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David Bautz, PhD
(312) 265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Dogwood Therapeutics, Inc.

(DWTX-NASDAQ)

DWTX: First Patient Dosed in Phase 2b Trial of Halneuron in CINP; Debt Conversion Strengthens Balance Sheet…

Based on our probability adjusted DCF model that takes into account potential future revenues of Halneuron, IMC-1, and IMC-2, DWTX is valued at $11.00/share. This model is highly dependent upon continued clinical success of its development products and will be adjusted accordingly based on future clinical results.

Current Price (03/18/25)	$6.09
Valuation	**$11.00**

OUTLOOK

On March 18, 2025, Dogwood Therapeutics, Inc. announced that the first patient was dosed in the Phase 2b HALT-CINP clinical trial of its lead asset, Halneuron®. The goal is to recruit 100 patients and perform an interim analysis by the fourth quarter of 2025, which will enable changes to the study, if necessary, to improve trial outcomes.

On March 12, 2025, Dogwood announced a debt conversion with its largest shareholder. Under terms of the agreement, the existing $19.5 million loan plus accrued interest was converted into 284.2638 shares of Series A-1 Non-Voting Convertible Preferred Stock. Each share of Series A-1 Preferred Stock is convertible into 10,000 shares of Dogwood's common stock, subject to approval of the company's shareholders. Following the conversion Dogwood has no debt on its balance sheet.

SUMMARY DATA

52-Week High	**$17.40**
52-Week Low	**$1.85**
One-Year Return (%)	**-23.88**
Beta	**2.07**
Average Daily Volume (sh)	**3,010,327**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**12**
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 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**

Risk Level	**High**
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)
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 A	0 A	0 E	0 E
2025					0 E
2026					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$2.07 A	-$1.96 A	-$1.62 A	-$1.43 A	-$7.05 A
2024	-$1.68 A	-$1.15 A	-$2.05 A	-$1.49 E	-$6.43 E
2025					-$4.57 E
2026					-$1.90 E

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Business Update

First Patient Dosed in Phase 2b Trial of Halneuron®

On March 18, 2025, Dogwood Therapeutics, Inc. (DWTX) announced that the first patient was dosed in the Phase 2b HALT-CINP (Halneuron Treatment of Chemotherapy-Induced Neuropathic Pain) trial. This is a four-week study that will examine the safety and efficacy of Halneuron in patients with moderate-to-severe CINP. The primary efficacy endpoint is the change from baseline at Week 4 in the weekly average of daily 24-hour recall pain intensity scores, which will be recorded in e-diary's on participants smartphones. Secondary efficacy endpoints include Patient Global Impression of Change (PIGC), PROMIS Fatigue, PROMIS Sleep, PROMIS-29, Pain Interference, Hospital Anxiety and Depression Scale (HADS), and Neuropathic Pain Symptom Inventory (NPSI). The target enrollment is currently 200 patients, which is subject to adjustment following a planned interim readout in the fourth quarter of 2025 following enrollment of 100 patients. The interim analysis will allow for changes to the study, if necessary, to improve trial outcomes.

Halneuron (tetrodotoxin, TTX), a sodium channel blocker, was originally discovered in the pufferfish and subsequent research has identified the toxin in 13 phyla (in both *Eukarya* and *Bacteria*) that includes both marine and terrestrial eukaryotes (Lago *et al*., 2015). As a natural poison, TTX is extremely effective and is the most potent non-peptide neurotoxin known. It blocks the influx of sodium through voltage-gated sodium channels (Na_Vs), thereby preventing the initiation and propagation of action potentials in almost all neurons and muscle cells (Stevens *et al*., 2011).

Mammals possess nine voltage-gated sodium channels, $Na_V1.1$-$Na_V1.9$. TTX binds to $Na_V1.1$, $Na_V1.2$, $Na_V1.3$, $Na_V1.4$, $Na_V1.6$, and $Na_V1.7$ (Nieto *et al*., 2012). $Na_V1.7$ is expressed in all types of dorsal root ganglion (DRG) neurons, sympathetic neurons, Schwann cells, and neuroendocrine cells (Catterall *et al*., 2005). It is responsible for the perception of pain, which is supported by multiple lines of evidence. Individuals with loss-of-function mutations in the *SCN9A* gene (which encodes the alpha-subunit of $Na_V1.7$) experience a complete inability to sense pain (Cox *et al*., 2006) while those with a gain-of-function mutation in *SCN9A* experience erythromelalgia (Dib-Hajj *et al*., 2005). In animal models, $Na_V1.7$ nociceptor-specific knockout mice showed increased mechanical and thermal pain thresholds (Nassar *et al*., 2004). These results led researchers to hypothesize that TTX could be a potential therapeutic to control pain.

