2022年11月19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2022年11月18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
Sponsored – Impartial - Comprehensive

November 18, 2022
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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Well Financed to Get Through Tough Market Conditions…

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 (11/18/22)	$2.18
Valuation	**$27.00**

OUTLOOK

MediciNova, Inc. (MNOV) recently filed form 10-Q with financial results for the third quarter of 2022. The company is currently developing MN-166 and MN-001 for multiple indications. Importantly, MediciNova is well financed to advance both compounds with capital sufficient to fund operations for at least the next several years. While many small cap biotech companies are currently trading below cash value, MediciNova is not, which we ascribe to its pipeline value and management's fiscal prudence. While the stock is down slightly for the year, we believe it has tremendous upside potential as the pipeline advances and the overall market conditions improve.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$1.99**
One-Year Return (%)	**-34.73**
Beta	**0.82**
Average Daily Volume (sh)	**34,108**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$107**
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	**Below Avg.**
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)
2021	4 A	0 A	0 A	0 A	0 A
2022	0 A	0 A	0 A	0 E	0 E
2023					0 E
2024					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.00 A	-$0.09 A	-$0.07 A	-$0.04 A	-$0.21 A
2022	-$0.07 A	-$0.08 A	-$0.07 A	-$0.09 E	-$0.31 E
2023					-$0.36 E
2024					-$0.40 E

WHAT'S NEW

Business Update

Well-Financed to Advance the Pipeline

MediciNova, Inc. (MNOV) is developing MN-166 and MN-001 for a number of indications with high unmet medical needs. Importantly, with $62.5 million of cash + CDs and an operating cash burn of about $12 million per year, the company is well-financed to advance both compounds with sufficient capital to fund operations for at least the next several years. In the current market environment, it is very difficult for small, unprofitable companies to raise capital without significant dilution occurring through discounts, warrants and/or debt. Some of those companies will not be able to raise capital on any terms which means bankruptcy is a distinct possibility. As such, companies that do not have near-term funding needs have a major advantage compared to those that will need to access the capital markets in the next 6-12 months. In addition, companies such as MediciNova that have proven to be financially responsible continue to trade above their cash level, with small-cap biotech companies trading for less than cash continuing to be very common (approximately 16% of those companies as of the end of the second quarter of 2022 [Biocentury]). MediciNova also has a history of using non-dilutive funding to advance its trials, with current studies in degenerative cervical myelopathy (DCM), chemotherapy-induced peripheral neuropathy (CIPN), methamphetamine dependence, and alcohol dependence all funded by third-parties (aside from the cost of drug supply). Having a healthy balance sheet, a proven ability to access non-dilutive funding sources, and a management team dedicated to fiscal responsibility are areas where investors will need to be more selective in the future. We believe MediciNova has proven itself in all three areas.

Nearer-Term Readouts from BARDA Project and Glioblastoma Trial

In regards to data readouts that are expected or possible over the next 6-12 months, investors should focus on the Biomedical Advanced Research and Development Authority (BARDA)-funded project examining the potential for MN-166 as a treatment for chlorine gas-induced acute respiratory distress syndrome (ARDS) and acute lung injury (ALI) as well as the ongoing Phase 2 clinical trial in glioblastoma (GBM).

MN-166 in ARDS/ALI: In June 2022, the company announced a modification to its contract with BARDA to extend the period of performance until March 2023. MN-166 is being evaluated in preclinical efficacy models of chlorine gas-induced ARDS/ALI that could help support its use in ARDS/ALI caused by other ailments such as influenza, infections, severe burns, and pancreatitis. Under the FDA animal rule (FDA), development of medical countermeasures (MCMs) does not require human clinical trials to establish efficacy as these would not be ethical or feasible. The FDA can grant approval of a drug for an MCM indication based on well-controlled animal studies, when the results of these studies establish that the drug is reasonably likely to produce clinical benefit in humans. In addition, drugs approved as MCMs are eligible for a priority review voucher (PRV). A PRV allows the holder of the voucher to receive an expedited six-month review from the FDA for a new drug application (NDA) or a biologics license application (BLA) instead of the usual ten-month review. PRVs are fully transferable and in the past few years a number of them have sold for approximately $100 million each.

