2025年6月17日

B. Riley Securities 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 6 月 16 日、米国カリフォルニア州ロサンゼルスに本拠を置く投資銀行 B. Riley Securities の William Wood 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。

なお、当該レポートは、恐れ入りますが、権利の都合上、英文のままでのご案内となりますので、ご了承ください。

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https://www.brileysecurities.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。

MediciNova, Inc.（メディシノバ・インク）
東京事務所 IR 担当
E-mail infojapan@medicinova.com
URL https://medicinova.jp/

COMBAT-ALS Ph2/3 Trial Steadily Progressing to Imminent Enrollment Completion and Reporting on 1-Year Functional Efficacy Data in 2H26; Remain Buy, PT $6 to $5

Mayank Mamtani
646-885-5463
mmamtani@brileysecurities.com

William Wood, Ph.D.
703-312-1748
wwood@brileysecurities.com

STOCK DATA	
Market Cap (mil)	$65.2
52-Week Range	$1.12–$2.55
3-Month ADTV	12,733
Shares Outstanding (mil)	49.0
Float (%)	94.8
Short Interest	166,507
Beta	0.96
Fiscal Year-End	December

FINANCIAL DATA			
EPS (Operating) GAAP	2024A	2025E	2026E
1Q	$(0.06)	$(0.06)A	-
2Q	$(0.05)	$(0.07)	-
3Q	$(0.06)	$(0.08)	-
4Q	$(0.06)	$(0.10)	-
FY	$(0.23)	$(0.30)	$(0.33)

BALANCE SHEET DATA	
	1Q25
Cash & Equivalents	$36.6
Current Assets	$37.7
Total Assets	$52.4
Total Liabilities	$2.5
Shareholders' Equity	$49.9

$ in millions.

Summary and Recommendation

We revisit our Buy-rated thesis on under-the-radar MediciNova (MNOV, $5 PT), steadily progressing lead program MN-166 (ibudilast) through the ongoing Ph2b/3 COMBAT-ALS trial (n=217 so far, with 183 randomized) with full enrollment expected imminently, setting up full 1-year primary efficacy ALSFRS-R and survival readout in 2H26. Of note, interim blinded COMBAT-ALS study update 6- and 12-month ALFRS-R data, as reported at the 35th International Symposium on ALS/MND in late 4Q24, indicated positive correlations occurring in combined assessment of function and survival (CAFS) (0.71), modified CAFS score (0.70), ALSFRS-R (0.69), as well as ALSFRS-R subgroup analysis, e.g., bulbar score (0.74), fine motor score (0.71), and gross motor score (0.67), but not respiratory score. MNOV also announced the enrollment of the first patient into an NIH-funded expanded access program (EAP) for MN-166 in ALS patients that did not qualify for COMBAT-ALS, allowing for a larger sample size exposure, including patients in advanced stages of ALS. Mgmt. remains fully committed to driving the Ph2/3 COMBAT-ALS program forward, notably benefiting from no competitive active large-scale ALS trial enrollment/execution underway, as the field has unfortunately seen a plethora of recent failures. The underlying anti-inflammatory/neuroprotective MOA could also favorably benefit from NVO's oral semaglutide Ph3 EVOKE Alzheimer's (AD) program readout in 2H, alongside imminently expected INMB's Ph2 MINDFuL early AD trial evaluating their dominant negative soluble TNF alpha inhibitor XPro. Also of note, recent positive developments in the form of IMUX's vidofludimus calcium (vido) and SNY's dual-pronged approach to tolebrutinib and recently acquired TREM2 targeting VG-3927 (as part of $470M VIGL buy-out) are uniquely supportive of microglia targeting mechanism, thereby conferring further credence to MN-166's de-risking. Current cash in hand of $37M implies cash runway into 2027. Our updated model, now exclusively focused on ALS-related risk-adjusted revs and opex spend, lowers our PT from $6 to $5.