Halneuron Clinical Trials

Previous clinical trials investigating Halneuron include a Phase 2 cancer related pain (CRP) study and a Phase 2 CINP trial.

Phase 2 CRP Trial

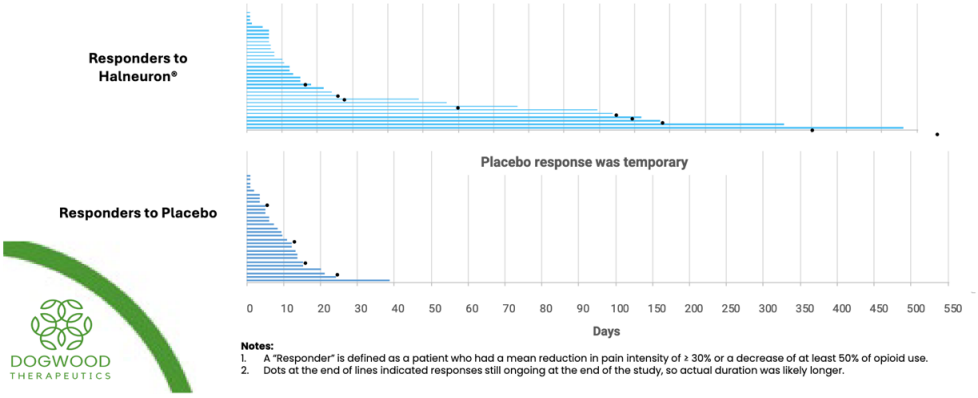
This was a randomized, double blind, parallel design, multicenter trial that enrolled 165 patients with moderate to severe inadequately controlled CRP. All patients were on standard of care pain management. Halneuron or placebo was administered twice a day for four days and all patients recorded their pain response from days 5-8 (early post-injection period) and from days 9-15 (late post-injection period). The results showed a statistically significant improvement in pain outcomes for Halneuron, with 51% of Halneuron patients experiencing a ≥30% reduction in pain compared to only 35% in the placebo group, as shown in the following image.

Pain Outcome – Co-Primary Endpoint (Pain Intensity Difference and/or Opioid Use)

	TTX [1]		Placebo [2]		Difference
Responder [3]	33	*51%*	29	*35%*	16%
Non-Responder	32	*49%*	55	*65%*	
Total	**65**		**84**		
p-value	**0.046**				

Source: Dogwood Therapeutics, Inc.

For Global Impression of Pain Change, 55% of Halneuron patients reported an improvement in pain compared to 24% of placebo patients. Conversely, 70% of placebo patients reported no change or worse pain compared to only 37% of patients. In addition to a positive pain response, the duration of pain relief was much higher for Halneuron patients, as shown in the following figure. The average pain response for Halneuron responders was 57.7 days compared to 10.5 days for placebo responders. Lastly, over one-quarter of Halneuron responders (27%) had pain relief that lasted for 30 days or longer after one cycle of treatment.



Source: Dogwood Therapeutics, Inc.

Phase 2 CINP Trial

This was a randomized, double blind, dose-finding, placebo controlled, multicenter study in patients with CINP. Various doses of Halneuron were tested over four days of treatment followed by measurement over four weeks. The study included a total of 125 patients across five dosing cohorts (four active and one placebo). The results showed that a dose of 30 μg twice per day for four days demonstrated the highest level of pain reduction compared to placebo, with the responder analysis results given below.

