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MetaVia Inc. (MTVA-NASDAQ)

MTVA: Compelling Data for DA-1241 in Phase 2a MASH Trial…

Based on our probability adjusted DCF model that takes into account potential future revenues from DA-1241 and DA-1726, MTVA is valued at $23.00/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 (12/20/24)	$1.76
Valuation	**$23.00**

OUTLOOK

On December 18, 2024, MetaVia announced positive topline results from the Phase 2a clinical trial of DA-1241 in patients with presumed metabolic dysfunction-associated steatohepatitis (MASH). The results showed a statistically significant decrease in alanine aminotransferase (ALT) levels, the trials primary outcome, for DA-1241 100 mg at weeks 4 and 8 and statistically significant results were also seen in controlled attenuation parameter (CAP) and hemoglobin A1c. DA-1241 was well tolerated with only 35% of patients on the 100 mg dose reporting a treatment related adverse event (TEAE) compared to 28% on placebo. The company is continuing to evaluate the data and will report additional results, including MRI-PDFF and other exploratory endpoints, in 2025. The company is looking into combination therapy with an advanced compound to help move DA-1241 into late stage trials.

SUMMARY DATA

52-Week High	**$6.52**
52-Week Low	**$1.85**
One-Year Return (%)	**-42.19**
Beta	**-0.25**
Average Daily Volume (sh)	**266,132**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$16**
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 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 A	0 A	0 E	0 E
2025					0 E
2026					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.51 A	-$0.15 A	-$0.75 A	-$1.05 A	-$2.46 A
2024	-$1.32 A	-$1.85 A	-$0.55 A	-$0.69 E	-$3.80 E
2025					-$1.38 E
2026					-$1.15 E

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Business Update

Compelling Results for DA-1241 in Phase 2a MASH Trial

On December 18, 2024, MetaVia Inc. (MTVA) announced positive topline results from the 16-week Phase 2a clinical trial of DA-1241 in patients with presumed metabolic dysfunction-associated steatohepatitis (MASH). The trial had two parts: in Part 1, patients were randomized in a 1:2:1 ratio into three treatment groups (DA-1241 50 mg, DA-1241 100 mg, or placebo). In Part 2, patients were randomized in a 2:1 ratio into two treatment groups (DA-1241 100 mg + 100 mg sitagliptin, or placebo). The primary efficacy outcome was the change in alanine aminotransferase (ALT) levels from baseline at week 16.

The following table gives the least square mean ALT values for each treatment group at baseline, 4 weeks, 8 weeks, and 16 weeks. DA-1241 100 mg treatment resulted in a statistically significant decrease in ALT at week 4 and week 8 and was very near statistical significance at week 16. The combination therapy of DA-1241 and sitagliptin did not show a greater effect than monotherapy DA-1241. The company has imagined that DA-1241 will ultimately be used as a combination therapy, however from this data it is apparent that combination will not be with a DPP-4 inhibitor.

	Placebo (N=23)	DA-1241 100mg + Sitagliptin 100mg (N=34)	P value vs. PBO	DA-1241 50mg (N=12)	P value vs. PBO	DA-1241 100mg (N=22)	P value vs. PBO
Baseline Mean	68.4	63.2		65.8		57.2	
Week 4 LS Mean (95% CI)	-1.51 (-8.23, 5.21)	-8.38 (-13.89, -2.87)*	0.1195	-9.63 (-18.90, -0.35)*	0.1622	-13.44 (-20.32, -6.57)*	0.0159†
Week 8 LS Mean (95% CI)	0.13 (-7.83, 8.09)	-10.27 (-16.80, -3.73)*	0.0479†	-11.05 (-22.04, -0.05)*	0.1050	-12.25 (-20.40, -4.10)*	0.0342†
Week 16 LS Mean (95% CI)	-4.70 (-14.05, 4.65)	-8.24 (-15.91, -0.57)*	0.5624	-16.81 (-29.72, -3.89)*	0.1345	-18.09 (-27.67, -8.52)*	0.0506

Source: MetaVia Inc.

In addition to the change in ALT, a number of secondary efficacy endpoints were evaluated including reductions in controlled attenuation parameter (CAP; measure of fat in the liver):

	Placebo (N=23)	DA-1241 100mg + Sitagliptin 100mg (N=34)	P value vs. PBO	DA-1241 50mg (N=12)	P value vs. PBO	DA-1241 100mg (N=22)	P value vs. PBO
Baseline Mean (dB/m)	347.4	344.1		347.3		336.0	
Week 16 LS Mean CAP Score (dB/m) (95% CI)	-2.32 (-16.17, 11.52)	-20.62 (-31.99, -9.26)*	0.0452†	-8.94 (-28.08, 10.20)	0.5787	-24.32 (-38.54, -10.10)*	0.0308†

* Confidence interval excludes 0, suggesting a statistically meaningful difference.

