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Dogwood Therapeutics, Inc. (DWTX-NASDAQ)

DWTX: Phase 2b Trial in Chemotherapy Induced Neuropathic Pain Underway…

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 (05/13/25)	$4.78
Valuation	**$11.00**

OUTLOOK

On May 8, 2025, Dogwood Therapeutics, Inc. announced financial results for the first quarter of 2025 and provided a business update. The company recently commenced a Phase 2b trial of Halneuron® for the treatment of Chemotherapy Induced Neuropathic Pain (CINP). An interim data readout is expected in the fourth quarter of 2025. A recent $4.8 million capital raise, together with existing cash, is expected to finance operations through the first quarter of 2026. Dogwood is continuing to explore external funding and/or partnerships to advance IMC-2 into Phase 2b development as a treatment for Long Covid and IMC-1 as a treatment for fibromyalgia.

SUMMARY DATA

52-Week High	**$17.40**
52-Week Low	**$1.85**
One-Year Return (%)	**-51.05**
Beta	**1.98**
Average Daily Volume (sh)	**2,447,819**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$9**
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)
2024	0 A	0 A	0 A	0 A	0 A
2025	0 A	0 E	0 E	0 E	0 E
2026					0 E
2027					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$1.68 A	-$1.15 A	-$2.05 A	-$5.88 A	-$12.02 A
2025	-$8.45 A	-$2.00 E	-$2.00 E	-$2.00 E	-$12.90 E
2026					-$5.67 E
2027					-$4.45 E

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WHAT'S NEW

Business Update

Phase 2b Trial of Halneuron® in CINP underway; Interim Results Expected in 4Q25

Dogwood Therapeutics, Inc. (DWTX) recently initiated 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).

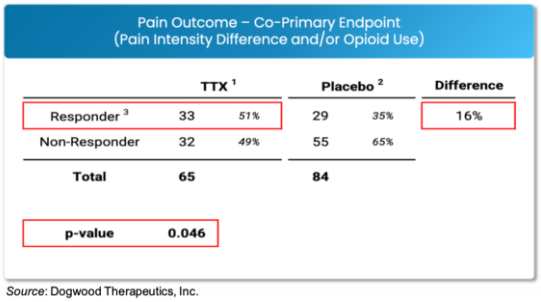
Mammals possess nine voltage-gated sodium channels, $Na_V1.1$-$Na_V1.9$. TTX binds to $Na_V1.1$, $Na_V1.2$, $Na_V1.3$, $Na_V1.4$, $Na_V1.6$, and $Na_V1.7$ (Nieto *et al*., 2012). $Na_V1.7$ is expressed in all types of dorsal root ganglion (DRG) neurons, sympathetic neurons, Schwann cells, and neuroendocrine 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.

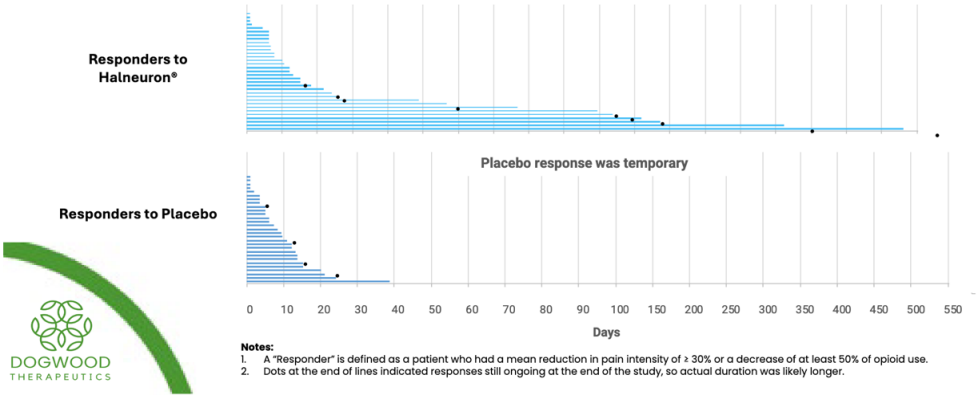
Phase 2 CRP Trial

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.



