
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **August 13, 2025**

DOGWOOD THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39811
(Commission
File Number)

85-4314201
(IRS Employer
Identification No.)

44 Milton Avenue
Alpharetta, GA
(Address of principal executive offices)

30009
(Zip Code)

Registrant's telephone number, including area code: **(866) 620-8655**

(Former name or former address, if changed since last report): Not Applicable

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001	DWTX	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 13, 2025, Dogwood Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the second quarter ended June 30, 2025. A copy of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference into this Item 2.02.

The information provided pursuant to this Item 2.02, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	<u>Press Release of the Company, dated August 13, 2025 (furnished herewith).</u>
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DOGWOOD THERAPEUTICS, INC.

By: /s/ Angela Walsh

Name: Angela Walsh

Title: Chief Financial Officer, Corporate Secretary and Treasurer

August 13, 2025



Exhibit 99.1

Dogwood Therapeutics Reports Second Quarter 2025 Financial Results

- Enrollment to-date of 52 patients in the ongoing Halneuron® Phase 2b Trial -
- Halneuron® Chemotherapy-Induced Neuropathic Pain (“CINP”) Phase 2b study interim data readout remains on track for Q4 2025 -
- Low discontinuation rate (5.8%) due to adverse events in the first 38 patients completing the trial suggests Halneuron® and placebo treatment have been generally well tolerated -
- Cash on hand of \$13.4 million provides operational runway through Q1 2026 -

ATLANTA, Ga., August 13, 2025 -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) (the “Company”), a development-stage biotechnology company developing new medicines to treat pain and fatigue-related disorders, today announced financial results for the second quarter ended June 30, 2025.

“With no FDA approved treatments to manage the neuropathic pain often resulting from chemotherapy treatment, we have the opportunity to potentially enjoy the benefits of being the first and only approved CINP treatment,” said Greg Duncan, Chief Executive Officer of Dogwood Therapeutics. “Further, we believe Halneuron’s® clinically significant effects in treating both general cancer pain and chemotherapy induced neuropathic pain highlights the significant potential to expand our Na_v 1.7 research pipeline to other forms of pain, including diabetic peripheral neuropathy, post herpetic neuralgia and acute surgical pain.”

“The Na_v 1.7 sodium channel plays a fundamental role in pain transmission, so modulation of this pathway is likely to be applicable to the treatment of both chronic and acute pain states” said Michael Gendreau, MD, PhD, Chief Medical Officer of Dogwood Therapeutics. “A genetic lack of functioning Na_v 1.7 channels leads to a condition known as Congenital Insensitivity to Pain Syndrome, a disorder characterized by the inability to feel pain. Patients who suffer from this condition illustrate the critical role Na_v 1.7 function represents as a pain treatment target.”

Key Highlights

- To-date, the Company has enrolled 52 patients in its ongoing Halneuron® Phase 2b CINP program this quarter, with potential to be the first FDA approved therapy for the treatment of CINP.



Dogwood Therapeutics Proprietary Pipeline Includes:

- **Halneuron®** is in Phase 2b development as a non-opioid, Na_v 1.7 inhibitor to treat pain conditions including the neuropathic pain associated with chemotherapy treatment. Halneuron® has been granted fast track designation from the Food and Drug Administration (“FDA”) for the treatment of CINP. Interim data from the ongoing Phase 2b CINP study are expected in Q4 2025.
- **IMC-1 (famciclovir + celecoxib)** is ready for Phase 3 development as a combination antiviral treatment for Fibromyalgia (“FM”). IMC-1 has been granted fast track designation by the FDA for the treatment of FM.
- **IMC-2 (valacyclovir + celecoxib)** is in Phase 2a development as a combination antiviral treatment for Long-COVID. Given the importance of Health and Human Services and Medicaid and Medicare funding of both COVID research and reimbursement of treatment, pervasive reductions in government health funding have resulted in us pausing current external research funding and partnership discussions until we have greater clarity on the commitment of U.S. Government resources to COVID illness.

Second Quarter 2025 Financial Results

Research and development expenses for the second quarter of 2025 were \$2.5 million, compared to \$0.3 million for the second quarter of 2024. The \$2.2 million increase quarter over quarter was primarily due to the impact of the business combination with Pharmagesic (the “Combination”) including increases in expenses for clinical trials of \$1.6 million related to the Halneuron® CINP Phase 2b study, as well as drug development and manufacturing costs of \$0.5 million and salaries and related personnel costs of \$0.2 million, offset by a decrease in regulatory costs of \$0.1 million.