† p < 0.05 vs. placebo

Source: MetaVia Inc.

and hemoglobin A1c (HbA1c):

	Placebo (N=23)	DA-1241 100mg + Sitagliptin 100mg (N=34)	P value vs. PBO	DA-1241 50mg (N=12)	P value vs. PBO	DA-1241 100mg (N=22)	P value vs. PBO
Baseline Mean	6.78	6.51		6.58		7.01	
Week 16 LS Mean (95% CI)	-0.10 (-0.23, 0.44)	-0.52 (-0.80, -0.25)*	0.0050†	-0.24 (-0.70, 0.22)	0.2357	-0.48 (-0.82, -0.13) *	0.0179†

* Confidence interval excludes 0, suggesting a statistically meaningful difference.

† p < 0.05 vs. placebo

Source: MetaVia Inc.

Lastly, DA-1241 was well tolerated during the study, with only 34.6% of participants reporting any treatment emergent adverse event (TEAE), compared to 28.1% of placebo-treated patients. In addition, there were no serious treatment related adverse events and no participants on DA-1241 discontinued due to a TEAE.

N (%)	Placebo (N=32)	DA-1241 100mg + Sitagliptin 100mg (N=36)	DA-1241 50mg (N=14)	DA-1241 100mg (N=26)
Subjects with any Treatment Related AE	9 (28.1%)	10 (27.8%)	4 (28.6%)	9 (34.6%)
Mild	8 (25.0%)	9 (25.0%)	4 (28.6%)	8 (30.8%)
Moderate	1 (3.1%)	1 (2.8%)	0	1 (3.8%)
Severe	0	0	0	0
Subjects with any Treatment related SAE	0	0	0	0
Subjects with any TEAE leading to study discontinuation	0	1 (3.1 %)	0	0
Subjects with any TEAE leading to study drug discontinuation	1 (3.1 %)	0	0	0

Source: MetaVia Inc.

While it is always difficult to do between-trial comparisons, we still feel it is important for investors to be aware of how DA-1241 compares to other MASH therapies. Rezdiffra® (resmetirom) was approved in March 2024 for the treatment of MASH based in part on the results of a 36-week Phase 2 trial (Harrison *et al*., 2019) and a 52-week Phase 3 trial (Harrison *et al*., 2024). The following table provides a comparison between the results for DA-1241 at 16 weeks and resmetirom at either 12 weeks (for change in ALT) or 52 weeks (for change in CAP and HbA1c). The results show that treatment with DA-1241 for 16 weeks led to a greater change in ALT, a similar change in CAP, and a greater decrease in HbA1c, all of which are indicative of the drug having positive liver-specific effects. In addition, there were fewer treatment emergent adverse events (TEAEs) reported for DA-1241. Overall, we believe the key takeaway for investors is that DA-1241 is showing positive liver-specific effects over a relatively short treatment period that compare favorably to an already approved MASH therapy.

	DA-1241 100 mg	Resmetirom
Alanine Aminotransferase (U/L) LS Mean Change from Baseline (CFB)	-18.09 (week 16)	-8.2* (week 12)
Controlled Attenuation Parameter (dB/m) LS Mean CFB Difference from placebo	-22.0 (week 16)	-26.9^ (week 52)
HbA1c LS Mean % CFB Difference from placebo	-0.38 (week 16)	0.05^ (week 52)
Any Treatment Emergent Adverse Event	34.6%	80.8%^

Sources: Zacks SCR; MetaVia Inc.; *Harrison et al., 2019 PMID: 31727409; ^Harrison et al., 2024 PMID: 38324483

Conclusion

We're very encouraged by the results seen with DA-1241 100 mg in the Phase 2a trial in patients with presumed MASH. The drug was well tolerated and led to positive changes in multiple liver-specific parameters. In addition, the large decrease in HbA1c over such a short treatment period is very encouraging and could prove to be a key differentiating feature of the drug. We look forward to additional data from the trial being reported in 2025, including MRI-PDFF results.

The stock reacted negatively to the data release and there are likely multiple reasons for this, including the fact that the combination arm of DA-1241 and sitagliptin did not show as strong an effect as DA-1241 monotherapy. However, we don't believe investors should focus on this as it is unlikely to offer any read-through to potential future combination therapies that the company may pursue. MetaVia is actively looking to form a partnership, collaboration, or licensing deal to advance DA-1241 into a late-stage MASH trial in combination with another agent, and while we are unsure what form that will take it is unlikely to be with a DPP-4 inhibitor. We anticipate an update from the company on the DA-1241 program following the full analysis of the data set. Following these results, we have slightly increased the probability of approval for DA-1241 in our model, which has increased our valuation to $23 per share.