Responder Analyses: 30% reduction in average NPRS[1] score from baseline to any 10 consecutive days

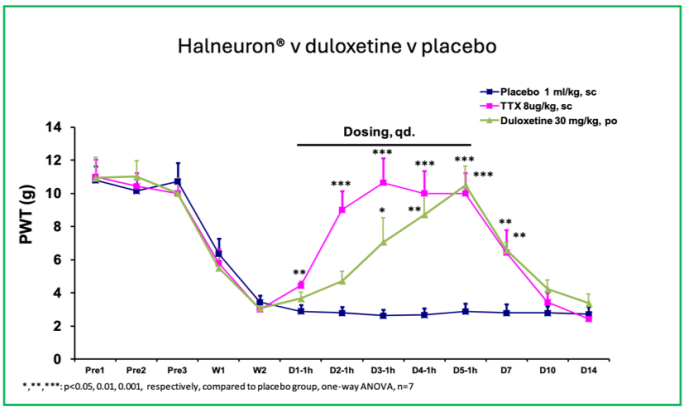
	TTX [2]	Placebo [3]
Yes	15 (58%)	8 (32%)
No	11 (42%)	17 (68%)
P-Value	**0.027**	
Odds Ratio (vs Placebo)	3.9	
95% CI for Odds Ratio	(1.08, 14.09)	

Source: Dogwood Therapeutics, Inc.

Background on CINP

CINP is the result of injury to the somatosensory nervous system following chemotherapy treatment (Colvin, 2019). For agents such as paclitaxel and oxaliplatin, the rate of CINP is up to 81% and 98%, respectively (Hershman *et al*., 2010; Gebremedhn *et al*., 2018). CINP begins as an acute pain syndrome that coincides with drug administration, however it can progress to a chronic condition following multiple rounds of therapy.

The only drug endorsed to treat CINP by the American Society of Clinical Oncology (ASCO) is duloxetine, which showed a significant reduction in pain in a Phase 3 clinical trial (Lavoie Smith *et al*., 2013). However, the drug is not FDA approved for the treatment of CINP. In addition, in a preclinical oxaliplatin-induced neuropathic pain model, Halneuron was superior to duloxetine based on the paw withdrawal threshold (PWT), a measure of pain tolerance.



- Halneuron®, at 8 µg/kg, sc, significantly increased the PWT in rats with oxaliplatin-induced neuropathy
- Duloxetine (positive control) at 30 mg/kg, q.d., increased the PWT in rats with oxaliplatin-induced neuropathy, but to a lesser degree compared to Halneuron®
- The effects of both compounds lasted approximately a week following cessation of dosing

Source: Dogwood Therapeutics, Inc.

There are an estimated 1.7 million CINP patients in the seven major markets (U.S., EU5, Japan). Opioids currently account for 30% of the global CINP market, which is estimated to be approximately $1.5 billion. The company also has plans to target CRP, which has a patient population approximately 7.5 times as large as CINP and a market worth approximately $5 billion.

Financial Update

On March 12, 2025, Dogwood announced the conversion of the company's $19.5 million debt to equity with its largest shareholder, CK Life Sciences Int'l, (Holdings), Inc. Under terms of the agreement, the principal amount of all loans made to Dogwood along with accrued interest will be deemed repaid in exchange for 284.2638 shares of Series A-1 Non-Voting Convertible Preferred Stock. Each share of A-1 Preferred Stock is convertible into 10,000 shares of Dogwood common stock, subject to shareholder approval. This will remove all debt from the company's balance sheet. On March 13, 2025, the company announced a securities purchase agreement for 578,950 shares of common stock at a price of $8.26 per share. Gross proceeds from the offering are approximately $4.8 million. Dogwood is now financed through the first quarter of 2026.

