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MetaVia Inc. (MTVA-NASDAQ)

MTVA: Additional Positive Topline Results for DA-1726 in Phase 1 MAD Study…

Based on our probability adjusted DCF model that takes into account potential future revenues from DA-1241 and DA-1726, MTVA is valued at $21.00/share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results.

Current Price (05/22/25)	$0.88
Valuation	**$21.00**

OUTLOOK

On May 14, 2025, MetaVia Inc. (MTVA) announced financial results for the first quarter and provided a business update. The company recently announced positive topline results from the Phase 1 MAD trial of DA-1726 in obesity that showed statistically significant weight loss and potential best-in-class results for glucose control, waist reduction, and tolerability. MetaVia will be adding additional cohorts to the study to determine a maximum tolerated dose. The company also recently presented positive 16-week results for DA-1241 in patients with presumed MASH that showed the drug significantly reduced markers of liver injury, inflammation, and fibrosis. An end-of-Phase 2 meeting with the FDA is planned for the first half of 2025.

SUMMARY DATA

52-Week High	**$5.00**
52-Week Low	**$0.65**
One-Year Return (%)	**-79.83**
Beta	**0.21**
Average Daily Volume (sh)	**541,134**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**1**
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 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	0 A	0 A	0 A	0 A	0 A
2025	0 A	0 E	0 E	0 E	0 E
2026					0 E
2027					0 E

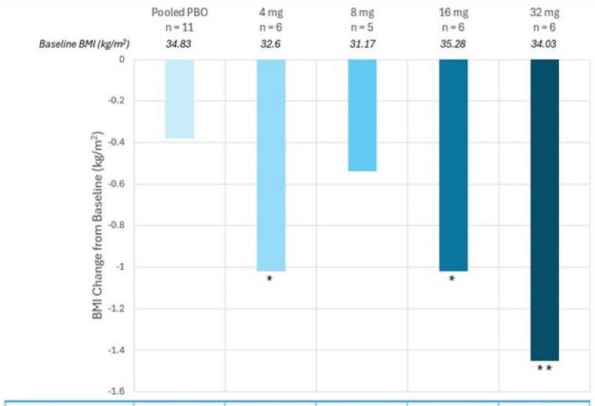
Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$1.32 A	-$1.85 A	-$0.55 A	-$0.50 A	-$3.56 A
2025	-$0.36 A	-$0.32 E	-$0.31 E	-$0.36 E	-$1.38 E
2026					-$1.12 E
2027					-$1.02 E

Business Update

Additional Positive Data from Phase 1 MAD Study of DA-1726 in Obesity

On April 22, 2025, MetaVia Inc. (MTVA) announced additional positive topline results from the multiple ascending dose (MAD) Part 2 of the Phase 1 clinical trial of DA-1726 in obesity. The company had previously announced positive data from this trial, which we discussed in our last report. The additional data showed a clear dose-response in body weight reduction across the 8 mg to 32 mg range and indicating the potential for greater efficacy at higher doses and longer treatment durations. The following image shows the change in body mass index (BMI), showing a clear dose-dependent effect from the 8 mg to the 32 mg cohort.



Maximum Change in BMI	-0.9	-2.0	-1.9	-2.1	-2.1
Change in BMI (kg/m²)	-0.4	-1.0	-0.5	-1.0	-1.5
Placebo Adjusted		-0.6	-0.2	-0.6	-1.1
p-Value vs. Placebo		0.0188	0.7280	0.0240	0.0005

*p<0.05 **p<0.001

Source: MetaVia Inc.

One of the concerns with targeting GLP-1 and glucagon receptors is the potential for increased heart rate. Novo Nordisk discontinued the development of NN1177, a dual glucagon/GLP-1 co-agonist, despite achieving weight loss up to 12.6% at week 12 after multiple Phase 1 trials showed an increase in heart rate (5-22 beats per minute), impaired glucose tolerance, and increased markers of inflammation (fibrinogen and C-reactive protein) (Friedrichsen *et al*., 2023). Thus, determining cardiac safety is of the utmost importance for DA-1726 given its similar mechanism of action. In the Phase 1 study, the mean heart rate for subjects on DA-1726 showed a slight decrease from baseline in all treatment groups besides the 16 mg group where the baseline was significantly lower than the others. In addition, there were no onsets of QTcF (QT interval corrected for heart rate using the methods of Fridericia) and no risk of cardiovascular events.