PROJECTED FINANCIALS

MetaVia Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 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	$9.2	$4.9	$8.1	$4.5	$5.0	$22.5	$13.0	$15.0
Acquired in-process R&D	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
General & Administrative	$6.7	$2.0	$2.0	$1.7	$2.0	$7.7	$7.7	$8.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($15.9)	($6.9)	($10.1)	($6.3)	($7.0)	($30.2)	($20.7)	($23.0)
Operating Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Non-Operating Expenses (Net)	$3.4	$0.2	$0.0	$0.6	$0.0	$0.8	$0.0	$0.0
Pre-Tax Income	($12.5)	($6.7)	($10.1)	($5.7)	($7.0)	($29.4)	($20.7)	($23.0)
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	**($12.5)**	**($6.7)**	**($10.1)**	**($5.7)**	**($7.0)**	**($29.4)**	**($20.7)**	**($23.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.46)**	**($1.32)**	**($1.85)**	**($0.55)**	**($0.69)**	**($3.80)**	**($1.38)**	**($1.15)**
YOY Growth	-	-	-	-	-	-	-	-
Basic and Diluted Shares Outstanding	5.1	5.1	5.4	10.2	10.2	7.7	15.0	20.0

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

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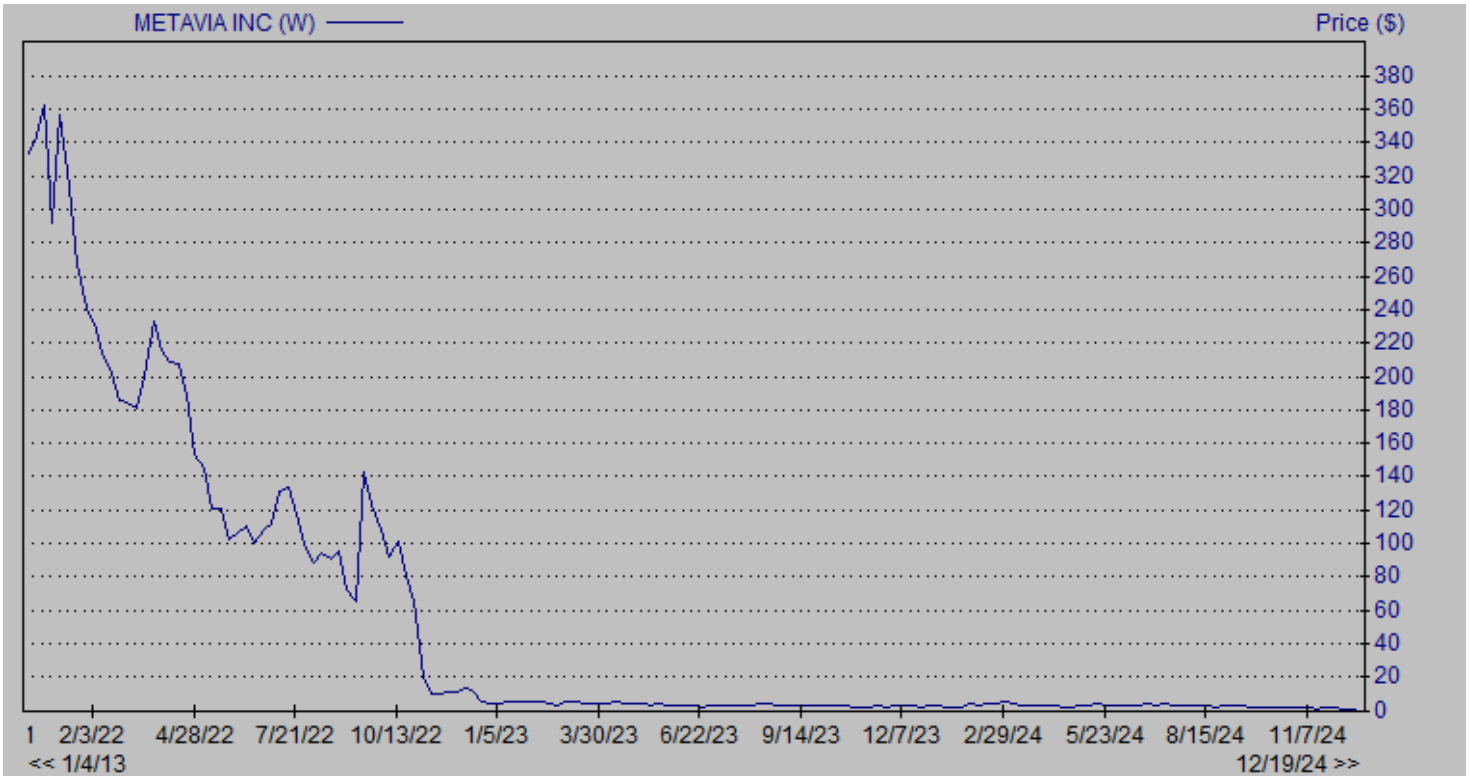
HISTORICAL STOCK PRICE



Source: Zacks SCR

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