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CervoMed Inc.

(CRVO-NASDAQ)

CRVO: Enrollment Set to Complete in Phase 2b RewinD-LB Trial in 2Q24; Topline Data 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 (05/31/24)	$19.69
Valuation	**$30.00**

OUTLOOK

On May 15, 2024, CervoMed Inc. (CRVO) announced financial results for the first quarter of 2024 and provided a business update. Enrollment is ongoing in the RewinD-LB Phase 2b clinical trial of neflamapimod in patients with dementia with Lewy bodies (DLB). We anticipate enrollment completing in the second quarter of 2024 with topline data from the trial expected in the fourth quarter of 2024. In April 2024, the company completed a provate placement of up to $149.4 million, which consisted of $50 million upfront and up to an additional $99.4 million if the warrants issued in connection with the offering are exercised in full.

SUMMARY DATA

52-Week High	**$25.93**
52-Week Low	**$4.20**
One-Year Return (%)	**244.55**
Beta	**1.50**
Average Daily Volume (sh)	**25,846**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$121**
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	2.3 A	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	-$0.41 A	-$0.28 E	-$0.33 E	-$0.35 E	-$1.34 E
2025					-$1.62 E
2026					-$2.00 E

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Business Update

Enrollment of Phase 2b RewinD-LB Trial to Complete in 2Q24; Topline Data in 4Q24

CervoMed Inc. (CRVO) is currently conducting the Phase 2b RewinD-LB trial of neflamapimod in patients with dementia with Lewy bodies (DLB). Trial participants will receive either 40 mg neflamapimod administered TID or matching placebo. Approximately 80 subjects will be enrolled into each group. Those with elevated ptau181 levels will be excluded. Dosing will continue for 16 weeks in the main, placebo controlled portion of the trial with a 36-week open label treatment extension for those completing the initial 16 weeks of the trial.

The primary outcome of the trial is improvement in dementia severity as assessed by change from baseline to week 16 in CDR-SB score. Secondary outcomes include effects on cognition (as assessed by DBL-specific cognitive test battery), motor function (as assessed by TUG test), and global rating of treatment effect (as assessed by the ADCS-Clinician Global Impression of Change). Tertiary outcomes include neuropsychiatric outcomes (as assessed by the NPI-12), effect on fluctuations in cognition (as assessed by the Dementia Cognitive Fluctuations Scale), impact on resting-state EEG, and (in a subset of patients) basal forebrain atrophy as assessed by structural MRI.

In January 2023, CervoMed was awarded a $21.0 million grant from the National Institutes on Aging (NIA) to support the RewinD-LB trial. Funds from the grant are disbursed as costs are incurred. As of March 31, 2024, $10.1 million has been received from the NIA grant, with approximately $10.9 million in funding remaining.

We anticipate enrollment in the trial being completed in the second quarter of 2024 and topline results being announced in the fourth quarter of 2024.

Integrated Summary of Phase 2a Clinical Results Published in JPAD

In February 2024, CervoMed announced that data from the Phase 2a AscenD-LB 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.

Financial Update

On May 15, 2024, CervoMed announced financial results for the first quarter of 2024. Grant revenue in the first quarter of 2024 was $2.3 million compared to $1.4 million for the first quarter of 2023. The revenue in both quarters was derived from the $21.0 million grant awarded to the company from the NIA to support the RewinD-LB trial. R&D expenses for the first quarter of 2024 were $2.8 million compared to $1.8 million for the first quarter of 2023. The increase was primarily due to the increase in outsourced CRO and related site expenses related to the RewinD-LB trial. G&A expenses for the first quarter of 2024 were $2.1 million compared to $1.0 million for the first quarter of 2023. The increase was primarily due to public company related costs, including insurance, increased headcount, and stock-based compensation.

As of March 31, 2024, CervoMed had approximately $6.4 million in cash and cash equivalents. On April 1, 2024, CervoMed closed 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 11.4 million.

Conclusion

We look forward to the completion of enrollment in the RewinD-LB trial in the second quarter of 2024 and release of topline results in the fourth quarter of 2024. The company has also alluded to exploring opportunities to expand the therapeutic potential of neflamapimod as a treatment in additional cholinergic dysfunction driven neurological conditions, thus we will be very interested to hear additional details regarding those plans. With no changes to our model our valuation remains at $30 per share.

