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April 16, 2025
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MetaVia Inc. (MTVA-NASDAQ)

MTVA: Positive Phase 1 MAD Data for DA-1726; Excellent Tolerability Profile and Mean Day 26 Weight Loss of 4.3%…

Based on our probability adjusted DCF model that takes into account potential future revenues from DA-1241 and DA-1726, MTVA is valued at $25.00/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 (04/16/25)	$0.81
Valuation	**$25.00**

OUTLOOK

On April 15, 2025, MetaVia Inc. (MTVA) announced positive results from the 4-week Phase 1 multiple ascending dose (MAD) trial of DA-1726 for the treatment of obesity. The results showed a mean weight loss of 4.3% at Day 26 in the 32 mg dose with only mild gastrointestinal (GI) adverse events reported in 4/6 subjects, most of which resolved within 24 hours. In addition, a mean reduction in waist circumference of 1.6 inches was demonstrated along with a mean lowering of -5.3 mg/dL in fasting blood glucose. The company is planning to initiate Part 3 of the Phase 1 trial in Wegovy® early drop-out patients in an effort to show superiority with respect to tolerability and safety. Part 3 of the Phase 1 trial should initiate in the 4Q25.

SUMMARY DATA

52-Week High	**$5.00**
52-Week Low	**$1.45**
One-Year Return (%)	**-60.67**
Beta	**0.22**
Average Daily Volume (sh)	**25,244**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$13**
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	**Average**
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 E	0 E	0 E	0 E	0 E
2026					0 E
2027					0 E

Earnings per Share

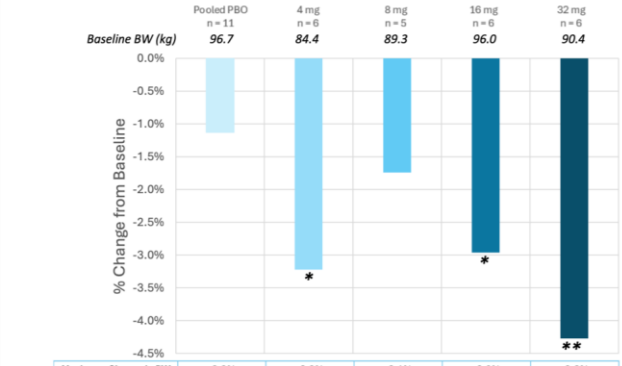
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$1.32 A	-$1.85 A	-$0.55 A	-$0.50 A	-$3.56 A
2025	-$0.57 E	-$0.62 E	-$0.52 E	-$0.51 E	-$2.26 E
2026					-$1.65 E
2027					-$1.53 E

Business Update

Positive Phase 1 MAD Data for DA-1726

On April 15, 2025, MetaVia Inc. (MTVA) announced positive results from the Phase 1 Part 2 multiple ascending dose (MAD) trial of DA-1726 in obesity. The results showed that the cohort receiving 32 mg of DA-1726 with no titration had a maximum reduction in body weight from baseline ranging up to -6.3% and a mean body weight reduction of -4.3% (-3.1% placebo adjusted; *P*=0.0005). In addition, patients in the 32 mg cohort had a mean waist circumference reduction of 1.6 inches along with a mean reduction in fasting glucose of -5.3 mg/dL. Importantly, gastrointestinal (GI) adverse events (AEs) were generally mild and most were only seen after the first dose and resolved within 24 hours of occurrence.

The following chart shows the average weight loss on Day 26 for the different dosing cohorts. The 4 mg cohort had an outlier that skewed the overall average weight loss, however the 8 mg, 16 mg, and 32 mg cohorts show a clear dose response.



Maximum Change in BW	-2.9%	-6.9%	-6.1%	-6.0%	-6.3%
% Change in mean BW	-1.1%	-3.2%	-1.7%	-3.0%	-4.3%
kg Change in mean BW		-2.7 kg	-1.6 kg	-2.9 kg	-4 kg
Placebo Adjusted		-2.1%	-0.6%	-1.8%	-3.1%
p-Value vs. Placebo		0.0187	0.6740	0.0217	0.0005

Source: MetaVia, Inc. **p<0.05 **p<0.001*

DA-1726 showed an overall favorable safety and tolerability profile, as shown in the following chart. All of the AEs in the 32 mg cohort were considered mild and there were no treatment-related discontinuations. In addition, there was no diarrhea reported as well as no significant changes in heart rate in this cohort. The three subjects who experienced vomiting in the 32 mg cohort all reported it after the first dose but with no reoccurrence. Similarly, the two subjects who experienced mild nausea after the first dose reported that it resolved within 12 hours and there were no additional reports of nausea after the 2nd and subsequent doses. Overall, we view the AE profile observed thus far as a clear differentiator for DA-1726.