Key Points

Ph2/3 COMBAT-ALS trial ibudilast high-dose execution builds on the learnings of prior Ph2a program. MNOV remains laser-focused on ALS, currently evaluating 100 mg MN-166 in Ph2b/3 COMBAT-ALS trial for ALS (n=230) builds on the positive Ph2 study results evaluating 60 mg dose level. Based on a dose-dependent response seen in Ph2, longer 1-year treatment period now in Ph3, and inclusion of only late-stage ALS patients (where superior efficacy was observed in Ph2), we view for COMBAT-ALS trial to be uniquely de-risked to deliver on statistical significance on primary endpoint of change from baseline in the amyotrophic lateral sclerosis functional rating scale-revised (ALSFR-S) alongside potentially survival. Recall, MN-166 incorporates multi-modal mechanism of action, i.e., (1) phosphodiesterase (PDE) and macrophage migration factor (MIF) inhibition that reduces proinflammatory cytokine production and (2) targeting glial over-activation in the CNS, including IL-1, IL-6, TNF alpha, MCP-1, and MIF. By also inhibiting TLR-4, MN-166 is able to reduce the conversion of resting microglia into activated microglia, effectively reducing microglial activation, as also noted in improvement of neuroprotective factors such as NGF, BDNF, and GDNF. This multi-modal MoA collectively results in less neural inflammation and apoptosis, two key mechanisms involved in ALS as well as in MS (see below). Indeed, the earlier Ph2 data has noted 29.4% of patients responded vs 17.6% placebo during the 6-month blinded period, with ~35% of placebo patients during the double-blind portion converting into responders once switched to MN-166 during the 6-month OLE portion. ***(continued on pg. 2)***

Furthermore, Ph2/3 COMBAT-ALS interim analysis confirmed strong 6- to 12-month correlation in CAFS (0.71), ALSFRS-R (0.69), and functional domains, with the DSMB recommending continuation per protocol. COMBAT-ALS is running 6 months longer than typical ALS trials, which not only increased likelihood of technical success but also represents unique design to satisfy both FDA and EMEA exposure/duration requirements for approval. MNOV has previously been granted fast track and orphan disease designations in ALS for MN-166, with recent NIH grant secured to support MN-166 access as part of Expanded Access Program.

