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Dogwood Therapeutics, Inc.

(DWTX-NASDAQ)

DWTX: Over 50 Patients Enrolled Thus Far in Phase 2b Halneuron® Trial; Interim Read Out in 4Q25…

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 (08/20/25)	$4.81
Valuation	**$11.00**

OUTLOOK

On August 13, 2025, Dogwood Therapeutics, Inc. announced financial results for the second quarter of 2025 and provided a business update. Enrollment in the Phase 2b trial of Halneuron® for the treatment of Chemotherapy Induced Neuropathic Pain (CINP) has reached 52 patients. An interim data readout is expected in the fourth quarter of 2025. For the first 38 patients completing the trial there was a very low discontinuation rate (5.8%), suggesting that Halneuron and placebo treatment have both been generally well tolerated. Dogwood exited the second quarter of 2025 with $13.4 million, which we estimate will fund operations through the first quarter of 2026.

SUMMARY DATA

52-Week High	**$17.40**
52-Week Low	**$1.85**
One-Year Return (%)	**-2.19**
Beta	**1.80**
Average Daily Volume (sh)	**17,533**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$9**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**4**
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	**Above Avg.**
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 A	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	-$1.99 A	-$2.00 E	-$2.00 E	-$12.95 E
2026					-$5.67 E
2027					-$4.45 E

WHAT'S NEW

Business Update

Over 50 Patients Enrolled Thus Far in Phase 2b Trial of Halneuron® in CINP

Dogwood Therapeutics, Inc. (DWTX) is currently conducting 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 company recently reported that 52 patients have been enrolled thus far in the trial. There has been a low discontinuation rate (5.8%) seen thus far due to adverse events in the first 38 patients that have completed the trial, which suggests that Halaneuron and placebo treatment has been generally well tolerated. The trial has a planned interim readout following enrollment of 100 subjects. We anticipate the interim readout occurring in the fourth quarter of 2025. Currently the planned enrollment is 200 patients, however this number is subject to change depending on the results of the interim analysis.

Background on Halneuron

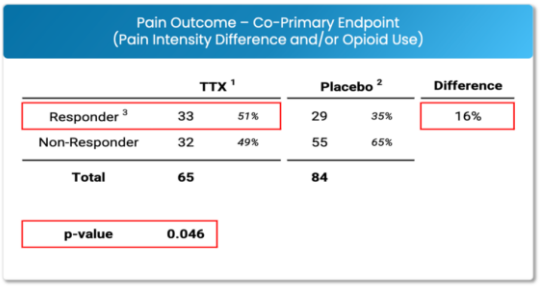
Halneuron (tetrodotoxin, TTX), a sodium channel blocker, was originally discovered in the pufferfish and subsequent research has identified the toxin in 13 phyla (in both *Eukarya* and *Bacteria*) that includes both marine and terrestrial eukaryotes (Lago *et al*., 2015). As a natural poison, TTX is 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

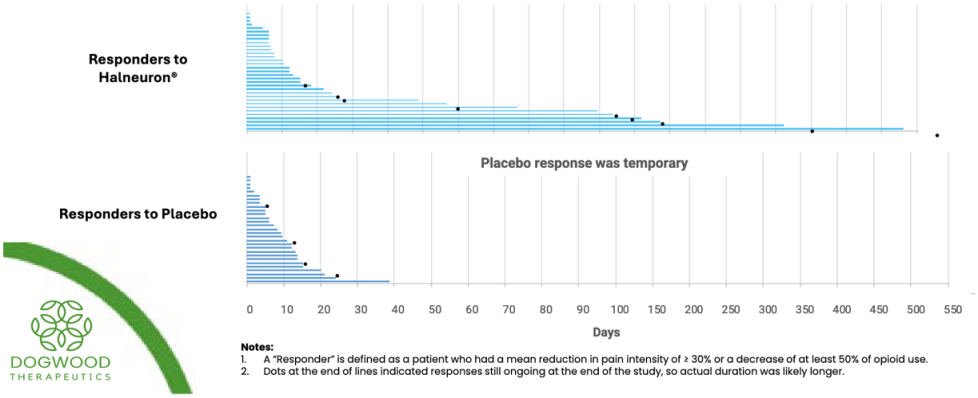
Previous clinical trials investigating Halneuron include a Phase 2 cancer related pain (CRP) study and a Phase 2 CINP trial.

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.