GI Treatment Emergent Adverse Events, by Severity

GI Treatment Emergent Adverse Events Number of subjects reporting (%)	Pooled PBO n = 12	Pooled DA1726 n = 24	4 mg n = 6	8 mg n = 6	16 mg n = 6	32 mg n = 6
Gastrointestinal disorders	**1 (8.3%)**	**6 (25.0%)**	**1 (16.7%)**	**0**	**1 (16.7%)**	**4 (66.7%)**
Mild	1 (8.3%)	5 (20.8%)	1 (16.7%)	0	0	4 (66.7%)
Moderate	0	1 (4.2%)	0	0	1 (16.7%)	0
Severe	0	0	0	0	0	0
Vomiting	**1 (8.3%)**	**4 (16.7%)**	**0**	**0**	**1 (16.7%)**	**3 (50.0%)**
Mild	1 (8.3%)	3 (12.5%)	0	0	0	3 (50.0%)
Moderate	0	1 (4.2%)	0	0	1 (16.7%)	0
Severe	0	0	0	0	0	0
Nausea	**1 (8.3%)**	**3 (12.5%)**	**0**	**0**	**1 (16.7%)**	**2 (33.3%)**
Mild	1 (8.3%)	2 (8.3%)	0	0	0	2 (33.3%)
Moderate	0	1 (4.2%)	0	0	1 (16.7%)	0
Severe	0	0	0	0	0	0
Constipation	**0**	**3 (12.5%)**	**1 (16.7%)**	**0**	**0**	**2 (33.3%)**
Mild	0	3 (12.5%)	1 (16.7%)	0	0	2 (33.3%)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Abdominal distension	**0**	**1 (4.2%)**	**0**	**0**	**0**	**1 (16.7%)**
Mild	0	1 (4.2%)	0	0	0	1 (16.7%)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Source: MetaVia, Inc.

The MAD data reported for DA-1726 compares well with other weight loss therapies, both in terms of efficacy and tolerability. The following charts are intended to put the MAD data for DA-1726 into context with what else has been reported and is not intended as a direct head-to-head comparison, particularly given the differences in the various clinical trials. However, it is clear that 32 mg DA-1726 (while still early with only 4-week data reported) has a number of positive characteristics, most notably in the tolerability profile, that could make it competitive in the obesity treatment space.

	DA-1726	Pemvidutide[1]	Mazdutide[2]	Survodutide[3]	Tirzepatide[4]
Developer	MetaVia	Altimmune	Innovent/Lilly	Boehringer Ingelheim/Zealand	Lilly
Status	Phase 1	Phase 3 ready	Phase 2/3	Phase 3	Marketed (Obesity/Zepbound®)
Action	GLP-1R/GCGR (3:1)	GLP-1R/GCGR (1:1)	GLP-1R/GCGR (Unknown)	GLP-1R/GCGR (8:1)	GLP-1R/GIPR
Administration	Once weekly injection	Once weekly injection	Once weekly injection	Once weekly injection	Once weekly injection
Body Weight Loss in Phase 1 MAD	6.3% Max (32mg) 4.3% Mean (32mg) @ 4 weeks (26 days) (no titration)	Phase 1b 12 weeks (no titration) 10.3% (1.8mg) 9% (2.4mg)	*Placebo adjusted* *(Innovent 2022 trial)* Phase 1b 9.8% (9mg) @ 12 weeks 6.2% (10mg) @ 16 weeks	*Placebo adjusted* Phase 1 6 weeks 5.79% (titration to 0.45mg) 4.5% (titration to 3mg)	-4.05kg @ 4 weeks (10mg w/ titration, 7 healthy patients) Phase 3 20.9% @ 72 weeks
Fasting Glucose (mg/dL)	-5.3 @ Day 26 (32mg) Maximum -18 @ Day 26	-0.8 @ 12 weeks (2.4mg)	-2.3 @ 12 weeks (6mg)	Phase 1 6 weeks did not show any treatment effect at any time point Max -8.7 @ day 107 (close to week 16)	Phase 1 @ 4 weeks 10mg w/titration: -6.41 (healthy patients)
Waist Circumference (cm)	-4cm (1.6 inches) @ Day 33 (32mg) Maximum -10cm (4 inches) @ Day 33 -3.7cm @ Day 47 (32mg)	-10.2cm @ 24 weeks (2.4mg)	-5.8cm @ 12 weeks (9mg) -3.36cm @16 weeks (10mg)	-10.5cm @ 16 weeks (twice a week 1.8mg, obese T2D patients)	-4.9cm @ 12 weeks (15mg, obese T2D patients) -18.5cm @ 72 weeks (15mg)

