November 27, 2023

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

Brad Sorensen
312-265-9574
bsorensen@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

MIRA Pharmaceuticals (MIRA-NASDAQ)

MIRA: Acquires Potential Blockbuster Drug

MIRA is creating a THC analog that has the same benefits as THC without the negative side effects. We value MIRA at $22.70 using discounted cash flow analysis and a 20% discount rate.

Current Price (11/24/23)	$3.27
Valuation	**$22.70**

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.

MIRA announced that it has acquired an exclusive licensing agreement for a potential breakthrough treatment of depression, while also obtaining a non-dilutive cash infusion.

SUMMARY DATA

52-Week High	**$7.42**
52-Week Low	**$1.42**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**337,209**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$48**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**26**
Insider Ownership (%)	**N/A**
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**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**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 E	0 E	0 E	0 E
2024	0 E	0 E	0 E	0 E	0 E
2025	0 E	0 E	0 E	0 E	0 E

Earnings

	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) E	(0.26) E	(0.23) E	(0.68) E
2024	(0.16) E	(0.12) E	(0.11) E	(0.13) E	(0.52) E
2025	(0.16) E	(0.10) E	(0.09) E	(0.08) E	(0.43) E

© Copyright 2023, Zacks Investment Research. All Rights Reserved.

UPDATE

MIRA Pharmaceuticals is a preclinical-stage pharmaceutical 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. Adding to its continuing pursuit of the company's primary treatment, MIRA1, MIRA announced that it has acquired an exclusive license to develop and commercialize a product commonly known as 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. The terms of the deal appear to us to be fashioned in a way that is low risk for MIRA with the potential for a very high return:

- MIRA agreed to make a one-time payment to Miralogx, the owner of Ketamir, of $100,000 and issued warrants that give Miralogx the right to purchase up to 700,000 shares of MIRA at an exercise price of $2.00 per share any time prior to November 15, 2028.
    - Additionally, MIRA agreed to pay Miralogx royalty payments of 8% of net sales and other revenue from licensed products.
- In return, the MIRA obtains the rights to license and commercialize Ketamir and can borrow up to $3 million from Miralogx to fund the development of Ketamir.

We believe this is a deal that provides a great opportunity for MIRA at a relatively low cost. Ketamir is at the beginning of the approval process but initial tests that we've seen have proved quite promising. Additionally, this deal fits with the MIRA way of doing business by providing an existing treatment in a "better" way—fewer side effects, easier to use, quicker acting, etc.

There are currently roughly 30 antidepressants available to the public, but 33% of patients receive no relief from any of these treatment options, while, for the patients that the treatments do work for, the time to take effect can be lengthy. Additionally, one of the more popular treatments goes by the name Spravato, which is an esketamine marketed by Johnson and Johnson. Although the treatment is given by a nasal spray, patients are required to administer the medication at a certified treatment center where the patient can be observed for at least two hours in order to ensure no dangerous side effects begin. The FDA requires this REMS (risk evaluation and mitigation strategies) due to potential side effects such as sedation and dissociation, while also being concerned about the potential for abuse of the Schedule III substance. Despite these hurdles, sales for 2023 of Spravato are expected to be around $600 million. It's highly unlikely that Ketamir will face these same hurdles as the company announced that they had received a decision on Ketamir from the Drug Enforcement Agency: "The Drug Enforcement Administration (DEA) conducted a scientific review of the chemical structures of these substances in accordance with the definitions within the CSA and its implementing regulations. Based on this review, DEA determined that Ketamir-1 and Ketamir-2 are not controlled substances or listed chemicals under the CSA." That decision will make Ketamir, if and when it is approved by the FDA, much easier to obtain and use for patients.

There is still a long FDA process to go through, but in initial testing, Ketamir has been shown to have fewer side effects due to its design that avoids impacting the opiate receptor. Testing has also shown better bioavailability, meaning that the treatment gets into the bloodstream in a more efficient way through better absorption in the intestine. As seen in the table below, Ketamir taken orally has roughly the same bioavailability as what is considered the gold standard for Ketamine bioavailability—injection using an IV.