MN-166 was previously tested in a lipopolysaccharide (LPS) ARDS mouse model (Yang *et al*., 2020). While this model induces ARDS through a different mechanism than chlorine gas exposure, a number of the resulting phenotypes are similar between the two models. MN-166 was shown to reduce the overexpression of PDE4, reduce the overexpression of different inflammatory cytokines (e.g., TNF-α, IL-1b, IL-6, MCP-1), reduce pulmonary edema, and reduce lung cell apoptosis. Since ARDS can be induced by a number of different pathologic insults, success in one model system (e.g., LPS-induced ARDS) is likely to translate to success in other models (e.g., chlorine gas-induced ARDS). In addition to this preclinical study, in June 2022, MediciNova announced positive top-line results from a Phase 2 clinical trial of MN-166 in hospitalized COVID-19 patients at risk for ARDS. MN-166 demonstrated large improvements compared to placebo for all four clinical endpoints analyzed. The trial achieved statistical significance for one of the co-primary endpoints, the proportion of subjects free of respiratory failure. The trial also achieved statistical significance for the proportion of subjects discharged from the hospital.

GBM Trial: MN-166 is currently being evaluated in a Phase 2 clinical trial in combination with temozolomide (TMZ) for the treatment of GBM (NCT03782415) 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. In August 2021, MediciNova announced completion of a safety review of Part 1 of the trial, which enrolled 15 subjects. There were no concerning safety signals observed in Part 1 and there were no serious adverse events related to MN-166. Five out of 15 subjects completed cycle 6 without disease progression, i.e. 33% of subjects were progression-free at 6 months. This is very encouraging data as patients with GBM typically have a very poor prognosis. 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.

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.

An *in vivo* study was performed using RN1 GBM cells, which were intracranially injected into the brains of mice followed by no treatment or a combination of TMZ and MN-166 at two different concentrations. Results showed that mice treated with the combination of TMZ and MN-166 had significantly enhanced survival (median overall survival 114 days vs. 100.5 days, P=0.005) with suppression of MIF and CD74 also noted.

MediciNova recently announced the issuance of a new patent by the U.S. Patent and Trademark Office (USPTO) covering the use of MN-166 for the treatment of GBM, specifically patients that express unmethylated MGMT. The company now has broad coverage with three issued patents for the use of MN-166 in the treatment of GBM, with the other two covering the treatment of patients with GBM using MN-166 as part of a combination therapy and patients that express methylated MGMT.

While difficult to estimate exactly when data from the Phase 2 trial will be available, we estimate that topline results may be available during 2023.

Financial Update

On November 10, 2022, MediciNova (MNOV) filed form 10-Q with financial results for the third quarter of 2022. As expected, the company did not report any revenues in the third quarter of 2022. R&D expenses in the third quarters of 2022 and 2021 were $2.5 million and $2.1 million, respectively. The increase was primarily due to an increase in MN-166 related expenses partially offset by a decrease in stock option expenses. G&A expenses in the third quarter of 2022 were $1.4 million, compared to $1.6 million for the third quarter of 2021. The decrease was primarily due to lower stock option expenses.

MediciNova exited the third quarter of 2022 with approximately $62.5 million in cash, cash equivalents, and short-term investments. Investors should note that the 10-Q lists cash and cash equivalents as $52.5 million for this quarter, as the company moved $10 million of cash to investments (bank CDs) as means to increase interest income for a portion of the cash that will not be needed over the next 12 months. As of November 8, 2022, MediciNova had approximately 49.0 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 57.0 million shares.

Conclusion

At a time when access to capital is a major issue for unprofitable companies, a company like MediciNova stands out for its healthy balance sheet and prudent use of resources, two things that will be necessary as it advances its pipeline. We look forward to results from the BARDA-sponsored study as well as the GBM trial, both of which we anticipate could occur during 2023. We have made no changes to our model and our valuation remains at $27.