❖ ***Data in the above table were gathered from publicly available company reports, scientific journals and posters. As each clinical study presented above vary in protocol design, study population, baseline characteristics, duration, titration scheme and dose levels, this table is not intended to provide direct comparison nor a result of head-to-head study. This is only to show potential trends not direct comparison.***

1. Company presentations, including, Stephen A. Harrison et al., 2022 EASL Conference, Pemvidutide (ALT-801), a novel GLP-1/glucagon dual receptor agonist, achieves rapid and potent reductions in body weight and liver fat: Results of a placebo controlled, double blinded, first-in-human (FIH) clinical trial
2. Linong Jin et al., 2022, eClinicalMedicine 2022:54: 101691, Linong Ji et al., 2021, eclinicalMedicine 39 (2021) 101088
3. Arvid Jungnik et al., 2022, Wiley, DOI: 10.1111/dom.14948, Matthias Blüher et al., 2023, Diabetologia DOI: 10.1007/s00125-023-06053-9
4. Tamer Coskun et al., 2018, Molecular Metabolism 18, DOI: 10.1016/j.molmet.2018.09.009, Juan Pablo Frias et al., 2020, Wiley, DOI: 10.1111/dom.13979

MetaVia 3

Source: MetaVia, Inc.

In particular for the tolerability profile, we note that DA-1726 did not induce diarrhea (unlike the other four listed compounds), showed a lower rate of nausea (33% compared to 42.9-91%), and had no discontinuations due to AEs (compared to 7.5% at 6 weeks for survodutide). With reports that up to approximately 1/3rd of patients discontinue GLP-1 agonist therapy within 12 months of initiating (Do *et al*., 2024), a strong safety and tolerability profile is an important differentiating factor for an obesity therapy.

	DA-1726	Pemvidutide	Mazdutide	Survodutide	Tirzepatide
Developer	MetaVia	Altimmune	Innovent/Lilly	Boehringer Ingelheim/Zealand	Lilly
Status	Phase 1	Phase 3 ready	Phase 2/3	Phase 3	Marketed (Obesity/Zepbound®)
Action	GLP-1R/GCGR (3:1)	GLP-1R/GCGR (1:1)	GLP-1R/GCGR (Unknown)	GLP-1R/GCGR (8:1)	GLP-1R/GIPR
Administration	Once weekly injection	Once weekly injection	Once weekly injection	Once weekly injection	Once weekly injection
Adverse Events	*Phase 1 MAD (32mg) @ 4 weeks (26 days)*	*Phase 1 MAD (2.4mg) @ 12 weeks*	*Phase 1b (9mg) @ 12 weeks* 100% with at least 1 TEAE	*Phase 1 @ 6 weeks*	*Phase 1 MAD (10mg w/titration) @ 4 weeks*
	50% mild vomiting 2 subjects after 1st dose (n=3, resolved in 9h)	72.8% mild or moderate vomiting	37.5% vomiting	25.4% vomiting	42.9% vomiting
	33% mild nausea only after 1st dose (n=2, resolved in 12h)	91% mild or moderate nausea	62.5% nausea	70% nausea	42.9% nausea
	33% constipation no diarrhea	18.2% constipation	25% diarrhea	10.4% constipation	28.6% diarrhea
	16.7% abdominal distension (n=1, 14hr)	18.2% diarrhea	50% abdominal distension	28.4% diarrhea	14.3% abdominal distension
Discontinuations Due to AEs	No discontinuations	Phase 1 MAD @ 12 weeks, no discontinuations 19.6% @ 48 weeks	No discontinuations	Phase 1 @ 6 weeks 7.5% Phase 2 @ 46 weeks 24.6%	Phase 3: 6.2% for 15mg

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4. Tamer Coskun et al., 2018, Molecular Metabolism 18, DOI: 10.1016/j.molmet.2018.09.009

MetaVia 4

Source: MetaVia, Inc.

Due to the strong tolerability profile of DA-1726, the company will be adding at least one additional MAD cohort to try to determine the maximum tolerated dose of the drug. Those results could be available in the second half of 2025.

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 profile and weight loss. The interim data readout for this trial should occur in the first half of 2026.