Conclusion

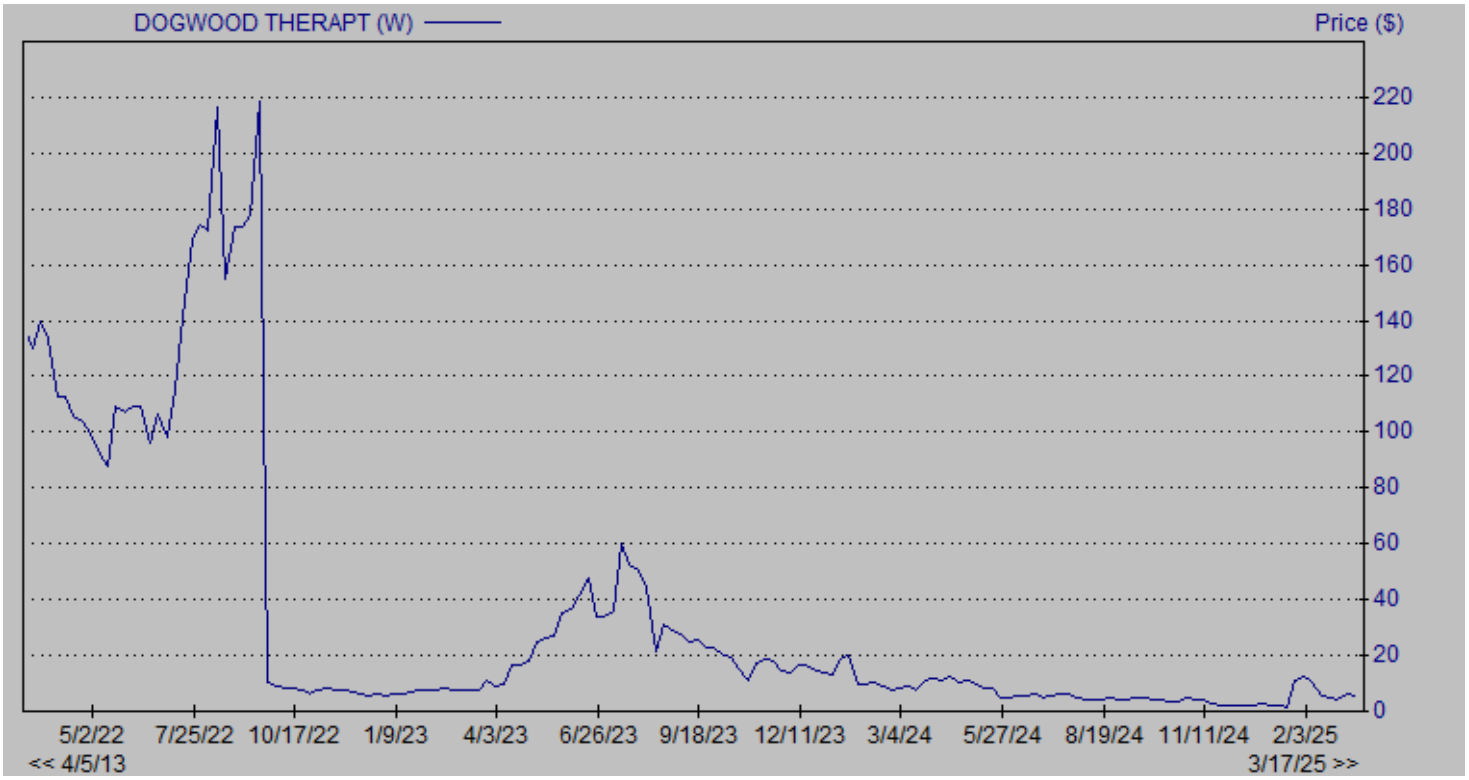
The debt conversion by Dogwood is a great strategic move by the company as it strengthens the balance sheet and eliminates any additional interest that would have been owed. The company is now financed through the first quarter of 2026, which is beyond the expected interim analysis of the ongoing Phase 2b trial of Halneuron and we look forward to updates on the trial as the year goes on. After taking the recent financing into account our valuation is now $11 per share.

PROJECTED FINANCIALS

Dogwood Therapeutics, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Halneuron	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
IMC-2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
R&D	$1.7	$0.3	$0.3	$0.5	$0.8	$2.0	$3.0	$4.0
SG&A	$3.7	$1.0	$0.7	$1.8	$0.9	$4.4	$3.5	$3.7
Operating Income	($5.4)	($1.3)	($1.1)	($2.3)	($1.7)	($6.4)	($6.5)	($7.7)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($5.3)	($1.3)	($1.0)	($2.3)	($1.7)	($6.3)	($6.4)	($7.6)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($5.3)	($1.3)	($1.0)	($2.3)	($1.7)	($6.3)	($6.4)	($7.6)
Reported EPS	**($7.05)**	**($1.68)**	**($1.15)**	**($2.05)**	**($1.49)**	**($6.43)**	**($4.57)**	**($1.90)**
Weighted Shares Outstanding	0.8	0.8	0.9	1.1	1.1	1.0	1.4	4.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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