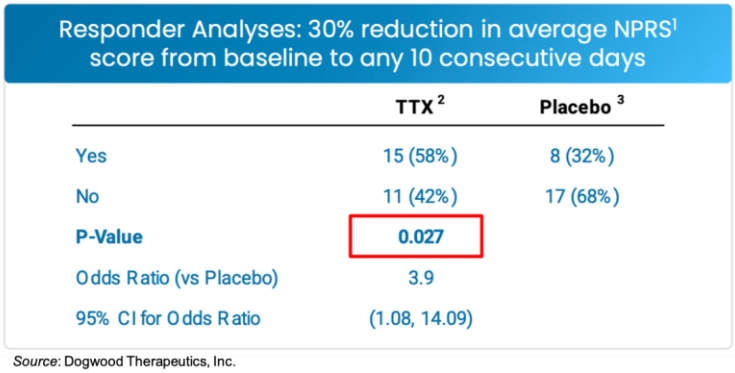
For Global Impression of Pain Change, 55% of Halneuron patients reported an improvement in pain compared to 24% of placebo patients. Conversely, 70% of placebo patients reported no change or worse pain compared to only 37% of patients. In addition to a positive pain response, the duration of pain relief 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.



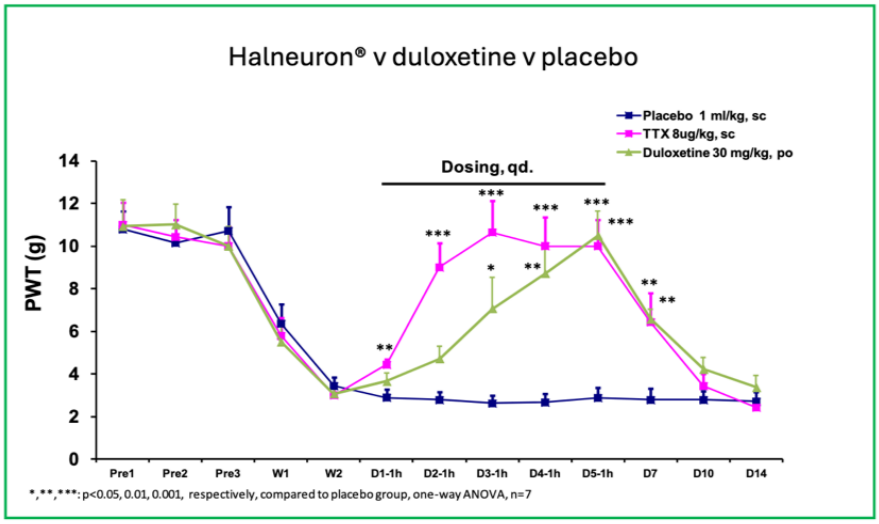
Source: Dogwood Therapeutics, Inc.

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. Due to reductions in government health funding for COVID and Long COVID research, Dogwood has paused external research funding and partnership discussions until there is greater clarity on the commitment of the U.S. Government to COVID illness.

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. Dogwood has been granted Fast Track designation by the FDA for the treatment of fibromyalgia.

Financial Update

On August 13, 2025, Dogwood announced financial results for the second quarter of 2025. As expected, the company did not report any revenues in the second quarter of 2025. R&D expenses for the quarter ending June 30, 2025 were $2.5 million compared to $0.3 million for the quarter ending June 30, 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 second quarter of 2025 were $1.3 million compared to $0.7 million for the second quarter of 2024. The increase was primarily due to increased legal and accounting fees along with higher salaries and personnel costs.

As of June 30, 2025, Dogwood had approximately $13.4 million in cash and cash equivalents. We estimate this is sufficient to fund operations through the first quarter of 2026. As of August 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 27.1 million.