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

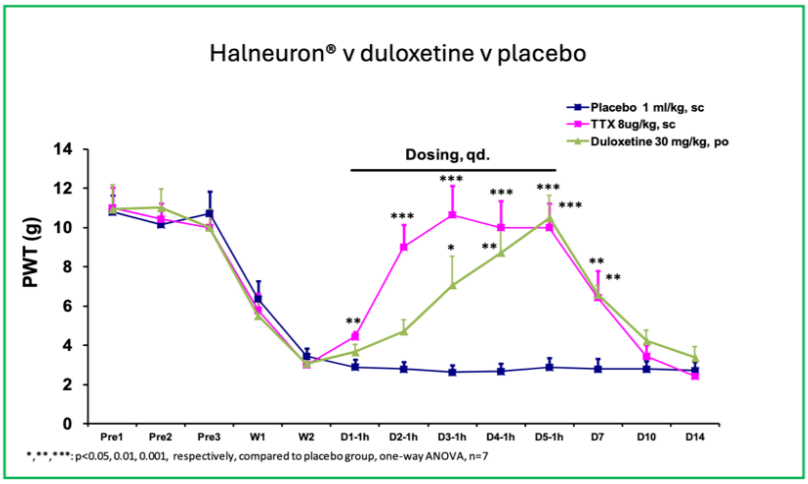
	TTX [2]	Placebo [3]
Yes	15 (58%)	8 (32%)
No	11 (42%)	17 (68%)
P-Value	**0.027**	
Odds Ratio (vs Placebo)	3.9	
95% CI for Odds Ratio	(1.08, 14.09)	

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.

IMC-1 and IMC-2 Update

IMC-2 (valacyclovir + celecoxib) is being developed as a treatment for Long COVID. In November 2024, Dogwood announced results from an investigator-initiated, double blind, placebo controlled study (BHC 201), which showed that while not statistically significant due to the small sample size (14-15 per group), the study demonstrated that low dose IMC-2 exhibited clinically meaningful improvements in fatigue and sleep disruption as compared to placebo treated patients while showing a favorable safety profile. The company is currently exploring external funding and/or a partnership to advance IMC-2 into Phase 2b development as a treatment for Long Covid.

IMC-1 (famciclovir + celecoxib) is being developed as a therapy for fibromyalgia. The company has received feedback from the U.S. FDA on a proposed Phase 3 program, in which the trials will focus on “new” patients that have not been in fibromyalgia trial previously, will utilize clinical research sites to deliver more consistent results, and will include two adequate and well controlled trials (one of which will be a full factorial design with each of the individual components of IMC-1 as separate comparator arms), a long-term safety trial, and a pharmacokinetic/food effect study. Dogwood is currently exploring partnerships for IMC-1 to execute the Phase 3 program.

Financial Update

On May 8, 2025, Dogwood announced financial results for the first quarter of 2025. As expected, the company did not report any revenues in the first quarter of 2025. R&D expenses for the quarter ending March 31, 2025 were $2.4 million compared to $0.3 million for the quarter ending March 31, 2024. The increase was primarily due to the impact of the business combination with Pharmagesic, increased costs for drug development and manufacturing, and increased salaries and related costs. G&A expenses for the first quarter of 2025 were $2.0 million compared to $1.0 million for the first quarter of 2024. The increase was primarily due to increased legal and accounting fees along with higher salaries and personnel costs.

As of March 31, 2025, Dogwood had approximately $17.5 million in cash and cash equivalents. We estimate this is sufficient to fund operations through the first quarter of 2026. As of May 6, 2025, Dogwood had

approximately 1.9 million common shares outstanding and, when factoring in stock options, warrants, and the Series A and Series A-1 convertible shares, a fully diluted share count of approximately 27.0 million.

