

**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): **November 7, 2024**

**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 November 7, 2024, Dogwood Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the third quarter ended September 30, 2024. 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release of the Company, dated November 7, 2024 (furnished herewith).</a>
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.

**VIRIOS THERAPEUTICS, INC.**

By: /s/ Angela Walsh  
Name: Angela Walsh  
Title: Chief Financial Officer, Corporate Secretary and Treasurer

November 7, 2024



Exhibit 99.1

## Dogwood Therapeutics Announces Third Quarter 2024 Financial Results

- Dogwood Therapeutics, Inc. (Nasdaq: "DWTX") formed in October by combination of Virios Therapeutics, Inc. and Pharmagesic (Holdings) Inc., 100% parent company of Wex Pharmaceuticals, Inc. (the "Combination") -
- Expanded pipeline with multiple programs in large markets with high unmet need -
- Strategic financing results in combined working capital of approximately \$23 million to fund operations and advance Phase 2b Halneuron® development through 2025 -
- Top-line results from Long-COVID Phase 2a study expected in mid-November 2024 -
- NaV 1.7 inhibition pain treatment, Halneuron®, Phase 2b study for chemotherapy-induced neuropathic pain expected interim readout 2H 2025-

ATLANTA, Ga., November 7, 2024 -- 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 third quarter ended September 30, 2024 and provided a business update.

"The formation of Dogwood Therapeutics last month represents a transformational expansion of our pipeline with the addition of Halneuron®, a non-opioid, novel NaV 1.7 modulator to treat neuropathic pain associated with chemotherapy, purposefully complementing our promising development assets IMC-1 and IMC-2," said Greg Duncan, Chief Executive Officer of Dogwood Therapeutics. "The concurrent strategic financing to be provided by an affiliate of CK Life Sciences Int'l. (Holdings) Inc. ("CKLS"), former owner of Pharmagesic (Holdings) Inc., provides us with operating capital through 2025. We see this as a win-win for legacy Virios shareholders and CKLS, with both short-term and medium-term value creation opportunities associated with forthcoming data from the Bateman-Horne Center ("BHC") managed IMC-2 Phase 2 Long-COVID trial, and the Halneuron® Phase 2b interim data projected for the second half of next year."

### Key Highlights

- Dogwood's expanded pipeline includes three late-stage assets: Halneuron®, currently in Phase 2b development for chemotherapy-induced neuropathic pain ("CINP"); IMC-1, poised for Phase 3 development as a treatment for fibromyalgia ("FM"); and IMC-2, currently in Phase 2 development to treat Long-COVID ("LC") sequelae.
  - In connection with the Combination, the Company announced that it raised \$19.5 million in committed debt financing by an affiliate of CKLS in two tranches with \$16.5 million funded as of October 7, 2024 and an additional \$3.0 million to be funded in 1Q 2025, subject to certain conditions. This financing is expected to fund research and operations
-



through several key milestones, including the release of results from the Halneuron® Phase 2b interim analysis assessment expected in 2H 2025.

- Top-line results from the ongoing BHC IMC-2 LC Phase 2a study, assessing two doses of the combination of valacyclovir + celecoxib versus placebo, are expected by mid-November 2024.

#### **Dogwood Therapeutics Proprietary Pipeline Includes:**

- **Halneuron®** is in Phase 2b development as a non-opioid, NaV 1.7 inhibitor to treat 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.

Next milestone: Interim data from the ongoing Phase 2b CINP study are expected in 2H 2025.

- **IMC-2 (valacyclovir + celecoxib)** is in Phase 2a development as a combination antiviral treatment for LC.

Next milestone: Topline data from an investigator led, double blind controlled proof of concept study, assessing two doses of IMC-2 vs placebo, are expected in mid-November 2024.

- **IMC-1 (famciclovir + celecoxib)** is ready for Phase 3 development as a combination antiviral treatment for FM. IMC-1 has been granted fast track designation by the FDA for the treatment of FM.

Next milestone: Dogwood is exploring partnerships for IMC-1 to execute the Phase 3 FM program agreed upon by the FDA.

#### **Third Quarter 2024 Financial Results**

Research and development expenses increased by \$0.2 million for the third quarter of 2024 compared to the third quarter of 2023. The quarter-over-quarter change was primarily due to increases in expenses associated with the grant to BHC for the second proof-of-concept study in LC of \$0.3 million offset by a decrease in regulatory expenses of \$0.1 million.

