# Zacks Small-Cap Research

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## MetaVia Inc. (MTVA-NASDAQ)

***MTVA: NeuroBo Becomes MetaVia; Topline Results for Phase 2a Trial of DA-1241 in MASH Expected in December 2024…***

Based on our probability adjusted DCF model that takes into account potential future revenues from DA-1241 and DA-1726, MTVA is valued at $22.00/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 (12/03/24) | $2.60 |
| **Valuation** | **$22.00** |

## OUTLOOK

On November 18, 2024, NeuroBo Pharmaceuticals, Inc. (NRBO) announced a strategic realignment with a name change to MetaVia Inc. (MTVA). The change became effective on November 29, 2024. We are republishing the latest research report under the MTVA ticker.

On November 7, 2024, MetaVia announced financial results for the third quarter of 2024 and provided a business update. The next clinical milestone will be the release of topline data from the Phase 2a trial of DA-1241 in MASH. The trial is exploring the efficacy of DA-1241 both as a monotherapy and in combination with sitagliptin. The primary endpoint is the change from baseline in alanine aminotransferase (ALT) levels at Week 16, and secondary endpoints are exploring additional metabolic parameters. Following the release of of positive topline results from the SAD Part 1 of the Phase 1 trial of DA-1726 in obesity, in the first quarter of 2025 we anticipate results from the MAD Part 2 of the Phase 1 trial.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$6.52** |
| **52-Week Low** | **$2.22** |
| **One-Year Return (%)** | **-33.67** |
| **Beta** | **-0.25** |
| **Average Daily Volume (sh)** | **31,361** |
| **Shares Outstanding (mil)** | **9** |
| **Market Capitalization ($mil)** | **$22** |
| **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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## WHAT'S NEW

**Business Update**

*NeuroBo Becomes MetaVia*

On November 18, 2024, NeuroBo Pharmaceuticals, Inc. (NRBO) announced a strategic realignment ahead of upcoming clinical milestones along with a corporate name change to MetaVia Inc. (MTVA). The change went into effect on November 29, 2024. We are republishing the latest research report under the MTVA ticker.

*Topline Results from Phase 2a Trial of DA-1241 in MASH Expected in December 2024*

MetaVia Inc. is developing DA-1241 as a treatment for metabolic dysfunction-associated steatohepatitis (MASH; formerly NASH). DA-1241 is a novel chemical entity that selectively activates GPR119, stimulates the secretion of insulin and incretin hormones such as glucagon-like peptide-1 (GLP-1), reduces plasma glucose levels without causing hypoglycemia, and lowers plasma lipid levels of both triglycerides and cholesterol.

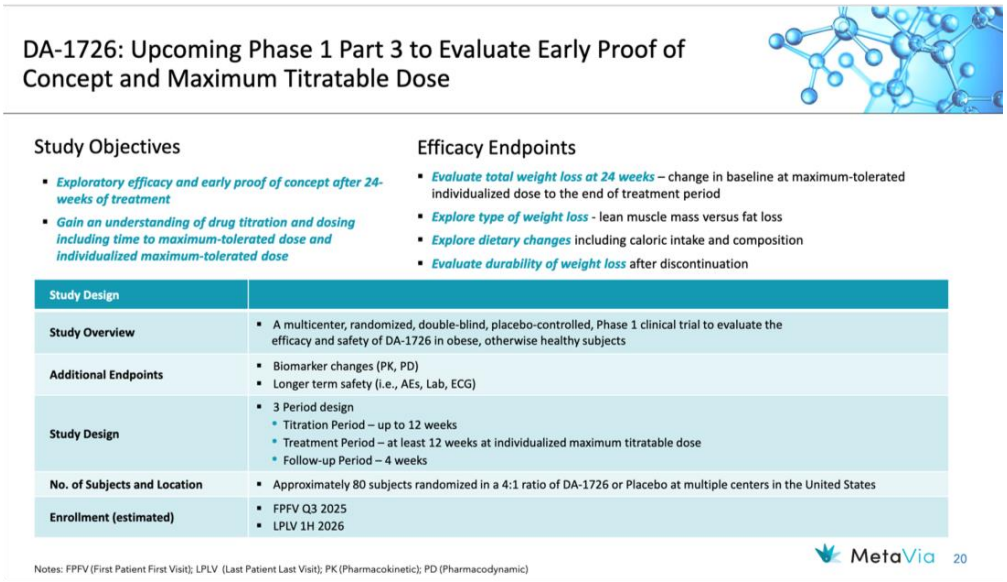
The current Phase 2a trial has two parts: Part 1 is examining DA-1241 as a monotherapy while Part 2 is examining DA-1241 in combination with sitagliptin. For Part 1, subjects were randomized in a 1:2:1 ratio into three treatment groups: DA-1241 50 mg, DA-1241 100 mg, or placebo. For Part 2, subjects were randomized in a 2:1 ratio into two treatment groups: DA-1241 100 mg/sitagliptin 100 mg or placebo. A total of 109 subjects were randomized into the study, with 95 subjects completing dosing. For both Part 1 and Part 2, the primary endpoint is the change from baseline in alanine aminotransferase (ALT) levels at Week 16. Secondary endpoints include the proportion of subjects with normalization of ALT, absolute change in total cholesterol, low and high-density lipoprotein cholesterol, triglycerides, and free fatty acids from baseline. We anticipate topline results from both Part 1 and Part 2 of the study in December 2024.

