's written feedback to the company's pre-IND documentation.

Preclinical studies using Ketamir-2 have shown full pain reversal in animals, including the normalization of pain thresholds in validated neuropathic pain models, along with an encouraging safety profile. Ketamir-2 was designed to address the limitations of existing neuropathic pain treatments through its selective targeting of the N-methyl-D-aspartate (NMDA) receptor, an ion channel in the central nervous system that plays a key role in synaptic function and is involved in many neurological and psychiatric disorders.

Unlike ketamine, Ketamir-2 does not cause sedation or hyperactivity side effects often associated with psychiatric conditions such as schizophrenia, bipolar disorder, and

attention deficit hyperactivity disorder (ADHD). Ketamir-2 is being developed as a non-addictive, non-opioid pain therapy.

MIRA now enters a 30-day waiting period, during which the FDA examines the IND filing for safety guidelines to ensure that research subjects are not at an unreasonable risk, before it can initiate its Phase I clinical trial in healthy human volunteers. The IND application will go into effect on January 18, 2025, unless the FDA notifies MIRA otherwise.

We anticipate results from MIRA's Phase I trial will be available by mid-2025 and will give investors an initial indication whether the safety, tolerability, pharmacokinetics, and pharmacodynamics signals observed in animals may translate to humans.

Beyond neuropathic pain, MIRA is targeting major depressive disorder (MDD), major depressive disorder with suicidal ideation (MDD-SI), treatment resistant depression (TDI), and post-traumatic stress disorder (PTSD) as potential additional indications for Ketamir-2.

We reiterate our BUY rating and 12-month price target of $7.50.

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 Our Price Target

- **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 in the $1.00-$2.00 range. 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.

Valuation

We arrive at our 12-month target price of $7.50 per share using a discounted cash flow model (DCF) out to FY 2027.

Our discount rate of 60% may be reverse engineered as follows:

- Expectation of probable success rates of 24% for the MIRA-55 and Ketamir-2 assets to successfully complete clinical development through proof-of-concept (Phase 2), and 15% for additional assets to obtain FDA approval and reach the market in 2027
- We project a 2026 sale of the MIRA-55 and Ketamir-2 assets for $600 million, based on comparable transactions of Phase Ib/Phase II assets in the CNS space, and 2027 product revenue of $40 million, corresponding with free cash flow of $398.2 million in 2026 and $5.7 million in 2027

- A discount rate of 60% implies that a discount factor of 0.244 (or close to 24%) will be applied to free cash flow from year 3 (i.e. FY 2026), and a discount factor of 0.153 (or close to 15%) will be applied to free cash flow from year 4 (i.e. FY 2027)
- The year 4 discount factor is calculated as $1/(1+60\%)^4$ or $1/1.6^4$

In other words, the 60% discount rate reflects a 24% probability of 2026 forecast revenue to be realized from the sale of MIRA-55 and Ketamir-2 and a 15% probability of 2027 forecast revenue to be realized from other products. Accordingly, a 60% discount rate applies discount factors of 0.244 and 0.153, respectively, to 2026 and 2027 projected revenue.

Our key assumptions for our DCF valuation are detailed below:

1. **Product gross margin** of 86% for product revenue, per IQVIA valuation of MIRA-55 and Ketamir-2 NPV.
2. We expect **R&D expenses** to grow by 15% per year from FY 2025 onward as product candidates move toward later and more expensive stages of clinical development, additional indications are being explored, and new product candidates are added to the product portfolio.
3. We expect **SG&A expenses** to grow by 10% from FY 2025 to FY 2026, then grow to 40% of revenue from 2027 onward as MIRA scales in preparation of bringing product to market.
4. Minimal **depreciation and amortization** amounts, as MIRA Pharmaceuticals is expected to continue to outsource product development and manufacturing activities.
5. **Interest** amounts are based on anticipated use of the $3 million line of credit available for Ketamir-2 development.
6. Applied **U.S. Federal corporate income tax rate** of 21%.
7. **Opening NOL balance** equals accumulated deficit as of 12/31/22 (from balance sheet)
8. **Net working capital** estimates anticipated capital raise of $10.0 million in 2025 and sale of the MIRA-55 and Ketamir-2 assets for $600 million in 2026, following Phase II proof-of-concept studies. For 2027, net working capital increase is modeled as 15% of revenue.
9. **Discount rate** of 60% reflects a 15% probability of 2027 forecast revenue to be realized.
10. **Terminal value calculation** employs an EV/TTM Revenue multiple of 5.69, calculated as the median of four comparable M&A transactions: (1) acquisition of Beacon Therapeutics by Syncona Limited (LSE:SYNC) on 10/24/2022; (2) acquisition of LogicBio Therapeutics by Alexion Pharmaceuticals on 10/3/2022; (3) acquisition of Bukwang Pharmaceutical Co. by OCI Holdings Co. on 2/22/2022; and (4) acquisition of Akciju sabiedriba Grindeks by Dashdirect Limited on 5/24/2019.
11. The 12/31/23 **cash on balance sheet** figure derives from MIRA's 10K filing.