Heart Rate (bpm)	Baseline N	Baseline	Day 8	Day 15	Day 22	Day 29	Mean HR change
4 mg	6	82.8	-15.7	-17.2	-9.7	-13.2	-14.0
8 mg	6	77.7	-4.0	-6.0	-5.4	-6.0	-5.4
16 mg	6	58.8	6.0	9.5	7.7	7.5	7.7
32 mg	6	70.7	0.2	-3.5	1.7	-1.3	-0.7
Pooled Placebo	12	67.6	-3.0	-4.0	-4.4	0.7	-2.7

Source: MetaVia Inc.

We're very encouraged by the results from the MAD Part 2 of the Phase 1 trial of DA-1726 as the drug appears to be effective, well tolerated, and shows no signs of any potential negative cardiovascular effects. The company is planning to add additional cohorts to the study to examine higher doses of DA-1726 as the 32 mg dose appears to be very well tolerated.

In addition, MetaVia will be initiating Part 3 of the Phase 1 trial in the second half of 2025. The trial will utilize the 32 mg dose and focus on Wegovy® early drop-out patients with the goal being to explore the potential of DA-1726 to have a superior tolerability/safety and weight loss profile. The interim data readout for this trial should occur in the first half of 2026.

Data on DA-1241 Presented at EASL Congress 2025

On May 7, 2025, MetaVia announced that data from the Phase 2a clinical trial of DA-1241 was presented in a late-breaking poster session at the European Associate for the Study of the Liver (EASL) Congress 2025. A copy of the poster can be found here. The Phase 2a trial enrolled a total of 109 subjects with presumed metabolic dysfunction-associated steatohepatitis (MASH) and qualifying baseline alanine aminotransferase (ALT). Subjects were randomized to receive DA-1241 50 mg, DA-1241 100 mg alone, DA-1241 100 mg with dipeptidyl peptidase 4 inhibitor (DPP4i), or placebo in a 1:2:2:2 ratio once daily for 16 weeks. The primary efficacy endpoint was the change from baseline in ALT after 16 weeks. We previously reported on the topline results, which can be seen here.

Additional data from the study shared during the poster session included a subgroup analysis of subjects with baseline ALT levels between 40 and 200 U/L, in which DA-1241 treatment led to dose-dependent reductions in ALT, with the 100 mg dose producing a significant 22.8 U/L decrease after 16 weeks ($P<0.05$ vs. placebo). The effects were seen regardless of diabetes status and were also accompanied by improvements in non-invasive tests used to monitor MASH such as FAST, CAP, MRI-PDFF, and NIS-4 score. Liver fat, as measured by CAP, was reduced by 23.0 dB/m with DA-1241 100 mg compared to just 1.4 dB/m with placebo.

We anticipate the company conducting an 'End-of-Phase 2' meeting with the FDA to discuss the regulatory path forward for DA-1241 in the first half of 2025.

Financial Results

On May 14, 2025, MetaVia announced financial results for the first quarter of 2025. As expected, the company did not report any revenues in the first quarter of 2025. R&D expenses for the first quarter of 2025 were approximately $2.3 million compared to approximately $4.9 million for the first quarter of 2024. The decrease was primarily due to decreased expenses related to DA-1241 partially offset by higher expenses related to DA-1726. G&A expenses were approximately $1.6 million for the first quarter of 2025 compared to $2.0 million for the first quarter of 2024. The decrease was primarily due to lower consulting and other G&A expenses.

As of March 31, 2025, MetaVia had approximately $11.2 million in cash and cash equivalents. Subsequent to the end of the quarter, the company raised gross proceeds of $10.0 million from the sale of 9,479,345 shares of common stock at $0.71 per share and 4,605,162 pre-funded warrants to purchase shares of common stock at a price of $0.709 per pre-funded warrant. We estimate the company has sufficient capital to fund operations into 2026. As of May 14, 2025, MetaVia had approximately 19.6 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 5.1 million.

