2023年2月28日

# Zacks Small-Cap Researchによる当社レポートの発表に関するお知らせ

現地時間の2月27日、米国シカゴに本拠を置く投資家向け情報サービス企業Zacks Small-Cap ResearchのDavid Bautz氏による、当社レポートが発表されましたので、参考情報としてお知らせいたします。

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【Zacks Small-Cap Research公式webサイト】
https://scr.zacks.com/

※当該レポートは、本書の下部にございますので、スクロールしてご確認ください。

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# MediciNova, Inc. (MNOV-NASDAQ)

## *MNOV: Phase 1/2 Clinical Trial of MN-166 in GBM Fully Enrolled…*

Based on our probability adjusted DCF model that takes into account potential future revenues from MN-166 in ALS, progressive MS, addiction, and as an MCM; and MN-001 in NAFLD, MNOV is valued at $27.00/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 (02/27/23) | $2.23 |
| **Valuation** | **$27.00** |

## OUTLOOK

MediciNova, Inc. (MNOV) recently filed form 10-K with financial results for the full year 2022. The company recently announced that the Phase 1/2 clinical trial MN-166 (ibudilast) in combination with temozolomide (TMZ) in patients with glioblastoma is fully enrolled. Efficacy data from Part 2 of the trial may be available in the second half of 2023. In December 2022, MediciNova presented positive results from a subgroup analysis of the completed Phase 2 clinical trial of MN-001 that showed patients with Type 2 diabetes (T2DM) showed greater improvement in serum lipid profile than those without T2DM. A trial evaluating MN-001 in patients with T2DM, non-alcoholic fatty liver disease (NAFLD), and hypertriglyceridemia is currently ongoing.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$3.14** |
| **52-Week Low** | **$1.97** |
| **One-Year Return (%)** | **-7.47** |
| **Beta** | **0.91** |
| **Average Daily Volume (sh)** | **15,434** |
| **Shares Outstanding (mil)** | **49** |
| **Market Capitalization ($mil)** | **$109** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **25** |
| **Insider Ownership (%)** | **17** |
| **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 2018 Estimate** | **N/A** |
| **P/E using 2019 Estimate** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Average** |
| **Type of Stock** | **Small-Value** |
| **Industry** | **Med-Biomed/Gene** |

## 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 E | 0 E | 0 E | 0 E | 0 E |
| 2024 | | | | | 0 E |
| 2025 | | | | | 0 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2022 | -$0.07 A | -$0.08 A | -$0.07 A | -$0.06 A | -$0.29 A |
| 2023 | -$0.07 E | -$0.07 E | -$0.08 E | -$0.08 E | -$0.30 E |
| 2024 | | | | | -$0.32 E |
| 2025 | | | | | -$0.35 E |

## WHAT'S NEW

**Business Update**

*GBM Trial Fully Enrolled*

On January 12, 2023, MediciNova, Inc. (MNOV) announced that the Phase 2 trial of MN-166 (ibudilast) in combination with temozolomide (TMZ) for the treatment of glioblastoma (GBM) is fully enrolled (NCT03782415). This is a two-part trial taking place at Dana-Farber Cancer Institute; Part 1 of the trial evaluated the safety and tolerability of MN-166 in combination with TMZ and determined the optimal dose of MN-166 to use in Part 2 of the study. Part 2 will evaluate the efficacy of MN-166 and TMZ as measured by the proportion of subjects who are progression-free at 6 months. Additional outcome measures will include overall survival, response rate, and median six-month progression-free survival.

On February 20, 2023, MediciNova announced the presentation of new data regarding tumor tissue analysis and clinical outcome from Part 1 of the study (the dose ranging portion of the trial). The tumor tissues were analyzed to determine potential predictors of tumor response to MN-166 and TMZ combination therapy. Study participants were divided into two groups: non-responders (disease progression within five months of receiving MN-166/TMZ) and responders (no disease progression for five months after receiving MN-166/TMZ). The data showed that responders had a lower percentage of CD3+ T cells than non-responders ($P$<0.05). In addition, CD74 expression was also lower in the responders compared to the non-responders ($P$=0.06). The best predictor for tumor progression for five months in recurrent GBM patients was CD3 expression.