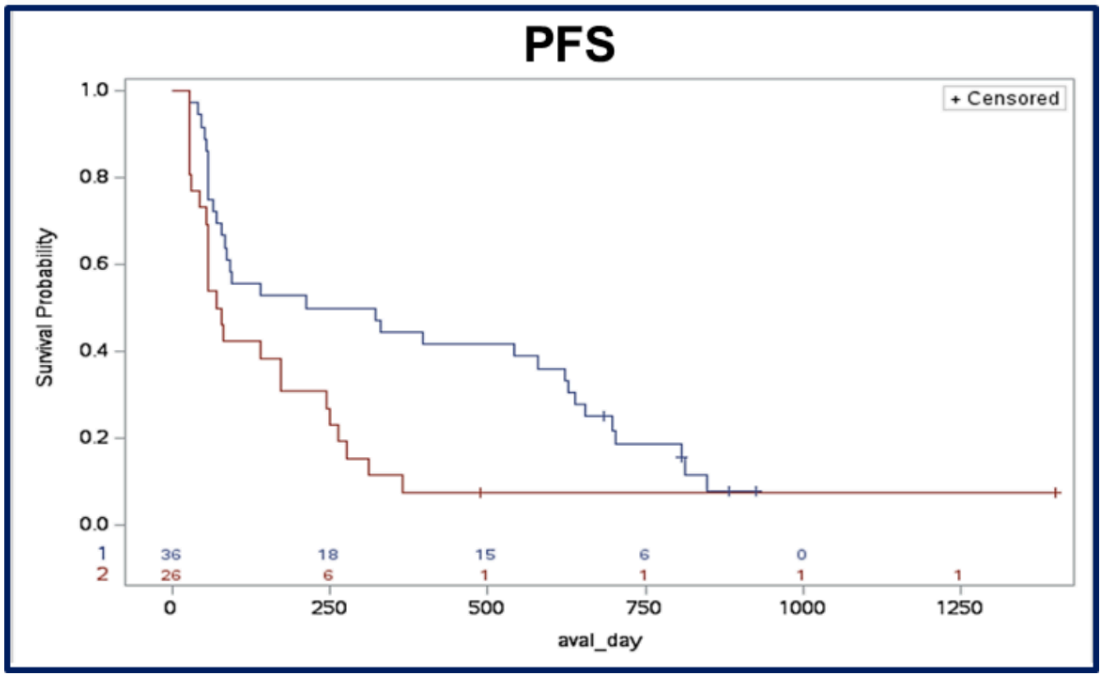
- **Ibudilast more than just ALS, multiple Ph2 ready/paused programs provide additional shots on goal.** Apart from ALS, MNOV also has a Ph3 ready trial in non-active SPMS with MN-166, based on overall benign safety profile, as well as efficacy in Ph2 SPRINT-MS demonstrating a statistically significant 48% reduction in whole-brain atrophy over 96 weeks (p=0.04), outperforming Ocrevus (ocrelizumab, 17.5%) and Mayzent (siponimod, 15%) in their respective pivotal MS studies. Despite these encouraging findings, MNOV views likely strategic partnership plays a role in pursuing subsequent Ph3. In addition, MN-166 (ibudilast) has also been evaluated for the treatment of glioblastoma (GBM) in Ph 1/2 open-label MN-166-GBM-1201study, enrolling a total of 62 patients, 26 with recurrent GBM (rGBM) and 36 newly diagnosed (nGBM). All received 100 mg/day MN-166 in combination with 12 cycles of temozolomide (TMZ), a common chemotherapy. In nGBM, MN-166 led to a median progression free survival (mPFS) was 8.7 months, 6-month PFS rate was 44.4%, 6-month OS was 97.2%, 12-month overall survival (OS) was 80.6%, and median OS was 21.0 months. In rGBM, MN-166 demonstrated somewhat lessened efficacy vs nGBM patients with mPFS of 2.4 months, 6-month PFS rate of 30.8%, 6-month OS of 80.8%, 12-month OS was 26.9%, and mOS of 8.6 months (Exhibits 1 to 3). Notably, the 6-month PFS rate in rGBM exceeded historical controls. Overall, MN-166 was well tolerated with TMZ. MNOV also has secured Orphan Disease Designation for the treatment of glioblastoma.
- **Ph2 execution also underway for MN-001 in MASH + hypertriglyceridemia.** Additional pipeline candidate, MN-001 (Tipelukast), is aimed at evaluating tipelukast to treat MAFLD/MASH with hypertriglyceridemia. MN-001 also has multiple MoA candidate (i.e., leukotriene & 5-lipoxygenase (5-LO) pathway inhibitor and PDE (phosphodiesterase) 3,4 inhibitor) leading to anti-inflammatory effects alongside reductions in serum triglycerides and arachidonic acid update in hepatocytes. Evaluated in the Ph2 open label study, MN-001-NATG-201, where patients received 250 mg/day for 4 wks and 500 mg/day for 8 wks, MN-001 reduced serum triglycerides by 50.8% (p=0.098) in T2DM patients (n=10) and by 17.8% in non-T2DM patients (n=9) (Exhibit 4). Serum HDL-C increased by 15.8% in T2DM (p<0.0002) and by 8.3% in nonT2DM. MN-001 is currently in a 24-week randomized, placebo-controlled Ph2 trial (MN-001-NATG-202) with 40 patients (43 enrolled, 26 randomized as of Dec 2024). Primary endpoints are change in liver fat via CAP score and change in fasting triglycerides at wk 24. Secondary endpoints include changes in HDL-C, LDL-C, total cholesterol, and safety/tolerability. All three programs (MS, GBM, and MASH) are currently paused with focus entirely on ALS advancement.

Exhibit 1. Patients with nGBM Show Improved mOS and PFS to rGBM After MN116 + TMZ Treatment

	nGBM (N = 36)	rGBM (N =26)
Progression-Free Survival		
PFS6 rate	16 (44.4%)	8 (30.8%)
Median PFS (95% CI)	8.7 months (2.6, 20.5)	2.4 months (1.8, 5.7)
Overall Survival		
OS-6 months	35 (97.2%)	21 (80.8%)
OS-12 months	29 (80.6%)	7 (26.9%)
Median OS (95% CI)	21 months (17.7, 23.0)	8.6 months (7.8, 10.5)

