MIRA Pharmaceuticals, Inc. (Nasdaq: MIRA)

Rating: Buy

Price Target: $10.00
Share Price: $2.56

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Company Data	
Average Daily Volume (M)	3.224
52-Week Range	0.51-6.95
Shares Outstanding (M)	14.781
Market Cap (M)	74.05
Enterprise Value (M)	70.52
Total Cash (M), mrq	3.53
Total Debt (M)	0.001
Total Debt to Cap	0

Estimates				
FYE: Dec		2023A	2024E	2025E
EPS	Q1	(0.10)	(0.12)	(0.09)
	Q2	(0.10)	(0.08)	(0.08)
	Q3	(0.26)	(0.09)	(0.08)
	Q4	(0.20)	(0.12)	(0.12)
	FY	(0.64)	(0.41)	(0.37)
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

Source: E*Trade.

MIRA Pharmaceuticals on Track to Advance Its Two Preclinical Assets Toward Clinical Trials

Reiterate BUY rating and DCF-based 18-month price target of $10.00

Shares of MIRA Pharmaceuticals nearly tripled in value since July 19 on news about the continued preclinical success of its investigational drug candidate, Ketamir-2. The newly released data from *in vitro* studies elucidates a potential mechanism underlying Ketamir-2's superior oral absorption and ability to penetrate the blood-brain barrier more effectively than traditional ketamine. Improved penetration into target tissues would allow for lower doses of Ketamir-2 to achieve therapeutic effects.

MIRA Pharmaceuticals has advanced its two preclinical assets, Ketamir-2 and MIRA-55, through preclinical testing, generating encouraging results. We summarize recent company news below.

Ketamir-2

- MIRA Pharmaceuticals, Inc. advanced preclinical studies expanding the potential use of orally administered Ketamir-2, its differentiated oral ketamine analog, beyond treatment-resistant depression, to include treatment of severe post-traumatic stress disorder (PTSD) and neuropathic pain. According to Allied Market Research, the U.S. market for PTSD treatments is projected to reach $26 billion by 2031.

- While continuing to conduct animal studies evaluating pharmacodynamics and toxicology of Ketamir-2, MIRA is also optimizing its manufacturing process of Ketamir-2, reducing

production costs and overall cost of goods in advance of scaling up production under Good Manufacturing Practices (GMP).

- In preclinical studies to date, Ketamir-2 has compared favorably to ketamine on safety and efficacy metrics, as well as administration route, dosing, and bioavailability.

- MIRA expects to file an Investigational Drug Application (IND) for Ketamir-2 with the U.S. Food and Drug Administration (FDA) by the end of 2024 and to begin human clinical trials in early 2025.

- MIRA is also in discussions with several research centers to collaborate on exploring Ketamir-2's efficacy in treating cancer pain.

- The finding that Ketamir-2 is not a substrate for interaction with P-glycoprotein (P-gp), a membrane protein that pumps drugs out of cells, may allow Ketamir-2 to have better oral absorption and bioavailability, and to penetrate the blood-brain barrier more effectively than traditional ketamine, which is a P-gp substrate.

MIRA-55

- In May 2024, the U.S. Drug Enforcement Administration (DEA) determined that MIRA-55, MIRA's preclinical-stage oral pharmaceutical marijuana analog being developed for potential treatment of anxiety and cognitive decline, was not a controlled substance or listed chemical under the Controlled Substance Act and its governing regulations. This determination offers a significant regulatory advantage over marijuana, which is classified as a Scheduled drug, and significantly de-risks the MIRA-55 asset with respect to legal and regulatory complexities, elevated production costs, and manufacturing/transportation restrictions.

- In preclinical studies, MIRA-55 compared favorably to THC, the main psychoactive component in marijuana, showing enhanced efficacy, consistent anxiolytic effects, better stability and balance, and reduced side effects. At both the CB1 and CB2 cannabinoid receptors. MIRA-55 also demonstrated a more pronounced and sustained increase in agonist activity at increased concentrations, indicating the potential for greater effectiveness in activating cannabinoid receptors that mediate its therapeutic effects.

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. 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.

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

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 five-month price decline from its IPO price of $7.00 to its current price near $1.00. If MIRA fails to remain in compliance with the Nasdaq requirements the company's shares could be delisted. As a result, liquidity would drop and MIRA's ability to raise additional capital via equity or debt financing would be impaired. As a result, future financing conditions could be punitive and current shareholders might experience significant dilution.