*MAD Part 2 Results from Phase 1 Trial of DA-1726 Expected in 1Q25*

In September 2024, MetaVia announced positive topline results for the single ascending dose (SAD) Part 1 of the ongoing Phase 1 clinical trial of DA-1726 for the treatment of obesity. A total of 45 obese but otherwise healthy individuals were randomized in a double blind, 6:3 ratio to receive DA-1726 or placebo. The results showed that DA-1726 was safe, well tolerated, and had linear pharmacokinetics (PK). In regards to safety, only five subjects in the DA-1726 group reported adverse events (AEs) compared to three subjects in the placebo group. Due to the strong safety profile, at least one additional dosing cohort is being added to evaluate the maximum tolerated dose.

The multiple ascending dose (MAD) Part 2 of the trial is ongoing, with the first patient enrolled in June 2024. A total of 36 individuals are expected to be enrolled in Part 2 of the trial in a 6:3 ratio across four dosing cohorts. Each participant will receive four weekly administrations of DA-1726 or placebo. The last patient visit is expected in the fourth quarter of 2024 and topline results from Part 2 are expected in the first quarter of 2025.

The company continues planning for Part 3 of the trial, which we anticipate initiating in the third quarter of 2025, with an interim data readout in mid-2026 and topline results being reported in the second half of 2026. The following slide provides an overview of Part 3 of the trial, which will evaluate early proof of concept and maximum titratable dose of DA-1726.




*Source*: MetaVia Inc.

## Financial Update

On November 7, 2024, MetaVia announced financial results for the third quarter of 2024. As expected, the company did not report any revenues in the third quarter of 2024. R&D expenses for the third quarter of 2024 were approximately $4.5 million compared to approximately $2.3 million for the third quarter of 2023. The increase was primarily due to higher expenditures for DA-1241 and DA-1726 related to the Phase 2a trial for DA-1241 and the Phase 1 trial of DA-1726. G&A expenses were approximately $1.7 million for the third quarter of 2024 compared to $1.6 million for the third quarter of 2023. The increase was primarily due to higher employee compensation and benefits partially offset by lower legal and professional fees.

As of September 30, 2024, MetaVia had approximately $21.7 million in cash and cash equivalents. We anticipate the company currently has sufficient capital to finance operations into the third quarter of 2025. Assuming positive results from the MAD Part 2 portion of the Phase 1 trial, we expect the Series A warrants from the June 2024 financing could be exercised in the first half of 2025 resulting in gross proceeds of $20 million. As of August 9, 2024, MetaVia had approximately 8.6 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 23.1 million.