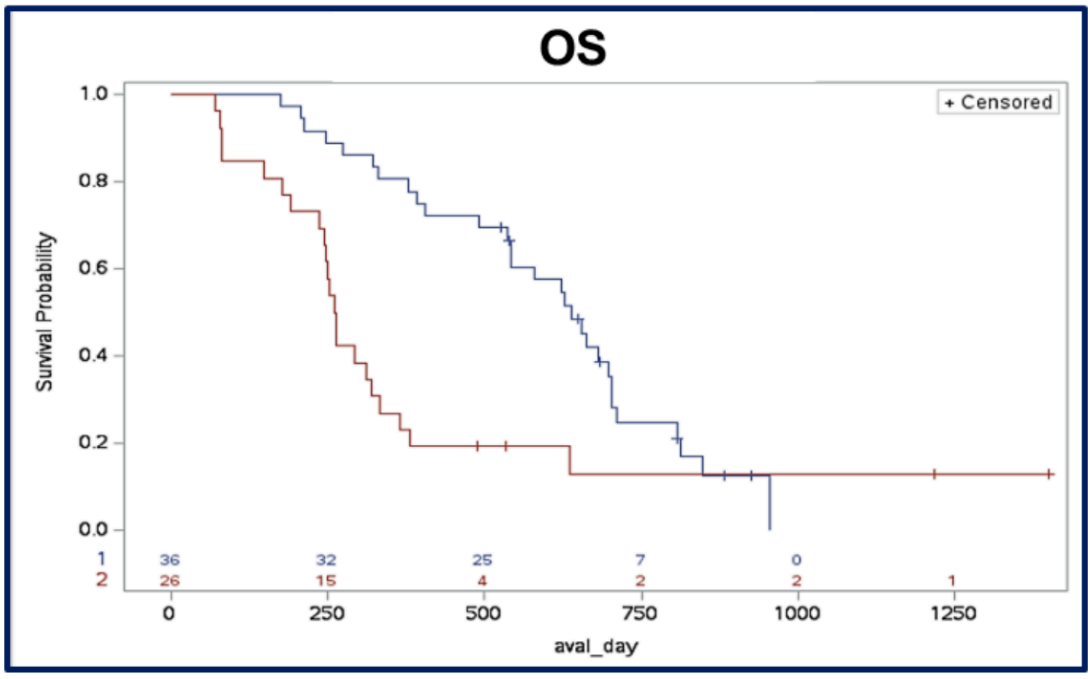
Source: MNOV Corporate Deck

Exhibit 2. Patients with nGBM Show Improved PFS to rGBM After MN116 + TMZ Treatment



Source: MNOV Corporate Deck

Exhibit 3. Patients with nGBM Show Improved mOS to rGBM After MN116 + TMZ Treatment



Source: MNOV Corporate Deck

Exhibit 4. MN001 Treated Subjects With T2DM Show Reduction in Serum TG levels And Significant Increase in HDL-C Levels

	Serum TG level (mg/dL)			Serum HDL-C level (mg/dL)		
Timepoints	All subjects (n=19)	**With T2DM (n=10)**	w/o T2DM (n=9)	All subjects (n=19)	**With T2DM (n=10)**	w/o T2DM (n=9)
Baseline	345.7	444.7	235.7	38.7	36	41.8
Week 8	206.9	218.8	193.8	41.9	41.7	42.2
Mean % change from Baseline (p-value)	- 40.2%	-50.8% (p=0.098)	-17.8%	+ 8.3%	+15.8% (p<0.0002)	+0.9%

Source: MNOV Corporate Deck

Valuation

We derive our 12-month $5 price target on a discounted cash flow (DCF) analysis of revenue and cash flow projected through 2034. We use a 14.5% discount rate, in line with other early clinical-stage biotech companies, and a 2% terminal growth rate.

Risks

Clinical risk. It is uncertain if clinical efficacy and safety for MN-166 and MN-001 will be observed in current and future clinical trials, particularly the newly initiating Ph. III PMS and ALS trials.

Regulatory risk. The regulatory pathway for MNOV's pipeline candidates could be uncertain, and it is unclear whether positive data will be sufficient for regulatory filing. Additionally, there is no certainty that MN-166 and MN-001 will be approved and/or reimbursed. If the regulatory path is more complex and/or time consuming than anticipated, there could be a materially negative impact on our estimates and price target, even with success in achieving clinical endpoints.

Commercialization risk. The market potential of MediciNova's therapies may not be as significant as projected. In particular, we highlight competition for MN-166 in the Progressive Multiple Sclerosis therapeutics space from Ocrevus from Roche and siponimod from Novartis. In addition, MediciNova will need to establish a sales and medical affairs infrastructure in the U.S., Europe, and other geographies for its pipeline candidates.

Financing risk. With approximately $37M in cash, MediciNova will likely need to raise additional capital for continued clinical candidate development, perhaps via additional equity or convertible debt financing, before reaching profitability, likely resulting in equity share dilution. MediciNova is likely to be seeking partners for ibudilast in progressive MS and ALS, and the company is likely to seek an up-front payment to limit dilution to shareholders from future equity raises.