The use of MN-166 in GBM is based on a proteomic profiling study of GBM samples from 30 GBM patients which was presented at the 2017 American Society of Clinical Oncology (ASCO) annual meeting (McDonald *et al*). The results showed that macrophage migration inhibitory factor (MIF) was expressed in "poor responders" (e.g., those that lived < 1 year). MIF is an inflammatory-related cytokine that is secreted by cancer stem cells. The researchers then examined an additional 168 GBM samples and found co-expression of MIF and its receptor CD74 in 57% of the samples. In addition, co-expression of MIF and CD74 was significantly associated with poor survival. These results point to MIF being a suitable target for GBM treatment. MN-166 is an inhibitor of MIF (Cho *et al*., 2010).

*Additional Positive Developments from MN-001 Study in NAFLD*

In December 2022, MediciNova announced the presentation of positive results from a subgroup analysis of the completed Phase 2 clinical trial of MN-001 (tipelukast) for the treatment of hypertriglyceridemia (HTG). In the trial, MN-001 significantly reduced serum triglycerides in participants with non-alcoholic fatty liver disease (NAFLD) and HTG. The subgroup analysis examined was conducted in participants with and without type 2 diabetes mellitus (T2DM). The results showed that:

- The T2DM group showed a greater reduction in serum triglyceride level at Week 8 compared to those without T2DM (50.8% reduction for those with T2DM versus 17.8% reduction for those without T2DM, $P$=0.098).

- Those with T2DM had a mean high-density lipoprotein cholesterol (HDL-C) increase at Week 8 that was significantly greater than those without T2DM (15.8% versus 1.0%, $P$<0.0002).

- The T2DM group showed a greater reduction in serum low-density lipoprotein cholesterol (LDL-C) at Week 8 compared to those without T2DM (15.4% versus 6.7%).

These results are very encouraging as numerous studies have reported that approximately 50% of patients with metabolic syndrome also have NAFLD. It also supports the rationale for the company's ongoing clinical trial of MN-001 in patients with NAFLD, T2DM, and HTG.

*Long COVID Trial Cleared to Initiate by Health Canada*

On February 8, 2023, MediciNova announced that Health Canada granted authorization to commence RECLAIM (Recovering from COVID-19 Lingering Symptoms Adaptive Integrative Medicine Trial), which is a grant-funded, multi-center, randomized clinical trial to evaluate MN-166 and other therapies for the treatment of Long COVID. The University Health Network is conducting the trial, which is being funded by the Canadian government through the Canadian Institutes of Health Research.

This study is an excellent opportunity for MediciNova. Since it is a grant funded study the company will not have to expend any financial resources other than drug supply. Grant funding is incredibly competitive, thus the fact that a study involving MN-166 got selected for funding is very encouraging. Lastly, Long COVID could represent a tremendous opportunity given the number of patients that could be affected by the condition.

Following an infection with SARS-CoV-2, the virus that causes COVID-19, approximately 30% of patients will experience symptoms that last for weeks or months, which is referred to as Long COVID. The range of symptoms varies from patient to patient, however the most commonly reported (from a meta analysis) were fatigue (58%), headache (44%), attention disorder (27%), hair loss (25%), and dyspnea (24%) (Lopez-Leon *et al*., 2021). With approximately 200 million individuals already having been infected with SARS-CoV-2 in the U.S., and greater than one billion around the world, there are a very large number of potential Long COVID patients. There are currently no treatment options available for Long COVID.

*New Parenteral Formulation for MN-166*

In January 2023, MediciNova announced the completion of a Phase 1 clinical trial to evaluate MN-166 10 mg intravenous infusion in healthy volunteers. The parenteral formulation had a favorable safety profile and was well tolerated. In addition, there were no concerning adverse events (AEs), all AEs were mild, all study drug-related AEs were mild, and none of the AEs were unexpected.

This new formulation will provide health care providers another option for administering MN-166, such as in acute care settings where a patient is unable to take an oral dose, and potentially other indications that require injections in precise locations. Lastly, a parenteral formulation will allow MN-166 to be evaluated in additional target indications that aren't currently available with an oral formulation.