## Conclusion

We look forward to topline results from the Phase 2a trial of DA-1241 in MASH in December 2024. Comparisons with other MASH therapies will likely be difficult as this is a small Phase 2a trial and these results will be used to confirm the safety of DA-1241 and look for trends in efficacy as the company plans larger, confirmatory trials. With no changes to our model our valuation remains at $22 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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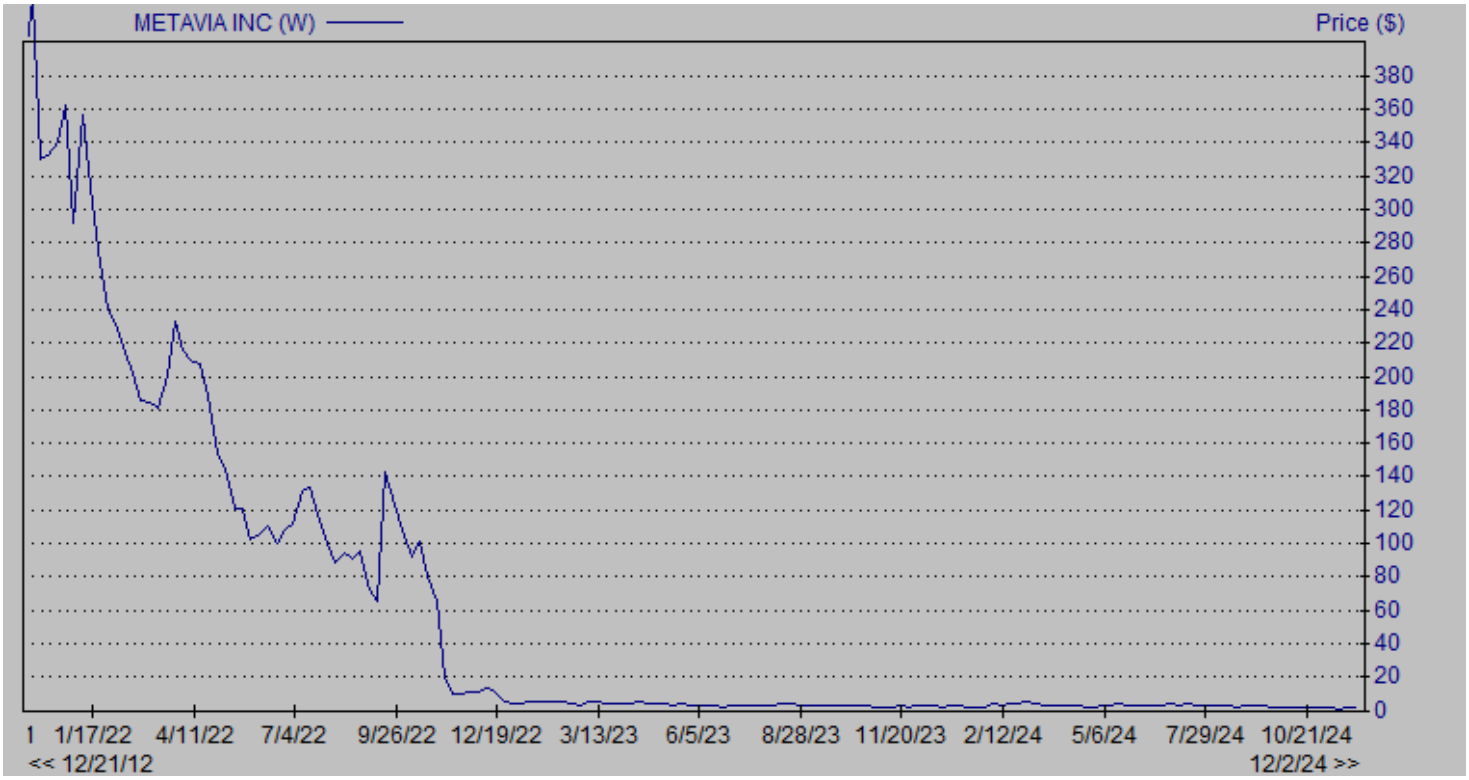
## HISTORICAL STOCK PRICE




Source: Zacks SCR

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