Stock price volatility. Share price volatility is common for developmental biopharma firms like MediciNova.

MediciNova, Inc. (MNOV)
Income Statement

$ in millions, except EPS	2018A	2019A	2020A	2021A	2022A	2023A	1Q24A	2Q24A	3Q24A	4Q24A	2024A
Revenue	0.0	0.0	0.0	4.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
Cost of sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross profit	0.0	0.0	0.0	4.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
Research & development expense	5.6	6.1	7.5	8.5	9.1	5.7	1.8	1.6	1.9	1.9	7.2
SG&A expenses	10.0	8.0	6.7	5.7	5.5	5.2	1.4	1.4	1.4	1.3	5.5
Total operating expenses	15.6	14.0	14.2	14.3	14.6	10.9	3.1	3.0	3.3	3.2	12.7
Operating profit (loss)	**-15.6**	**-14.0**	**-14.2**	**-10.2**	**-14.6**	**-9.9**	**-3.1**	**-3.0**	**-3.3**	**-3.2**	**-12.7**
Interest income (expense)	0.9	1.1	0.4	0.1	0.8	1.8	0.4	0.4	0.4	0.4	1.7
Other income (expense)	0.0	0.0	0.0	-0.1	-0.2	-0.5	0.0	0.0	0.0	0.0	0.0
Pre-Tax Income (loss)	**-14.7**	**-12.9**	**-13.9**	**-10.1**	**-14.1**	**-8.6**	**-2.8**	**-2.6**	**-2.9**	**-2.8**	**-11.0**
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss) to common stockholders	-14.7	-12.9	-13.9	-10.1	-14.1	-8.6	-2.8	-2.6	-2.9	-2.8	-11.0
Basic EPS attributable to stockholders	**-$0.36**	**-$0.30**	**-$0.31**	**-$0.21**	**-0.29**	**-0.17**	**-0.06**	**-0.05**	**-0.06**	**-0.06**	**-$0.23**
Diluted EPS attributable to stockholders	**-$0.36**	**-$0.30**	**-$0.31**	**-$0.21**	**-0.29**	**-0.17**	**-0.06**	**-0.05**	**-0.06**	**-0.06**	**-$0.23**
Shares, basic (million)	41.125	43.159	44.413	48.596	49.045	49.046	49.046	49.046	49.046	49.046	49.046
Shares, diluted (million)	41.125	43.159	44.413	48.596	49.045	49.046	49.046	49.046	49.046	49.046	49.046

Cash Flow Statement

$ in millions	2018A	2019A	2020A	2021A	2022A	2023A	1Q24A	2Q24A	3Q24A	4Q24A	2024A
Net increase/(decrease) in cash and cash equivalents	34.3	1.5	-3.8	11.4	-52.9	32.5	-3.9	-2.8	-2.1	-1.9	-10.6
Cash and cash equivalents at beginning of period	28.0	62.3	63.8	60.0	71.4	18.5	51.0	47.1	44.3	42.3	51.0
Cash and cash equivalents at end of period	62.3	63.8	60.0	71.4	18.5	51.0	47.1	44.3	42.3	40.4	40.4
Operating Activities:											
Net income (loss)	-14.7	-12.9	-13.9	-10.1	-14.1	-8.6	-2.8	-2.6	-2.9	-2.8	-11.0
Stock-based compensation	6.3	4.1	3.2	1.7	0.6	0.7	0.2	0.2	0.5	0.3	1.2
Depreciation and amortization	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in carrying amount of right-of-use asset							0.0	0.0	0.0	0.0	0.2
Other operating items	0.0	0.0	0.0	0.2	0.2	0.3	0.0	0.0	0.0	0.0	0.0
Changes in assets and liabilities:											
Accounts receivables, prepaid expenses, and other assets	-0.1	-0.5	0.1	0.1	0.2	0.3	-0.6	-0.4	0.2	0.3	-0.5
Accounts payable, accrued liabilities, and other current liabilities	-0.7	0.2	-0.2	-1.0	0.3	0.0	-0.8	0.0	0.1	0.4	-0.3
Deferred tax liability	0.0	0.0	0.0	-0.2	-0.1	-0.2	-0.1	0.0	0.0	0.0	-0.2
Net cash provided by (used) in operating activities	**-9.1**	**-9.1**	**-10.8**	**-9.4**	**-12.9**	**-7.4**	**-3.9**	**-2.8**	**-2.0**	**-1.9**	**-10.6**
Investing Activities:											
Acquisitions of property and equipment	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	0.6	0.0	0.0	0.0	-40.0	39.9	0.0	0.0	0.0	0.0	0.0
Net cash provided by (used) in investing activities	**0.6**	**0.0**	**0.0**	**0.0**	**-40.0**	**39.9**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Financing Activities:											
Proceeds from issuance of common stock	42.8	10.6	7.1	20.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Common stock issuance costs		0.0	0.0	-0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance of equity under ESPP	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash provided by (used) in financing activities	**42.8**	**10.6**	**7.1**	**20.8**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Effects of foreign exchange rates on cash	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	0.0	**0.0**