*Phase 2 Alcohol Use Disorder Trial Fully Enrolled*

In January 2023, MediciNova announced that the Phase 2b clinical trial of MN-166 for the treatment of alcohol use disorder (AUD) has completed enrollment. This is a randomized, double blind, placebo controlled outpatient clinical trial that enrolled 102 treatment-seeking individuals with moderate or severe AUD (NCT03594435). Participants took MN-166 (50 mg) or placebo twice a day for 12 weeks and completed the NIAAA-developed web-based program *Take Control*. The primary endpoint of the trial is the decrease in percent heavy drinking days (defined as ≥5 drinks for men and ≥4 drinks for women) compared to placebo over the course of the 12-week trial. Secondary endpoints will test the efficacy of MN-166 on: 1) the number of drinks consumed per day; 2) the number of drinks consumed per drinking day; 3) the percentage of days abstinent; 4) the percentage of subjects with no heavy drinking days; and 5) the percentage of subjects who are abstinent.

This is an NIH sponsored study being conducted by Dr. Lara Ray, who previously conducted two positive small trials of MN-166 in AUD. MediciNova provided drug supply and regulatory support for the study, however the company is not expending any financial resources for the trial. Data from the trial is likely later this year.

**Financial Update**

On February 16, 2023, MediciNova filed Form 10-K with financial results for the full year 2022. The company did not report any revenues in 2022 compared to $4.0 million for the year ended December 31, 2021. The revenue in 2021 was related to the achievement of milestones from an assignment agreement with Genzyme. Net loss for 2022 was $14.1 million, or $0.29 per share, compared to a net loss of $10.1 million, or $0.21 per share, for 2021. R&D expenses in 2022 were $9.1 million compared to $8.5 million in 2021. The increase was

primarily due to an increase in MN-166 and MN-221 related expenses. G&A expenses in 2022 were $5.5 million compared to $5.7 million in 2021. The decrease was primarily due to decreased non-cash stock-based compensation partially offset by increased compensation costs and increased accounting expenses.

MediciNova exited 2022 with approximately $58.5 million in cash and investments (bank CDs). We estimate the company has sufficient capital to fund operations at least through the end of 2024. As of February 13, 2023, the company had approximately 49.0 million shares outstanding and when factoring in stock options a fully diluted share count of approximately 57.0 million.

## Conclusion

MediciNova has multiple potential catalysts in 2023, including results from chlorine gas-induced acute lung injury preclinical studies under an agreement with BARDA and topline data for the recently fully enrolled Phase 1/2 GBM study and the Phase 2b AUD study, although we are unsure of the exact timing of those data releases. The subgroup analysis for the HTG study of MN-001 is very encouraging and provides solid support for the company's decision to focus on patients with T2DM in the ongoing clinical trial of MN-001 in NAFLD, T2DM, and HTG. We have made no changes to our model and our valuation remains at $27.

