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CervoMed Inc.

(CRVO-NASDAQ)

CRVO: $150 Million Financing Strengthens Balance Sheet; Topline Data for Phase 2b Trial in 4Q24…

Based on our probability adjusted DCF model that takes into account potential future revenues for neflamapimod in DLB, CRVO is valued at $30.00/share. This model is highly dependent upon continued clinical success of neflamapimod and will be adjusted accordingly based upon future clinical results.

Current Price (04/10/24)	$23.14
Valuation	**$30.00**

OUTLOOK

On April 1, 2024, CervoMed Inc. (CRVO) announced financial results for the fourth quarter and full year 2023 and provided a business update. The company recently announced a $149.4 million financing with top-tier institutional investors that is expected to help fund operations through the end of 2025. We anticipate enrollment in the ongoing RewinD-LB Phase 2b clinical trial of neflamapimod in patients with dementia with Lewy bodies (DLB) to complete in the 2Q24 with topline data from the trial expected in the 4Q24. In March 2024, the company presented biomarker data from the AscenD-LB Phase 2a trial of neflamapimod demonstrating that the drug reduced plasma levels of glial fibrillary acidic protein (GFAP) compared to placebo and those changes were inversely correlated with a change in CDR-SB.

SUMMARY DATA

52-Week High	**$25.93**
52-Week Low	**$4.20**
One-Year Return (%)	**272.64**
Beta	**1.50**
Average Daily Volume (sh)	**23,165**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$185**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
Insider Ownership (%)	**2**
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	**High**
Type of Stock	**Small-Growth**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.0 A	0.0 A	1.5 A	5.6 A	7.1 A
2024	2.0 E	2.0 E	2.0 E	2.0 E	8.0 E
2025					4.9 E
2026					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$2.01 A	-$3.04 A	$0.65 A	$1.83 A	-$0.82 A
2024	-$0.46 E	-$0.49 E	-$0.31 E	-$0.33 E	-$1.13 E
2025					-$1.62 E
2026					-$2.00 E

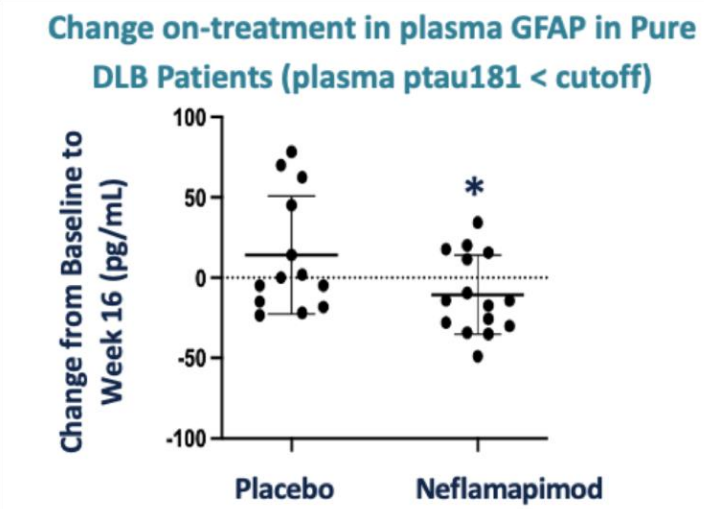
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Business Update

Biomarker Data Presented at AD/PD 2024

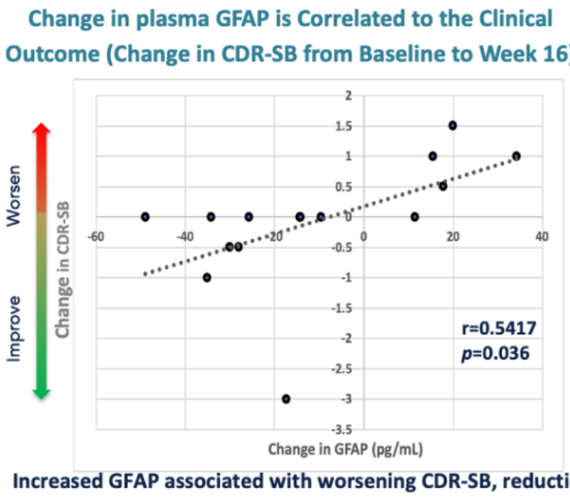
On March 5, 2024, CervoMed Inc. (CRVO) announced the presentation of biomarker data from the AscenD-LB Phase 2a trial of neflamapimod in patients with dementia with Lewy bodies (DLB) was featured in a poster presentation at the 18th International Conference on Alzheimer's and Parkinson's Disease (AD/PD) 2024. Another abstract presented by scientific collaborators from University College London (UCL) demonstrated p38 MAPK inhibition, including with neflamapimod, improved tau-induced axonal transport defects both *in vitro* and in a tauopathy mouse model.