Valuation

We arrive at our 24-month target price of $10.00 per share using a discounted cash flow model (DCF) out to FY 2027.

Our discount rate of 50% may be reverse engineered as follows:

- Expectation of probable success rates of 30% for the MIRA-55 and Ketamir-2 assets to successfully complete clinical development through proof-of-concept (Phase II), and 20% 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 $448.2 million in 2026 and $5.7 million in 2027
- A discount rate of 50% implies that a discount factor of 0.296 (or close to 30%) will be applied to free cash flow from year 3 (i.e. FY 2026), and a discount factor of 0.198 (or close to 20%) will be applied to free cash flow from year 4 (i.e. FY 2027)
- The year 4 discount factor is calculated as $1/(1+50\%)^4$ or $1/1.5^4$

In other words, the 50% discount rate reflects a 30% probability of 2026 forecast revenue to be realized from the sale of MIRA-55 and Ketamir-2 and a 20% probability of 2027 forecast revenue to be realized from other products. Accordingly, a 50% discount rate applies discount factors of 0.296 and 0.198, 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 50% reflects a 20% 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.

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	3,429.6	2,724.8	3,133.5	3,603.6
Selling, General & Administrative Expensee		8,095.5	1,517.7	2,073.8	2,281.2	16,000.0
Related Party Travel Costs		453.6	0.0	0.0	0.0	0.0
Total Operating Expenses		**10,934.9**	**4,947.3**	**4,798.6**	**5,414.7**	**19,603.6**
EBITDA		**-10,934.9**	**-4,947.3**	**-4,798.6**	**546,585.3**	**14,796.4**
Depreciation and amortization		-15.0	-18.0	-21.0	-24.0	-30.0
EBIT		**-10,949.9**	**-4,965.3**	**-4,819.6**	**546,561.3**	**14,766.4**
Interest		1,025.3	200.0	300.0	300.0	0.0
EBT		**-11,975.2**	**-5,165.3**	**-5,119.6**	**546,261.3**	**14,766.4**
TAX CALCULATIONS						
Tax rate		21%	21%	21%	21%	21%
EBT		(11,975.2)	(5,165.3)	(5,119.6)	546,261.3	14,766.4
Taxes Paid - without NOLs		0.0	0.0	0.0	114,714.9	3,100.9
NOLs Applied		0.0	0.0	0.0	30,037.5	0.0
Taxes Paid - with NOLs		0.0	0.0	0.0	108,407.0	3,100.9
New NOLs Created		(10,949.9)	(4,965.3)	(4,819.6)	0.0	0.0
NOL - Opening Balance		9,302.7	20,252.6	25,217.9	30,037.5	0.0
Increase in NOL		10,949.9	4,965.3	4,819.6	-30,037.5	0.0
NOL - Closing Balance		20,252.6	25,217.9	30,037.5	0.0	0.0
Memo Item: Taxes Paid		**0.0**	**0.0**	**0.0**	**108,407.0**	**3,100.9**
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	-4,965.3	-4,819.6	546,561.3	14,766.4
less Taxes Paid		0.0	0.0	0.0	108,407.0	3,100.9
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)**	**174.6**	**(10,299.9)**	**398,178.3**	**5,695.5**
Memo Item: Free Cash Flow (w/out tax shield)						
PRESENT VALUE OF FREE CASH FLOWS						
Discount Rate	50.00%					
Discount Period		0.000	1.000	2.000	3.000	4.000
Discount Factor		1.000	0.667	0.444	0.296	0.198
PV (FCFs)		(16,132.9)	116.4	(4,577.7)	117,978.8	1,125.0
PV (FCFs)	98,510					
TERMINAL VALUE						
Terminal Value (Future Value)						227,600.0
Terminal Value (Present Value)	44,958					
NOLs						
Future Value						0.0
Present Value	0					
ENTERPRISE VALUE	**143,468**					
plus Cash on Balance Sheet	4,603					
plus Cash From Option Exercise	-					
less Debt	-					
Common Equity Value	148,070					
Common shares outstanding	14,781					
Implied common equity value per share	**$10.02**					

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	25.00	1	100.00

As of July 2024.

In August 2023, Kingswood Investments, a division of Kingswood Capital Partners, managed MIRA Pharmaceutical's initial public offering. Kingswood received compensation from MIRA Pharmaceuticals for investment banking activity during 2023.

MIRA Pharmaceuticals Rating History as of July 23, 2024

Source: E*Trade.

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