MIRA Pharmaceuticals, Inc. (Nasdaq: MIRA)

Rating: Buy

Price Target: $7.50
Share Price: $1.73

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Company Data	
Average Daily Volume (M)	1.857
52-Week Range	0.51-6.40
Shares Outstanding (M)	16.27
Market Cap (M)	28.14
Enterprise Value (M)	24.61
Total Cash (M), mrq	2.82
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)	(0.13)	(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

Source: E*Trade.

October 30, 2024

MIRA Pharmaceuticals Announces Superiority of Ketamir-2 to Gabapentin (Neurontin) in Preclinical Studies

Ketamir-2 achieved 60% greater efficacy than the FDA-approved neuropathic pain treatment gabapentin in reducing chemotherapy-induced pain, according to MIRA

MIRA Pharmaceuticals's stock experienced significant price and volume increases following the company's announcement that its Ketamir-2 product candidate induced near-complete normalization of pain sensitivity in a mouse model of chemotherapy-induced neuropathy, under experimental conditions where gabapentin provided only moderate relief.

Neuropathic pain was induced in mice through administration of four doses of paclitaxel, a common chemotherapy drug. Pain sensitivity was measured using the Von Frey filament test, a mechanical sensitivity test that measures an animal's experience of pain in response to stimuli. To perform the test, animals are placed on a wire mesh surface and calibrated filaments of varying stiffness are applied through the underside of the mesh to the animal's hind paw, to determine the minimum amount of force required to make the animal withdraw its paw. The force exerted by the filament is inversely proportional to its length and directly proportional to its width.

MIRA's results build on earlier successes across various pain models, further validating Ketamir-2's potential as an effective pain management drug with fewer side effects than gabapentin and pregabalin. Besides chemotherapy-induced pain, MIRA is planning to advance Ketamir-2 for the treatment of diabetic neuropathy.

Neuropathic pain is a expanding health indication, with increasing prevalence linked to conditions like diabetes, chemotherapy-induced nerve damage, and post-herpetic neuralgia. Chronic pain markets are large and growing, with gabapentin (Neurontin) expected to reach $4.95 billion in sales by 2033 and pregabalin (Lyrica) expected to reach $2.20 billion in sales by 2032.

MIRA is on track to submit an Investigational New Drug application for neuropathic pain indications in December 2024 and begin Phase I clinical trials in humans during the first quarter of 2025. MIRA has completed the design of its Phase I clinical trial, which will assess safety, tolerability, and pharmacokinetics in humans. The company's primary goal is to demonstrate efficacy in humans as early as possible in subsequent Phase II studies.

Looking ahead, MIRA aims to broaden Ketamir-2's therapeutic applications to include major depressive disorder with suicidal ideation, treatment-resistant depression, and post-traumatic stress disorder, potentially leading to additional IND filings in 2025.

We reiterate our BUY rating and 14-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 near $2.00. 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.

Valuation

We arrive at our 14-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.

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	25.00	1	100.00

As of October 2024.

MIRA Pharmaceuticals Rating History as of October 29, 2024

Source: E*Trade.

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