EFFECT OF NEFLAMAPIMOD TREATMENT ON PLASMA GLIAL FIBRIALLARY ACIDIC PROTEIN (GFAP) LEVELS IN PATIENTS WITH DEMENTIA WITH LEWY BODIES (DLB). This analysis examined the effect of neflamapimod on plasma GFAP in the overall and pure DLB populations. The data showed that in the overall population there was a mean 3.7 pg/mL increase in GFAP levels in placebo-treated patients compared to a mean 12.3 pg/mL reduction in the neflamapimod-treated patients (*P*=0.13). The following figure shows that in the pure DLB patient population (i.e., patients with pre-treatment plasma ptau118 below the cutoff for Alzheimer's disease (AD)-related co-pathology), there was a mean 14.1 pg/mL increase in placebo-treated patients compared to a mean 10.6 pg/mL reduction in neflamapimod-treated patients (P=0.04).



Source: CervoMed Inc.

For the pure DLB patient population, the following graph shows that treatment with neflamapimod resulted in a significant correlation (r=0.542, *P*=0.036) between the effects of GFAP and clinical outcomes assessed by change from baseline to week 16 in CDR-SB (Clinical Dementia Rating - Sum of Boxes; used to monitor dementia symptoms), with increased GFAP being associated with worsening CDR-SB and a reduction in GFAP being associated with improved CDR-SB. There was no correlation observed in placebo-treated patients.



Increased GFAP associated with worsening CDR-SB, reduction in GFAP associated with improvement on CDR-SB among neflamapimod recipients with pure DLB (r=0.54, p=0.036). The correlation was not seen in placebo-recipients (r=0.31, p=NS)

Source: CervoMed Inc.

IN VIVO IMAGING OF AXONAL TRANSPORT REVEALS EARLY PATHOLOGICAL CHANGES INDUCED BY TAU MUTATIONS AND THEIR REVERSIBILITY. Researchers from University College London evaluated the effect of p38 MAPK inhibition on frontotemporal dementia (FTD) linked tau mutation both *in vivo* and *in vitro*. FTD-linked mutations induced aberrant tau envelopes (clusters) along axons, an effect that was reversed by inhibition of p38 MAPK. Neflamapimod was administered twice daily for five days at a dose of 3 mg/kg and was demonstrated to enhance axonal transport in the rTg450 transgenic mouse model of FTD that contains the P301L mutation in the tau gene. The authors concluded that inhibition of p38 MAPK potentiated axonal transport reduces tau phosphorylation and supports the inhibition of p38 MAPK as a promising therapeutic strategy in tauopathies.

Integrated Summary of Phase 2a Clinical Results Published in JPAD

In February 2024, CervoMed announced that data from the Phase 2a AscenD-LB Phase 2a trial evaluating neflamapimod in patients with DLB were published in the *Journal of Prevention of Alzheimer's Disease* (JPAD) (Prins *et al*., 2024). Results published for the first time include an integrated summary of the effects of neflamapimod 40 mg three-times-a-day (TID) compared to placebo in A) the overall patient population that contains patients with DLB with evidence of AD and patients with pure DLB; and B) the pure DLB patient population. As the following table shows, the magnitude of the neflamapimod treatment effect compared to placebo is substantially higher in the pure DLB patient population. The pure DLB patient population also showed significant improvement in working memory (assessed by the International Shopping List Test [ISLT] recognition) that is not evident in the overall patient population.

	Overall Study Population				**Patients With Pure DLB (Plasma ptau181 < cutoff)**			
	N= NFMD TID, Placebo	Difference[1] (95% CI)	*p*-value	Cohen's *d* Effect size	*N*= NFMD TID, Placebo	Difference[1] (95% CI)	*p*-value	Cohen's *d* Effect size
NTB	19,37	+0.17 (0.00,0.35)	0.049	0.47	11,19	+0.21 (-0.07,0.49)	0.13	0.56
Attention	19,36	+0.28 (0.04,0.51)	0.023	0.41	11,18	+0.42 (0.07,0.78)	0.023	0.78
CDR-SB	20,38	-0.56 (-0.96, -0.16)	0.007	0.31	11,22	-0.60 (-1.04, -0.06)	0.031	0.74
TUG	20,38	-1.4 (-2.6, -0.2)	0.024	0.50	11,20	-3.1 (-4.7, -1.6)	<0.001	0.74
ISLT	20,42	+0.32 (-0.48,1.12)	NS	0.15	11,22	+2.1 (0.0,4.2)	0.053	0.55
ISLT- RECOGNITION	19,39	+0.47 (-0.17,1.11)	0.15	0.17	10,21	+1.4 (0.02,2.5)	0.024	1.0

Source: CervoMed Inc.