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MIRA Pharmaceuticals

MIRA Pharmaceuticals, Inc.						
Valuation of the firm and common equity as of 12/31/2023						
		Fiscal Year Ending				
		12/31/23	**12/31/24**	**12/31/25**	**12/31/26**	**12/31/27**
$(000s)						
Sale of Phase II Assets		0.0	0.0	0.0	600,000.0	0.0
Royalties on Sale of Assets		0.0	0.0	0.0	48,000.0	0.0
Net Product Sales		0.0	0.0	0.0	0.0	40,000.0
Revenue		**0.0**	**0.0**	**0.0**	**552,000.0**	**40,000.0**
Cost of Goods Sold		0.0	0.0	0.0	0.0	5,600.0
Gross Profit		**0.0**	**0.0**	**0.0**	**552,000.0**	**34,400.0**
% Gross Margin						*86.0%*
Operating Expenses						
Research & Development Expense		2,385.8	3,582.7	3,724.8	4,283.5	4,926.0
Selling, General & Administrative Expensee		8,095.5	4,456.2	5,103.1	5,613.4	16,000.0
Related Party Travel Costs		453.6	0.0	0.0	0.0	0.0
Total Operating Expenses		**10,934.9**	**8,038.9**	**8,827.9**	**9,896.9**	**20,926.0**
EBITDA		**-10,934.9**	**-8,038.9**	**-8,827.9**	**542,103.1**	**13,474.0**
Depreciation and amortization		-15.0	-18.0	-21.0	-24.0	-30.0
EBIT		**-10,949.9**	**-8,056.9**	**-8,848.9**	**542,079.1**	**13,444.0**
Interest		1,025.3	-144.8	300.0	300.0	0.0
EBT		**-11,975.2**	**-7,912.1**	**-9,148.9**	**541,779.1**	**13,444.0**
TAX CALCULATIONS						
Tax rate		21%	21%	21%	21%	21%
EBT		(11,975.2)	(7,912.1)	(9,148.9)	541,779.1	13,444.0
Taxes Paid - without NOLs		0.0	0.0	0.0	113,773.6	2,823.2
NOLs Applied		0.0	0.0	0.0	37,158.4	0.0
Taxes Paid - with NOLs		0.0	0.0	0.0	105,970.3	2,823.2
New NOLs Created		(10,949.9)	(8,056.9)	(8,848.9)	0.0	0.0
NOL - Opening Balance		9,302.7	20,252.6	28,309.5	37,158.4	0.0
Increase in NOL		10,949.9	8,056.9	8,848.9	-37,158.4	0.0
NOL - Closing Balance		20,252.6	28,309.5	37,158.4	0.0	0.0
Memo Item: Taxes Paid		**0.0**	**0.0**	**0.0**	**105,970.3**	**2,823.2**
NET WORKING CAPITAL						
as % of Revenue						15.0%
WC - Opening		-875.6	4,322.4	-799.5	4,701.8	44,701.8
Increase in WC		5,198.0	-5,121.9	5,501.3	40,000.0	6,000.0
WC - Closing		4,322.4	-799.5	4,701.8	44,701.8	50,701.8
Memo Item: Change in Net Working Capital		**5,198.0**	**-5,121.9**	**5,501.3**	**40,000.0**	**6,000.0**
CAPEX		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
FREE CASH FLOWS						
EBIT		-10,949.9	-8,056.9	-8,848.9	542,079.1	13,444.0
less Taxes Paid		0.0	0.0	0.0	105,970.3	2,823.2
plus Depreciation/Amortization		15.0	18.0	21.0	24.0	30.0
less Change in Net Working Capital		5,198.0	-5,121.9	5,501.3	40,000.0	6,000.0
less Capex		0.0	0.0	0.0	0.0	0.0
less Payments to Other Forms of Capital		0.0	0.0	0.0	0.0	0.0
Free Cash Flows		**(16,132.9)**	**(2,917.0)**	**(14,329.2)**	**396,132.7**	**4,650.7**
Memo Item: Free Cash Flow (w/out tax shield)						
PRESENT VALUE OF FREE CASH FLOWS						
Discount Rate	60.00%					
Discount Period		0.000	1.000	2.000	3.000	4.000
Discount Factor		1.000	0.625	0.391	0.244	0.153
PV (FCFs)		(16,132.9)	(1,823.1)	(5,597.3)	96,712.1	709.6
PV (FCFs)	73,868					
TERMINAL VALUE						
Terminal Value (Future Value)						227,600.0
Terminal Value (Present Value)	34,729					
NOLs						
Future Value						0.0
Present Value	0					
ENTERPRISE VALUE	**108,597**					
plus Cash on Balance Sheet	4,603					
plus Cash From Option Exercise	-					
less Debt	-					
Common Equity Value	113,200					
Common shares outstanding	14,781					
Implied common equity value per share	**$7.66**					

Source: Company reports, Kingswood research estimates.

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HOLD	0	0.00	0	0.00
SELL	0	0.00	0	0.00
NOT RATED	1	20.00	1	100.00

As of December 2024.

MIRA Pharmaceuticals Rating History as of December 19, 2024

As of December 19, 2024. Source: E*Trade.

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