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): **May 7, 2025**

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39070**	**32-0463781**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1000 Skokie Blvd., Suite 350, Wilmette, IL	**60091**
(Address of principal executive offices)	(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:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
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 May 7, 2025, Monopar Therapeutics Inc. (Monopar) issued a press release announcing a poster presentation of data on the long term efficacy and safety of its ALXN1840 (tiomolybdate choline) drug candidate for Wilson disease at the European Association for the Study of the Liver ("EASL") International Liver Congress 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

Exhibit No.	Description
99.1	Press Release Dated May 7, 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: May 7, 2025

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

Monopar Presents ALXN1840 Late-Breaker Data at EASL 2025

WILMETTE, Ill, May 7, 2025 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for patients with unmet medical needs, is presenting today data on the long term efficacy and safety of its ALXN1840 (tiomolybdate choline) drug candidate for Wilson disease at the European Association for the Study of the Liver ("EASL") International Liver Congress 2025, one of the most prominent global conferences in liver disease. Monopar's late-breaker poster presentation is available at the following link: https://www.monopartx.com/pipeline/ALXN1840/EASL-poster-may-2025.

The poster supports the potential use of ALXN1840 as a therapeutic option for Wilson disease, a rare and progressive genetic condition in which the body's pathway for removing excess copper is compromised, leading to damage from toxic copper build-up in tissues and organs such as the liver and brain. Efficacy data were pooled and analyzed from three clinical trials: Phase 2 WTX101-201, Phase 2 ALXN1840-WD-205, and Phase 3 WTX101-301 (n=255). For safety analysis, data from the Phase 2 ALXN1840-WD-204 trial were also included (n=266). The median treatment duration with ALXN1840 was 961 days (2.63 years) and 943.5 days (2.58 years) for the efficacy and safety datasets, respectively. The data presented highlight the following:

- Sustained improvements from baseline in the Unified Wilson Disease Rating Scale ("UWDRS") Part II (patient-reported symptoms) and Part III (clinician-assessed symptoms);
- Increased copper mobilization as evidenced by a sustained increase in dNCC (directly measured non-ceruloplasmin-bound copper);
- Improvements on the Clinical Global Impression – Improvement ("CGI-I") scale for ALXN1840 compared to standard of care;
- Improvement in the New Wilson Index (based on bilirubin, AST, INR, leukocytes, and albumin) for patients treated with ALXN1840;
- Higher patient-reported convenience and effectiveness of ALXN1840 compared to standard of care, including those who transitioned from standard of care to ALXN1840 in the extension portion of the Phase 3 clinical trial; and
- Fewer than 5% of patients experienced a drug-related serious adverse event ("SAE"), with no cases of a drug-related renal or urinary system SAE.

"These data show that the long-term efficacy, safety, and convenience profile of ALXN1840 are very encouraging and that ALXN1840 has the potential to provide a meaningful benefit to Wilson disease patients' daily lives," said Dr. Karl Weiss, Medical Director of Salem Medical Center Heidelberg, and lead author of the presentation at EASL.

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. Examples of these forward-looking statements include statements concerning: that Monopar's poster supports the potential use of ALXN1840 as a therapy for Wilson disease; and that ALXN1840 has the potential to provide a meaningful benefit to Wilson disease patients' daily lives. 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:

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