Conclusion

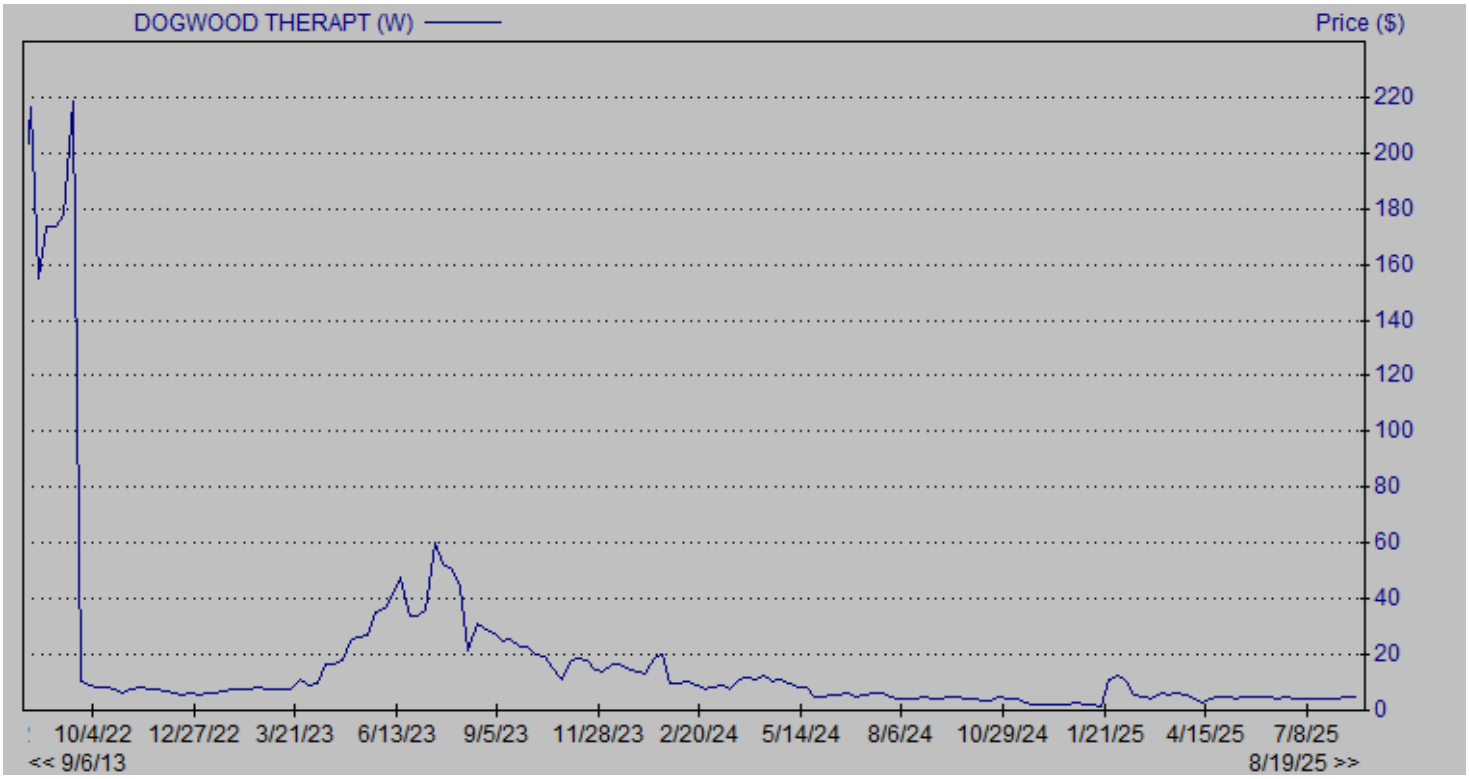
We look forward to the interim analysis of the Phase 2b trial of Halneuron, which we anticipate in the fourth quarter of 2025. We're encouraged to see the steady rate at which the trial is enrolling as well as the low discontinuation rate. With a cash runway through the first quarter of 2026 Dogwood is financed past the planned interim analysis. With no changes to our model our valuation remains at $11 per share.

PROJECTED FINANCIALS

Dogwood Therapeutics, Inc.	2024 A	Q1 A	Q2 A	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	$2.6	$2.0	$2.0	$9.0	$8.5	$8.8
SG&A	$8.7	$2.0	$1.4	$2.0	$2.0	$7.3	$8.5	$9.0
Operating Income	($12.2)	($4.4)	($3.9)	($4.0)	($4.0)	($16.4)	($17.0)	($17.8)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.1)	$6.3	$0.1	$0.0	$0.0	($6.2)	$0.0	$0.0
Pre-Tax Income	($12.4)	($10.7)	($3.8)	($4.0)	($4.0)	($22.5)	($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)	($3.8)	($4.0)	($4.0)	($23.8)	($17.0)	($17.8)
Reported EPS	**($12.02)**	**($8.45)**	**($1.99)**	**($2.00)**	**($2.00)**	**($12.95)**	**($5.67)**	**($4.45)**
Weighted Shares Outstanding	1.0	1.4	1.9	2.0	2.0	1.8	3.0	4.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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