General and administrative expenses increased by \$0.9 million for the third quarter of 2024 compared to the third quarter of 2023. The quarter-over-quarter change was primarily due to higher legal and professional fees related to the business combination in October 2024 of \$1.0 million offset by lower insurance expenses associated with being a public company of \$0.1 million.



Net loss for the third quarter of 2024 was \$2.3 million, or \$2.05 basic and diluted net loss per share, compared to a net loss of \$1.2 million, or \$1.62 basic and diluted net loss per share for the third quarter of 2023 (as adjusted to reflect the reverse stock split implemented on October 9, 2024).

The Company estimates that its current cash of \$2.0 million at September 30, 2024 along with the \$16.5 million in loan proceeds received on October 7, 2024 is not sufficient to fund operating expenses and capital requirements for at least the next 12 months. The Company will need to secure the additional \$3.0 million of loan proceeds available to us under the terms of the loan agreement in February 2025 to continue to fund our operations through 2025.

### **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, Nav 1.7 analgesic program is centered on lead development candidate, Halneuron<sup>®</sup> which is a voltage-gated sodium channel blocker, a mechanism known to be effective for reducing pain. Halneuron<sup>®</sup> treatment has demonstrated pain reduction of both general cancer related pain and CINP. Interim data from the forthcoming Phase 2 CINP study are expected in 2H 2025. The antiviral program includes IMC-1 and IMC-2, which are novel, proprietary, fixed dose combinations of nucleoside analog, anti-herpes antivirals and the anti-inflammatory agent, celecoxib, for the treatment of illnesses believed to be related to reactivation of previously dormant herpes viruses, including FM and LC. Top-line data from an ongoing IMC-2 Phase 2 LC study are expected in mid-November 2024. IMC-1 is poised to progress into Phase 3 development as a treatment for FM and is the focus of external partnership activities. For more information, please visit [www.dwtx.com](http://www.dwtx.com).

### **Follow Dogwood Therapeutics**

Email Alerts: <https://ir.dwtx.com/resources/email-alerts>

LinkedIn: <https://www.linkedin.com/company/dogwoodther/>

Twitter: <https://twitter.com/dogwoodther>

Facebook: <https://www.facebook.com/dogwoodther>

### **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 Amended Annual Report on Form 10-K/A for the year ended December 31, 2023 and the Company’s quarterly report on Form 10-Q for the quarterly period ended September 30, 2024, which are 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.

**Contact:**

IR@dwtx.com

-Financial Tables Follow-



**DOGWOOD THERAPEUTICS**  
**Selected Financial Data**  
(unaudited)

<b>Condensed Statements of Operations Data</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	535,162	374,200	1,214,964	1,429,757
General and administrative	1,766,010	900,089	3,470,133	2,879,036
Total operating expenses	<u>2,301,172</u>	<u>1,274,289</u>	<u>4,685,097</u>	<u>4,308,793</u>
Loss from operations	(2,301,172)	(1,274,289)	(4,685,097)	(4,308,793)
Other Income:				
Interest income	20,488	39,215	63,245	115,951
Total Other income	<u>20,488</u>	<u>39,215</u>	<u>63,245</u>	<u>115,951</u>
Net loss	<u>\$ (2,280,684)</u>	<u>\$ (1,235,074)</u>	<u>\$ (4,621,852)</u>	<u>\$ (4,192,842)</u>
Net loss per share of common stock — basic and diluted, as adjusted	<u>\$ (2.05)</u>	<u>\$ (1.62)</u>	<u>\$ (4.95)</u>	<u>\$ (5.63)</u>
Weighted average shares outstanding — basic and diluted, as adjusted	<u>1,110,317</u>	<u>763,750</u>	<u>932,872</u>	<u>774,586</u>

<b>Condensed Balance Sheet Data</b>	<b>September 30, 2024</b>	<b>December 31, 2023</b>
Cash	\$ 2,039,819	\$ 3,316,946
Total assets	2,283,249	4,165,442
Total liabilities	1,333,818	358,548
Total stockholders' equity	949,431	3,806,894

Source: Dogwood Therapeutics, Inc.