Conclusion

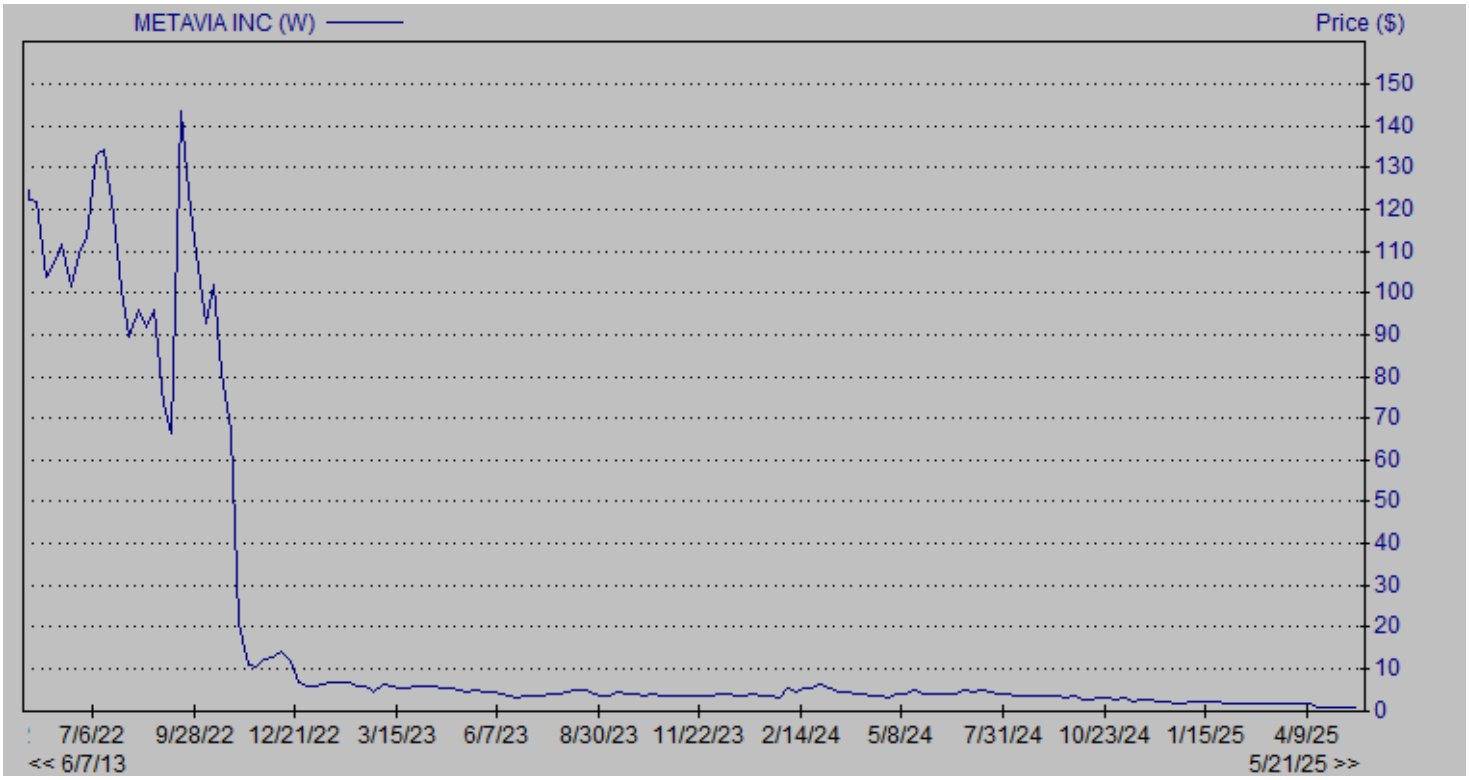
The market's reaction to the MAD data does not seem to align with the quality of the data that the company presented. We aren't sure why this is, but regardless we feel that DA-1726 has the potential to be a very competitive asset in the obesity space. We look forward to the data from the higher dose cohorts and for the company to initiate Part 3 of the trial with Wegovy early dropouts, which has the potential to clearly differentiate the asset. We had previously modeled for better terms for the company's next raise, thus after incorporating the most recent financing into our model our valuation is now at $21 per share.

PROJECTED FINANCIALS

MetaVia Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
DA-1241	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
DA-1726	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & Development	$21.6	$2.3	$4.6	$4.8	$5.0	$16.7	$20.0	$22.0
General & Administrative	$7.3	$1.6	$1.8	$2.0	$2.1	$7.5	$8.0	$8.5
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($28.8)	($3.9)	($6.4)	($6.8)	($7.1)	($24.2)	($28.0)	($30.5)
Operating Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Non-Operating Expenses (Net)	$1.2	$0.2	$0.0	$0.6	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($27.6)	($3.7)	($6.4)	($6.2)	($7.1)	($24.2)	($28.0)	($30.5)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($27.6)**	**($3.7)**	**($6.4)**	**($6.2)**	**($7.1)**	**($24.2)**	**($28.0)**	**($30.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.56)**	**($0.36)**	**($0.32)**	**($0.31)**	**($0.36)**	**($1.38)**	**($1.12)**	**($1.02)**
YOY Growth	-	-	-	-	-	-	-	-
Basic and Diluted Shares Outstanding	7.8	10.3	20.0	20.0	20.0	17.6	25.0	30.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



Source: Zacks SCR

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