Conclusion

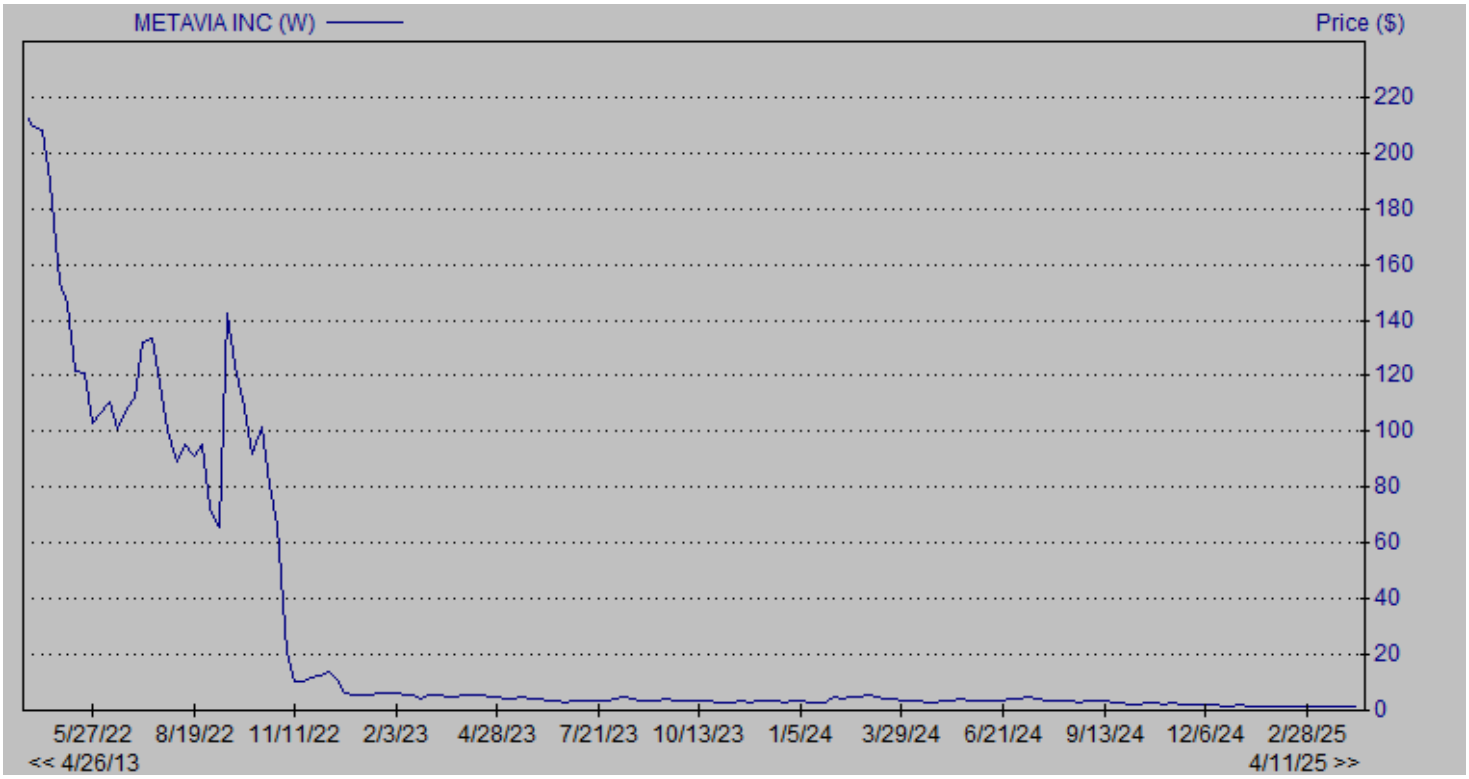
We think the MAD data presented for DA-1726 is very encouraging and we are perplexed at the reaction from the stock. While there were rumors that the company was selling stock into the initial pop in the share price that occurred in the pre-market, we confirmed with management that the company does not have an active ATM facility and that the company was not selling shares. With an additional data readout in the second half of 2025 from the additional MAD cohort(s) and interim data for Part 3 of the Phase 1 trial expected in the first half of 2026 we view the drop in the share price as a great buying opportunity. Based on this data, particularly the compelling safety and tolerability data, we have increased our valuation to $25 per share.

PROJECTED FINANCIALS

MetaVia Inc.	2024 A	Q1 E	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	$4.3	$4.6	$4.8	$5.0	$18.7	$20.0	$22.0
General & Administrative	$7.3	$1.7	$1.8	$2.0	$2.1	$7.6	$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)	($6.0)	($6.4)	($6.8)	($7.1)	($26.3)	($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)	($5.8)	($6.4)	($6.2)	($7.1)	($26.3)	($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)**	**($5.8)**	**($6.4)**	**($6.2)**	**($7.1)**	**($26.3)**	**($28.0)**	**($30.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.56)**	**($0.57)**	**($0.62)**	**($0.52)**	**($0.51)**	**($2.26)**	**($1.65)**	**($1.53)**
YOY Growth	-	-	-	-	-	-	-	-
Basic and Diluted Shares Outstanding	7.8	10.3	10.3	12.0	14.0	11.7	17.0	20.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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