MediciNova, Inc. (MNOV) -- Discounted Cash Flow Model																	
Fiscal year	2018A	2019A	2020A	2021A	2022A	2023A	2024A	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	Terminal value
Fiscal year end date	12/31/18	12/31/19	12/31/20	12/31/21	12/31/22	12/31/23	12/31/24	12/31/25	12/31/26	12/31/27	12/31/28	12/31/29	12/31/30	12/31/31	12/31/32	12/31/33	12/31/34	
Operating income (EBIT)	**(15.6)**	**(14.0)**	**(14.2)**	**(10.2)**	**(14.6)**	**(9.9)**	**(12.7)**	**(16.4)**	**(18.4)**	**(15.9)**	**(10.4)**	**25.3**	**39.1**	**56.8**	**79.4**	**93.4**	**109.3**	
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.7	8.6	12.5	17.5	20.7	24.3	
After tax operating income	(15.6)	(14.0)	(14.2)	(10.2)	(14.6)	(9.9)	(12.7)	(16.4)	(18.4)	(15.9)	(10.4)	19.6	30.5	44.2	61.9	72.7	85.0	
(+) depreciation and amortization	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.4	1.7	2.2	2.8	3.6	4.1	4.7	
(+/-) changes in WC	(1.6)	1.3	(1.0)	(0.8)	1.3	(0.4)	0.4	(1.9)	1.7	0.9	0.8	6.7	(5.1)	0.9	1.2	(2.1)	0.5	
(-) capital expenditures	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0	0.0	(0.3)	(0.8)	(3.6)	(4.7)	(6.1)	(7.9)	(9.0)	(10.2)	
(+) deferred taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
(+) other non-cash items	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Unlevered free cash flow	(17.1)	(12.8)	(15.2)	(11.0)	(13.4)	(10.4)	(12.2)	(18.3)	(16.7)	(15.2)	(10.1)	24.4	22.8	41.9	58.9	65.8	80.0	
Time period (years)								0.6	1.6	2.6	3.6	4.6	5.6	6.6	7.6	8.6	9.6	
Discount factor								0.9	0.8	0.7	0.6	0.5	0.5	0.4	0.4	0.3	0.3	
PV								(16.9)	(13.5)	(10.7)	(6.2)	13.1	10.7	17.2	21.1	20.6	21.9	

EV	226.5
+ Cash and Equivalents	36.6
- Long-term debt	0.0
Equity Value	263.0
Fully diluted shares outstanding (M)	49.0
Price/share (in $USD)	**$5.00**
WACC, chosen	14.5%
Terminal growth rate	2%

PV of Terminal Value			**minal Value**	169.0

Shares (10-Q, May. 13, 2025)				**Dilution**
0,000 shares, on exercise of warrants	0.000	shares	$0.00 WAEP	0.000
7,909,394 shares, on exercise of Stock options	7.909	shares	$4.73 WAEP	0.000
Possible dilution (million shares)				**0.000**

Assumptions	
Date	6/5/2025
Fiscal year ending (1-12)	12
Changes in related party & Other operating activities	
Projections discounted to (1-12)	12.00
Projections discounted to (month)	December
Shares outstanding	49.046

WACC Calculations	
Risk-free rate	2.0%
Adjusted beta	1.78
Rm-Rf	7.0%
Re	14.5%
Rd	0.0%
WACC, calculated	14.5%

Balance Sheet	
Total debt	-
Cash and equivalents	36.6
Net debt	(36.6)
Debt, as a % of capital	0.00%
Cash per share	$0.75
Closing price, 06-05-25	$ 1.33
MC ($M), 06-05-25	$ 65.23

*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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(1) As of midnight on the business day immediately prior to the date of this publication.

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