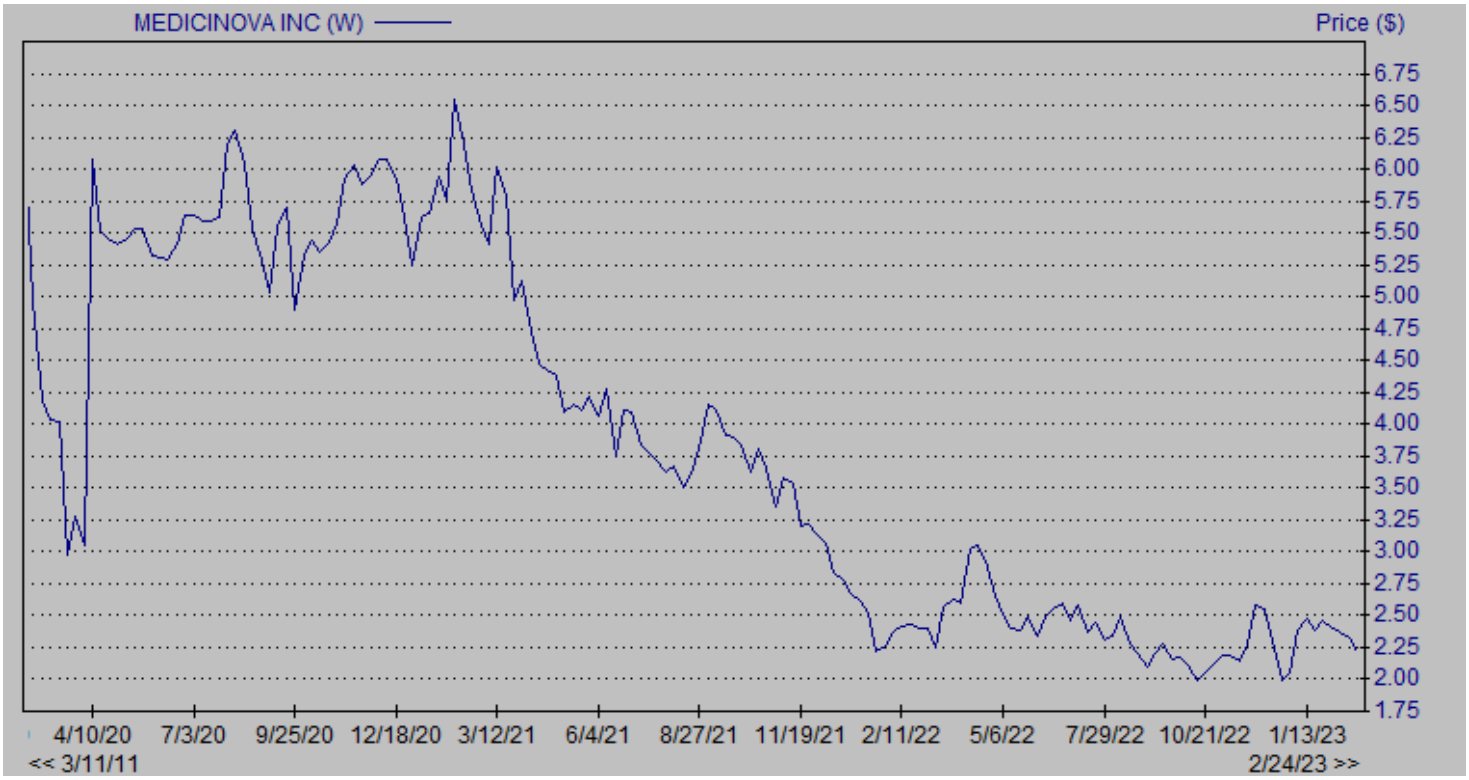
## PROJECTED FINANCIALS

**MediciNova Inc.**
Income Statement

| MediciNova, Inc. | 2022 A | Q1 E | Q2 E | Q3 E | Q4 E | 2023 E | 2024 E | 2025 E |
|---|---|---|---|---|---|---|---|---|
| MN-166 (Multiple Sclerosis) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| MN-166 (ALS) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| MN-166 (Addiction) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| MN-166 (DCM) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| MN-001 (NASH) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Grants & Collaborative Revenue | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| **Total Revenues** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| Cost of Sales | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Product Gross Margin* | - | - | - | - | - | - | - | - |
| Research & Development | $9.1 | $2.2 | $2.3 | $2.5 | $2.6 | $9.6 | $10.0 | $11.0 |
| General & Administrative | $5.5 | $1.3 | $1.4 | $1.5 | $1.6 | $5.8 | $6.0 | $6.5 |
| Other Expenses | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Operating Income | ($14.6) | ($3.5) | ($3.7) | ($4.0) | ($4.2) | ($15.4) | ($16.0) | ($17.5) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Non-Operating Expenses (Net) | $0.6 | $0.2 | $0.2 | $0.2 | $0.2 | $0.8 | $0.1 | $0.1 |
| Pre-Tax Income | ($14.1) | ($3.3) | ($3.5) | ($3.8) | ($4.0) | ($14.6) | ($15.9) | ($17.4) |
| Income Taxes Paid | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **Net Income** | **($14.1)** | **($3.3)** | **($3.5)** | **($3.8)** | **($4.0)** | **($14.6)** | **($15.9)** | **($17.4)** |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.29)** | **($0.07)** | **($0.07)** | **($0.08)** | **($0.08)** | **($0.30)** | **($0.32)** | **($0.35)** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Basic Shares Outstanding | 49.045 | 49.050 | 49.050 | 49.050 | 49.050 | 49.050 | 49.200 | 49.500 |

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

## HISTORICAL STOCK PRICE




Source: Zacks Small Cap Research

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