	Route	% Bioavailable	Tmax Min	Dose (mg/kg)	Time Dose (min)	Total Dose (mg)	mg/min
Ketamine	IV	100	3	0.5	40	30	0.75
	IN	26.5	15	1.4	10	84.00	8.4
	Oral	23	30	2.5	60	150	2.5
	Ketamir	60	30	0.83*	60	50	0.83

*Proportional to IV Dosing adjusting for Bioavailability = 100/60*0.5

Source: MIRA Pharmaceuticals

We'll learn more about Ketamir as human trials begin in 2024 but what gives us more confidence in this move is the fact that Dr. Adam Kaplin is involved and endorses Ketamir. Dr. Kaplan is one of the foremost experts on ketamine and was the Johns Hopkins Site Principal Investigator for Phase 3 clinical trials that led to the approval of Spravato. Additionally, the doctor founded and directed the Johns Hopkins Esketamine Clinic for Depression and has published multiple peer-reviewed articles about the use of ketamine for depression. In short, there is no other medical professional in our view that has more extensive expertise in this area and whose opinion on Ketamir we would value more highly.

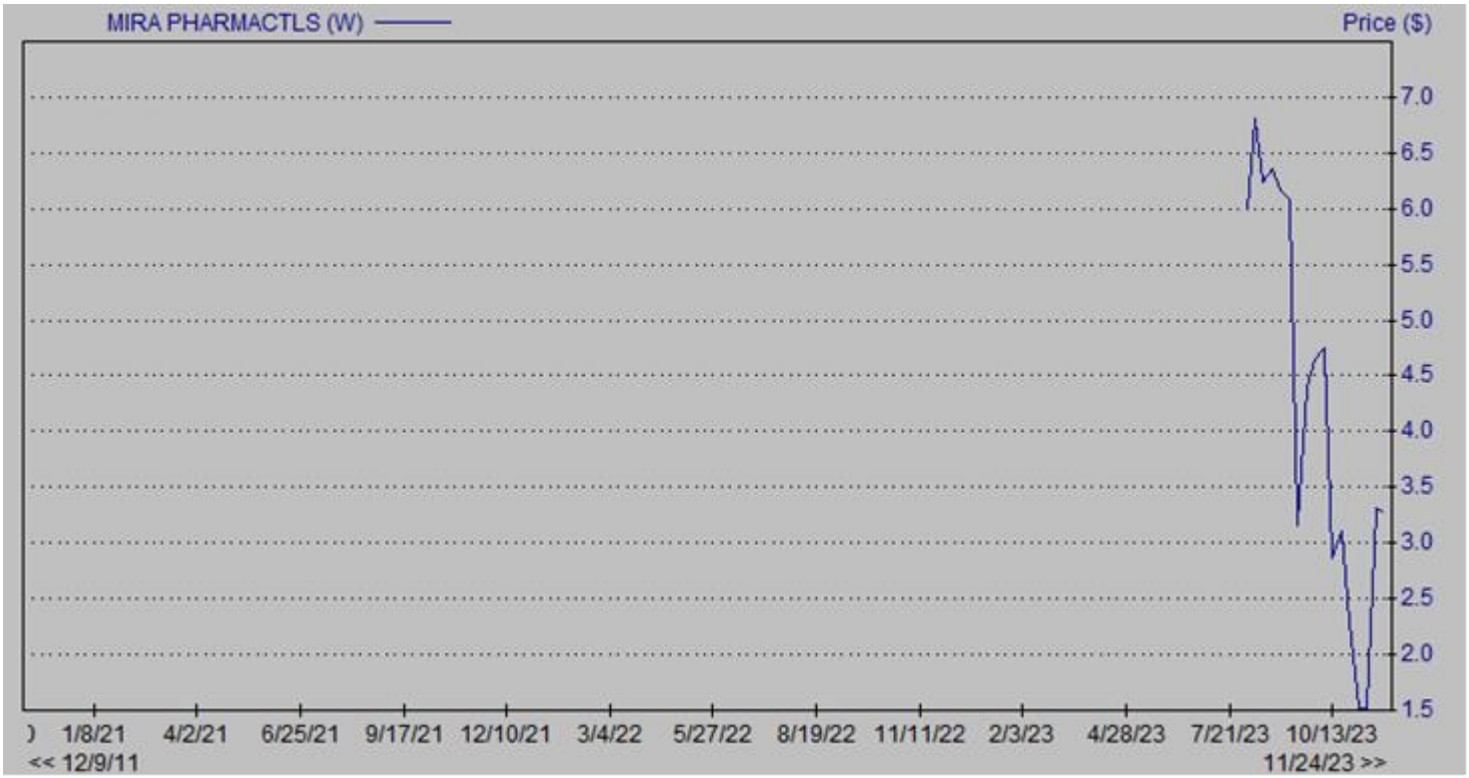
In judging how much value this deal adds to MIRA, we are also pleased to have an in-depth report from the very respected firm IQVIA, which is a provider of biopharmaceutical development and professional consulting services. IQVIA's report, which was investigated in depth, uses assumptions that we find reasonable and well thought out, both in terms of potential market size and the share of the market Ketamir may be able to capture if approved. Of course, we also look at similar drugs, such as Spravato mentioned above, and consider that Ketamir is at the beginning of a 20-year patent. However, as always, we attempt to err on the side of conservative valuations and recognize that Ketamir still has to endure the arduous FDA approval process. Due to Ketamir's good initial results and it being a derivative of an already approved drug, we give it better than average chances of being approved but give a weighting to future revenue from Ketamir a 10% weight at the current time, with the belief that percentage will rise rapidly as human trials show expected success. As a result, we are raising our valuation of MIRA from $16.50 to $22.70 and continue to believe that's a relatively conservative valuation.