General and administrative expenses for the second quarter of 2025 were \$1.3 million, compared to \$0.7 million for the second quarter of 2024. The \$0.6 million increase quarter over quarter was primarily due to increases in legal and accounting fees of \$0.2 million, salaries and related personnel costs of \$0.2 million, expenses associated with being a public company of \$0.1 million and other general and administrative costs of \$0.1 million.

Net loss attributable to common stockholders for the second quarter of 2025 was \$3.8 million, or \$1.99 basic and diluted net loss per share, compared to a net loss attributable to common stockholders of \$1.0 million, or \$1.15 basic and diluted net loss per share, for the second quarter of 2024.



About Dogwood Therapeutics

Dogwood Therapeutics (Nasdaq: DWTX) is a development-stage biopharmaceutical company focused on developing new medicines to treat pain and fatigue-related disorders. The Dogwood research pipeline includes two separate mechanistic platforms with a non-opioid analgesic program and an antiviral program. The proprietary, non-opioid, $\text{Na}_v 1.7$ analgesic program is centered on our lead development candidate, Halneuron®, which is a highly specific voltage-gated sodium channel modulator, a mechanism known to be effective for reducing pain transmission. In clinical studies, Halneuron® treatment has demonstrated pain reduction in pain related to general cancer and in pain related to chronic chemotherapy-induced neuropathic pain ("CINP"). Interim data from the ongoing Halneuron® Phase 2 CINP study are expected in Q4 of 2025.

Dogwood's antiviral program includes IMC-1 and IMC-2, which are novel, proprietary, fixed-dose combinations of anti-herpes antivirals and the anti-inflammatory agent celecoxib. These combination antiviral approaches are being applied to the treatment of illnesses believed to be related to reactivation of previously dormant herpesviruses, including fibromyalgia ("FM") and Long-COVID ("LC"). IMC-1 is poised to progress into Phase 3 development as a treatment for FM and is the focus of external partnership activities. IMC-2 has been assessed in both active control and double-blind, placebo-controlled clinical trials and, in both cases, demonstrated successful reduction of the fatigue associated with LC. The company has reached an agreement with FDA on using reduction in fatigue as the primary endpoint for future IMC-2 LC research.

For more information, please visit www.dwtx.com.

Forward-Looking Statements:

Statements in this press release contain "forward-looking statements," within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "suggest," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Dogwood's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the completion, timing and results of current and future clinical studies relating to Dogwood's product candidates. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are



described more fully in the section titled “Risk Factors” in the Annual Report on Form 10-K for the year ended December 31, 2024, which has been filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Dogwood undertakes no duty to update such information except as required under applicable law.

Investor Relations:

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IR@dwtx.com

-Financial Tables Follow-



DOGWOOD THERAPEUTICS
Selected Financial Data
(unaudited)

Condensed Statements of Operations Data	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	2,569,943	336,084	5,006,941	679,801
General and administrative	1,353,172	733,740	3,346,100	1,704,124
Total operating expenses	3,923,115	1,069,824	8,353,041	2,383,925
Loss from operations	(3,923,115)	(1,069,824)	(8,353,041)	(2,383,925)
Other (expense) income:				
Loss on debt conversion with related party	—	—	(6,134,120)	—
Interest income (expense), net	111,379	19,991	(35,711)	42,757
Exchange gain (loss), net	4,532	—	(18,742)	—
Total other income (expense), net	115,911	19,991	(6,188,573)	42,757
Loss before income taxes	(3,807,204)	(1,049,833)	(14,541,614)	(2,341,168)
Deferred income tax provision	(149)	—	(190,691)	—
Net Loss	(3,807,353)	(1,049,833)	(14,732,305)	(2,341,168)
Accrual of paid-in-kind dividends on Series A non-voting convertible preferred stock	—	—	(1,256,662)	—
Net loss attributable to common stockholders	<u>\$ (3,807,353)</u>	<u>\$ (1,049,833)</u>	<u>\$ (15,988,967)</u>	<u>\$ (2,341,168)</u>
Net loss per share of common stock — basic and diluted	<u>\$ (1.99)</u>	<u>\$ (1.15)</u>	<u>\$ (9.51)</u>	<u>\$ (2.78)</u>
Weighted average shares outstanding — basic and diluted	<u>1,911,128</u>	<u>916,031</u>	<u>1,680,827</u>	<u>843,174</u>

**Condensed Consolidated Balance Sheet Data**

	June 30, 2025	December 31, 2024
Cash	\$ 13,402,809	\$ 14,847,949
Total assets	96,692,527	94,308,246
Total liabilities	14,151,904	30,027,223
Total stockholders' equity (deficit)	6,878,599	(10,124,339)

Source: Dogwood Therapeutics, Inc.