

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 9, 2025**

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-39070</u> (Commission File Number)	<u>32-0463781</u> (I.R.S. Employer Identification No.)
<u>1000 Skokie Blvd., Suite 350, Wilmette, IL</u> (Address of principal executive offices)		<u>60091</u> (Zip Code)

(847) 388-0349

Registrant's telephone number, including area code

N/A

(Former name or former address, if changed since last report)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value	MNPR	The Nasdaq Stock Market LLC (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 7.01 Regulation FD Disclosure.

On November 9, 2025, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing the presentation of new data and analyses from the Phase 2 ALXN1840-WD-204 copper balance study at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2025.

The press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release Dated November 9, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Monopar Therapeutics Inc.

Date: November 10, 2025

By: /s/ Quan Vu
Name: Quan Vu
Title: Chief Financial Officer



Monopar Presents New Data and Analyses on Rapidly Improved Copper Balance in Wilson Disease Patients on Tiomolybdate Choline at AASLD - The Liver Meeting® 2025

Wilmette, Ill., November 9, 2025 – Monopar Therapeutics Inc. (“Monopar” or the “Company”) (Nasdaq: MNPR), a clinical-stage biopharmaceutical company developing innovative treatments for patients with unmet medical needs, is presenting new data and analyses today from the Phase 2 ALXN1840-WD-204 copper balance study at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2025, taking place in Washington, D.C., from November 7-11, 2025.

In an oral presentation titled “*Rapidly Improved Cu Balance in Wilson Disease Patients on Tiomolybdate Choline*,” Professor Aftab Ala, MBBS, M.D., FRCP, Ph.D., Professor of Hepatology and Consultant Hepatologist at the Institute of Liver Studies at King’s College Hospital in London, will be sharing results showing that treatment with ALXN1840 (tiomolybdate choline) led to a rapid and sustained improvement in daily copper balance in patients with Wilson disease, primarily through increased fecal copper excretion.

The mean daily copper balance among patients treated with ALXN1840 in the study (n=8) was significantly lower - indicating improvement - compared with their pre-treatment baseline. Copper balance improved both during the initial 15 mg once-daily dosing period (days 1-28) and over the entire treatment duration (days 1-39), which included patients receiving either 15 mg every other day or 30 mg once daily. Additional new nonclinical and clinical data supporting these findings from the ALXN1840-WD-204 study will also be presented.

The presentation materials are available on Monopar’s website (<https://www.monopartx.com/AASLD2025>), and the abstract can be accessed on the AASLD conference website (https://www.aasld.org/sites/default/files/2025-10/HEP_82_S1-FINAL.pdf).

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company with late-stage ALXN1840 for Wilson disease, and radiopharmaceutical programs including Phase 1-stage MNPR-101-Zr for imaging advanced cancers, and Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac225 for the treatment of advanced cancers. For more information, visit: www.monopartx.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements involve risks and uncertainties including, but not limited to: uncertainties related to the regulatory process that Monopar intends to initiate related to ALXN1840 and the outcome thereof; the rate of market acceptance and competitiveness in terms of pricing, efficacy and safety, of any products for which Monopar receives marketing approval, and Monopar’s ability to competitively market any such products as compared to larger pharmaceutical firms; Monopar’s ability to raise sufficient funds in order for the Company to support continued preclinical, clinical, regulatory, precommercial and commercial development of its programs and to make contractual milestone payments, as well as its ability to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of imaging agents and therapeutics. Actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Monopar’s filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Monopar undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made. Any forward-looking statements contained in this press release represent Monopar’s views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

CONTACT:

Monopar Therapeutics Inc.

Investor Relations
Quan Vu
Chief Financial Officer
vu@monopartx.com

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X: @MonoparTx LinkedIn: Monopar Therapeutics