MIRA continues to focus on the development of MIRA1, which we have written about extensively and believe has great promise, and now adds another potential blockbuster to its portfolio, supported by one of the leading scientists on the subject. Additionally, the company acquired this additional asset along with the access to cash to develop the product, meaning MIRA will not have to hijack funds from the crucial development of MIRA1 and can move along both paths simultaneously. We believe this was a move that will benefit MIRA and its shareholders and urge investors to take a look at MIRA before the expected positive test results start coming in.

PROJECTED INCOME STATEMENT & BALANCE SHEET

MIRA Pharmaceuticals Income Statement and Balance Sheet							
	2022A	1Q2023A	2Q2023A	3Q2023A	4Q2023E	2024E	2025E
Revenue	0	0	0	0	0	0	0
Operating Costs:							
General and Admin.	2,992,125	614,235	1,071,239	2,144,832	2,166,280	3,141,731	3,141,732
Travel Costs	1,704,350	453,550	0	0	0	1,789,568	476,228
Research and Dev.	2,351,465	271,606	(101,019)	1,015,252	1,066,015	2,469,038	2,592,490
Total Operating Costs	7,047,940	1,339,391	970,220	3,160,084	3,232,295	7,400,337	6,210,450
Interest Expense	10,250	1,653	(295,887)	0	0	0	0
Net Gain/(Loss)	(7,058,190)	(1,341,044)	(674,333)	(3,160,084)	(3,232,295)	(7,400,337)	(6,210,450)
Basic and diluted loss per share	(0.48)	(0.09)	(0.10)	(0.26)	(0.23)	(0.52)	(0.43)
Common Shares Outstanding	14,745,170	14,745,170	13,313,000	13,639,197	13,911,981	14,190,221	14,474,025
Assets							
Current Assets							
Cash	350,978	1,349	24,823	5,868,330	2,636,035	2,372,432	2,135,188
Deferred Offering Costs	143,427	189,688	353,372	0	0	0	0
Prepaid Expenses	0	60,031	42,524	202,817	204,845	206,894	208,963
Total Current Assets	494,405	251,068	420,719	6,071,147	2,840,880	2,579,325	2,344,151
Other Assets	363,669	146,512	3,404,417	2,947,065	3,006,006	3,066,126	3,127,449
Total Assets	858,074	397,580	3,825,136	9,018,212	5,846,887	5,645,452	5,471,600
Liabilities and SH deficit (equity)							
Current Liabilities							
Trade accts payable	811,738	918,618	659,101	779,573	787,369	795,242	803,195
Other current liablities	558,301	1,200,232	1,917,944	88,800	90,576	92,388	94,235
Total Current Liabilities	1,370,039	2,118,850	2,577,045	868,373	877,945	887,630	897,430
Non-current operating lease	84,267	68,206	51,472	34,528	32,802	31,162	29,603
Total Liabilities	1,454,306	2,187,056	2,628,517	902,901	910,746	918,791	927,034
Common Stock	6,657	6,657	6,657	1,478	6,657	6,657	6,657
Additional Paid-in Capital	8,699,830	8,847,630	13,099,830	23,611,517	23,847,632	24,086,108	24,326,970
Accumulated Deficit	(9,302,719)	(10,643,763)	(11,909,868)	(15,497,684)	(18,918,149)	(19,366,105)	(19,789,060)
Total SH deficit/(equity)	(596,232)	(1,789,476)	1,196,619	8,115,311	4,936,140	4,726,661	4,544,567
Total Liabilities and SH deficit/(equity)	858,074	397,580	3,825,136	9,018,212	5,846,887	5,645,452	5,471,600

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brad Sorensen, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.