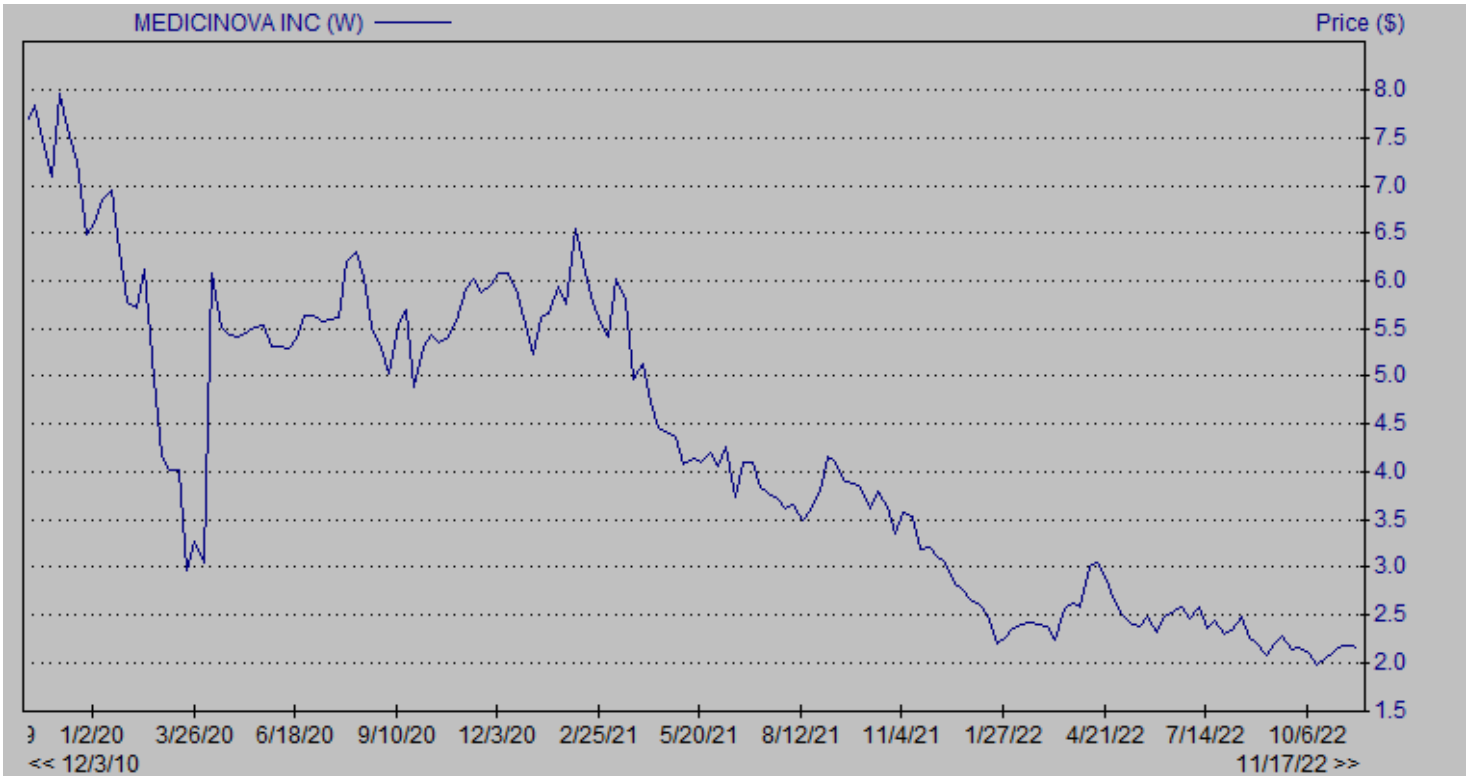
PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 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	$4.0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$4**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$8.5	$2.1	$2.6	$2.5	$2.4	$9.5	$10.0	$12.0
General & Administrative	$5.7	$1.3	$1.5	$1.4	$2.0	$6.3	$8.0	$9.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($10.2)	($3.4)	($4.1)	($3.9)	($4.4)	($15.8)	($18.0)	($21.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	$0.0	$0.1	$0.2	$0.0	$0.3	$0.1	$0.1
Pre-Tax Income	($10.1)	($3.4)	($4.0)	($3.7)	($4.4)	($15.4)	($17.9)	($20.9)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($10.1)**	**($3.4)**	**($4.0)**	**($3.7)**	**($4.4)**	**($15.4)**	**($17.9)**	**($20.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.21)**	**($0.07)**	**($0.08)**	**($0.07)**	**($0.09)**	**($0.31)**	**($0.36)**	**($0.40)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	48.596	49.043	49.046	49.046	49.100	49.059	50.000	52.000

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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