Electroencephalography (EEG) was the only biomarker evaluated in the AscenD-LB study. A total of 29 of 91 patients received EEG recordings at baseline and Week 16 (the remaining patients did not receive a Week 16 EEG primarily due to limitations imposed by the COVID-19 pandemic restrictions). The results showed that neflamapimod 40 mg TID led to improvement (P=0.01 vs. placebo TID) in beta functional connectivity. Deficits in beta band functional connectivity may be a key differentiator between DLB and AD.

MRI studies were not performed in the AscenD-LB trial, however MRI images pre-treatment and after 12 weeks of treatment with neflamapimod from a previously completed Phase 2a study in patients with early AD were examined to assess the effect of neflamapimod on the volume of the nucleus basalis of Meynert (NbM), the major cholinergic neuronal cluster in the basal forebrain. Results showed that after 12 weeks of treatment, NbM volume was 3.1% higher vs. baseline (*P*=0.03). Treatment with neflamapimod was also associated with higher functional dynamic connectivity between the NbM and deep grey matter at the end of treatment (mean 11% higher; *P*=0.04).

The results from AscenD-LB helped guide the design of the RewinD-LB Phase 2b trial, including the use of a single 40 mg TID dose regimen, enrolling patients with pure DLB, and utilizing CDR-SB as the primary endpoint. In addition, structural and functional MRI will be evaluated in a 40-patient subgroup to assess treatment effects on atrophy of the basal forebrain along with functional connectivity.

Joshua Boger Appointed as Chair of the Board

In February 2024, CervoMed announced the appointment of Joshua Boger, PhD to its Board of Directors and as Chair of the Board. Dr. Boger is an industry veteran with 40+ years of experience. He is currently Executive Chairman of Alkeus Pharmaceuticals. He founded Vertex Pharmaceuticals in 1989 and was Chief Executive Officer from 1992 until 2009. He continued to serve on the Vertex Board and Chair Vertex's Science & Technology Committee until 2017. Dr. Boger's vast experience will be invaluable to CervoMed as it progresses toward topline results from the RewinD-LB trial later this year and its potential advancement in the clinic.

Financial Update

On April 1, 2024, CervoMed announced financial results for full year 2023. The company reported grant revenue of $7.1 million for 2023 compared to no revenue for the same period in 2022. The revenue in 2023 was related to the $21.0 million grant awarded to the company by the National Institute on Aging (NIA) in January 2023 to support the Phase 2b trial of neflamapimod in DLB. R&D expenses in 2023 were $8.4 million compared to $1.3 million for 2022. The increase was primarily due to the Phase 2b trial beginning in the first quarter of 2023. G&A expenses in 2023 were $6.5 million compared to $2.1 million for the year ending December 31, 2022. The increase was primarily due to the reverse merger and public company related costs. Other income in 2023 was $5.4 million compared to $(2.4) million in 2022. The amount in 2022 was driven by an increase in the estimated fair value of the convertible notes while the increase in 2023 was driven by the stock price on the date of conversion as a result of the reverse merger.

As of December 31, 2023, CervoMed had approximately $7.8 million in cash and cash equivalents. In March 2023, the company announced a private placement of up to $149.4 million with leading institutional investors. The financing consisted of 2,532,285 units, with each unit comprised of (i) A) one share of common stock or B) one pre-funded warrant to purchase shares of common stock and (ii) one Series A warrant to purchase shares of common stock. Each unit had a purchase price of $19.745 (or $19.744 if it included pre-funded warrants). The Series A warrants have an exercise price of $39.24 and will expire on the earlier of 1) April 1, 2027 or 2) 180 days after the date that the company makes a public announcement of positive topline data from the Phase 2b RewinD-LB trial. Gross proceeds from the private placement were $50.0 million, with up to an additional $99.4 million tied to the exercise of the Series A warrants. We estimate the company currently has sufficient capital to finance operations through the end of 2025. Following the financing, we estimate the company currently has approximately

8.3 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 12.2 million.

Conclusion

The recent financing demonstrates the robust level of interest in the company from multiple high-tier institutional investors and helps to strengthen the balance sheet as the company gets closer to completing enrollment in the RewinD-LB trial, expected in the second quarter of 2024, and the release of topline data, which we anticipate in the fourth quarter of 2024. We have adjusted our model following the recent financing and have advanced it forward a year. Our valuation now stands at $30 per share.