PROJECTED FINANCIALS

CervoMed, Inc.	2023 A	Q1 A	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	$2.3	$2.0	$2.0	$2.0	$8.3	$5.9	$0.0
Total Revenues	**$7.1**	**$2.3**	**$2.0**	**$2.0**	**$2.0**	**$8.3**	**$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	$2.8	$2.2	$2.5	$2.7	$10.2	$10.5	$12.0
General & Administrative	$6.5	$2.1	$2.3	$2.4	$2.4	$9.2	$10.0	$12.0
Operating Income	($7.8)	($2.6)	($2.5)	($2.9)	($3.1)	($11.1)	($14.6)	($24.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$5.6	$0.1	$0.2	$0.2	$0.2	$0.7	$0.0	$0.0
Pre-Tax Income	($2.2)	($2.5)	($2.3)	($2.7)	($2.9)	($10.4)	($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)**	**($2.5)**	**($2.3)**	**($2.7)**	**($2.9)**	**($10.4)**	**($14.6)**	**($24.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.82)**	**($0.41)**	**($0.28)**	**($0.33)**	**($0.35)**	**($1.34)**	**($1.62)**	**($2.00)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.7	6.2	8.3	8.3	8.3	7.8	9.0	12.0

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

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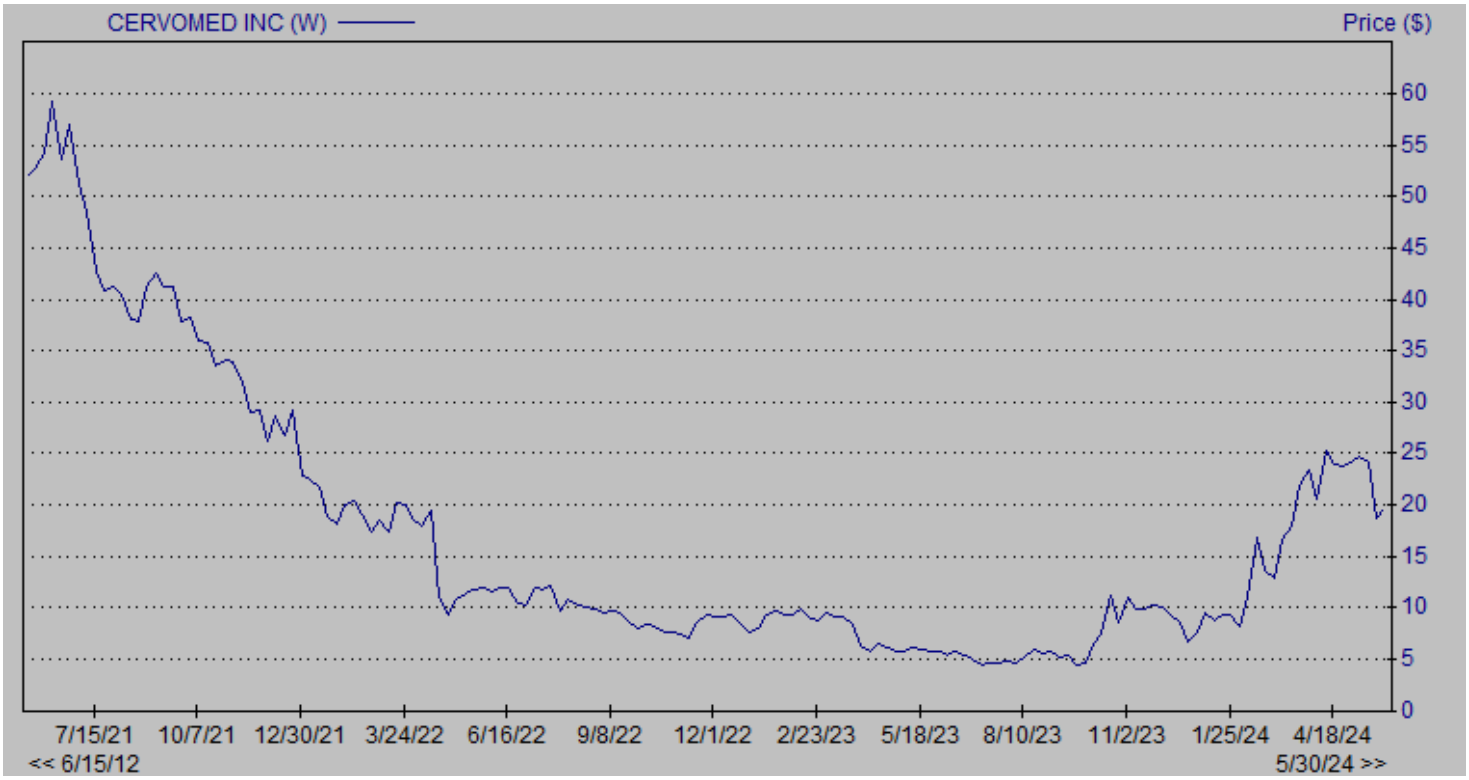

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