Conclusion

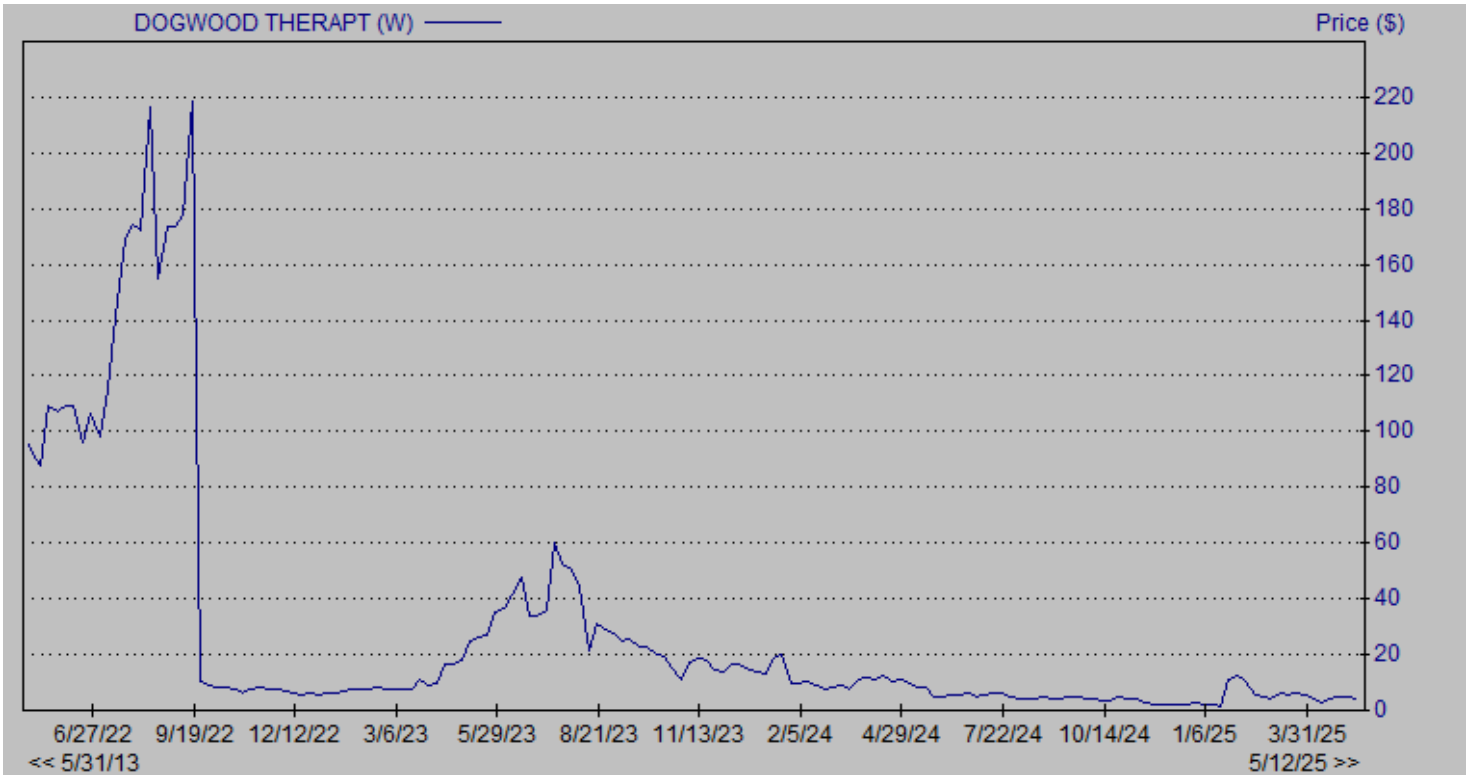
We look forward to the interim analysis of the Phase 2b trial of Halneuron, which we anticipate in the fourth quarter of 2025. In addition, we look forward to potential updates regarding IMC-1 or IMC-2. Following Dogwood's debt conversion and financing in March 2025, the company is now financed through the first quarter of 2026. With no changes to our model our valuation remains at $11 per share.

PROJECTED FINANCIALS

Dogwood Therapeutics, Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 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	$3.5	$2.4	$2.0	$2.0	$2.0	$8.4	$8.5	$8.8
SG&A	$8.7	$2.0	$2.0	$2.0	$2.0	$8.0	$8.5	$9.0
Operating Income	($12.2)	($4.4)	($4.0)	($4.0)	($4.0)	($16.4)	($17.0)	($17.8)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.1)	$6.3	$0.0	$0.0	$0.0	($6.3)	$0.0	$0.0
Pre-Tax Income	($12.4)	($10.7)	($4.0)	($4.0)	($4.0)	($22.7)	($17.0)	($17.8)
Taxes & Other	$0.0	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Accrual of paid-in-kind dividends on Series A Preferred Stock	$0.0	$1.3	$0.0	$0.0	$0.0	$1.3	$0.0	$0.0
Net Income	($12.4)	($12.2)	($4.0)	($4.0)	($4.0)	($24.0)	($17.0)	($17.8)
Reported EPS	**($12.02)**	**($8.45)**	**($2.00)**	**($2.00)**	**($2.00)**	**($12.90)**	**($5.67)**	**($4.45)**
Weighted Shares Outstanding	1.0	1.4	2.0	2.0	2.0	1.9	3.0	4.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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