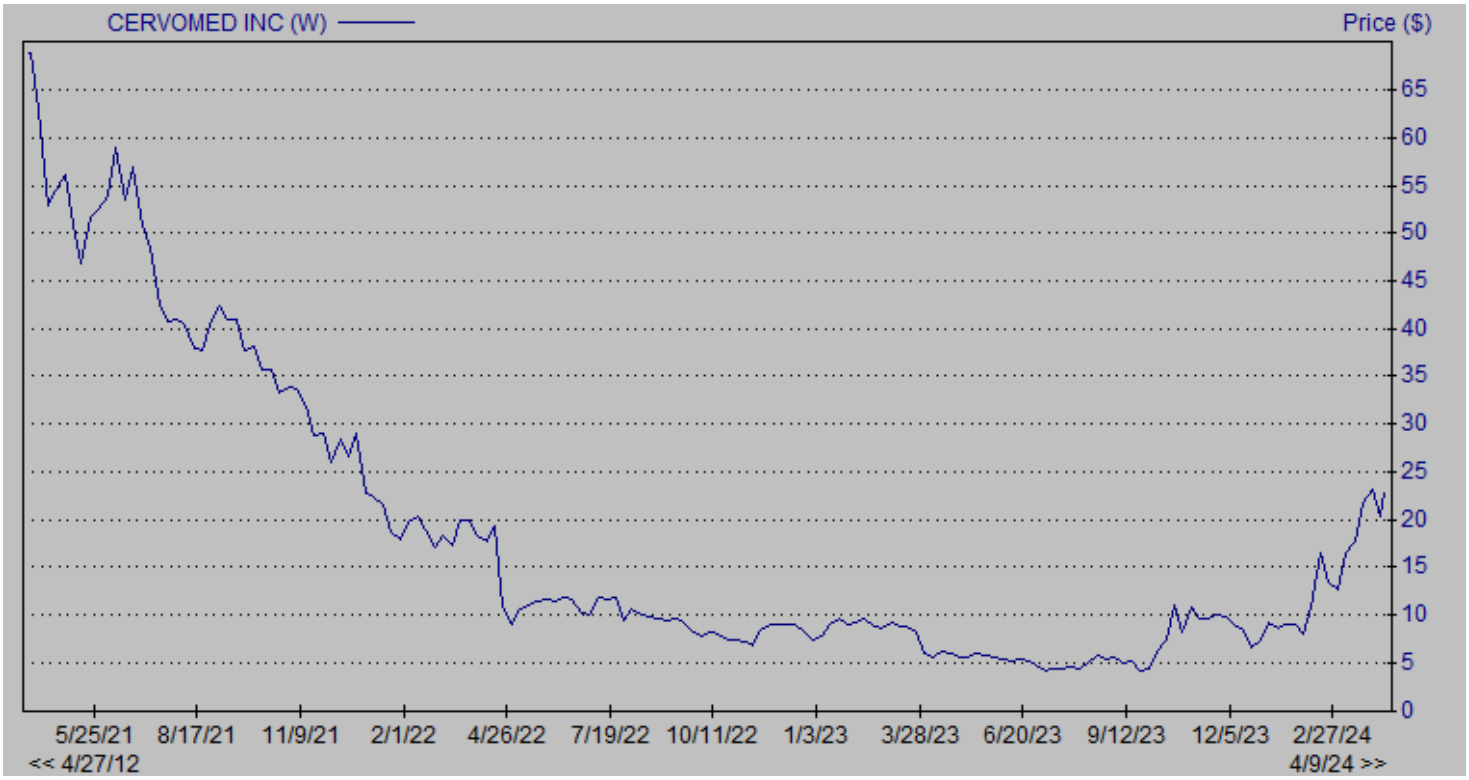
PROJECTED FINANCIALS

CervoMed, Inc.	2023 A	Q1 E	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 E
Neflamapimod	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grants & Collaborative Revenue	$7.1	$2.0	$2.0	$2.0	$2.0	$8.0	$5.9	$0.0
Total Revenues	**$7.1**	**$0.0**	**$0.0**	**$2.0**	**$2.0**	**$8.0**	**$5.9**	**$0.0**
Cost of Sales	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$8.4	$2.0	$2.2	$2.5	$2.7	$9.4	$10.5	$12.0
General & Administrative	$6.5	$2.2	$2.3	$2.4	$2.4	$9.3	$10.0	$12.0
Operating Income	($7.8)	($4.2)	($4.5)	($2.9)	($3.1)	($10.7)	($14.6)	($24.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$5.6	$0.2	$0.2	$0.2	$0.2	$0.8	$0.0	$0.0
Pre-Tax Income	($2.2)	($4.0)	($4.3)	($2.7)	($2.9)	($9.9)	($14.6)	($24.0)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($2.2)**	**($4.0)**	**($4.3)**	**($2.7)**	**($2.9)**	**($9.9)**	**($14.6)**	**($24.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.82)**	**($0.46)**	**($0.49)**	**($0.31)**	**($0.33)**	**($1.13)**	**($1.62)**	**($2.00)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.7	8.7	8.8	8.8	8.9	8.8	9.0	12.0

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

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