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): **June 26, 2026**

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 June 26, 2026, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing the presentation of new analyses from the Phase 3 FoCus trial of ALXN1840 (tiomolibdate choline) showing greater neurologic and global clinical benefit versus standard of care in Wilson disease patients. Monopar will present the analyses and a poster presentation at the 12th Congress of the European Academy of Neurology (EAN), which takes place June 27-30, 2026.

The press release and poster presentation are furnished as Exhibits 99.1 and 99.2, respectively, and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release Dated June 26, 2026.
99.2	Poster Presentation on Greater Clinical Benefit of ALXN1840 Versus Standard of Care in Neurologic Wilson Disease Patients in Phase 3 FoCus Trial.
104	Cover Page Interactive Data File - the cover page XBRL tags are 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: June 26, 2026

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

Monopar Presents New Analyses of Phase 3 FoCus Data at EAN 2026 Showing Greater Neurologic and Global Clinical Benefit with ALXN1840 Versus Standard of Care in Wilson Disease

WILMETTE, Ill., June 26, 2026 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. ("Monopar" or the "Company") (Nasdaq: MNPR), a clinical-stage biopharmaceutical company developing innovative treatments for patients with unmet medical needs, today announced that new analyses from the Phase 3 FoCus randomized controlled clinical trial of ALXN1840 (tiomolibdate choline, TMC) will be presented at the 12th Congress of the European Academy of Neurology (EAN 2026), June 27–30, 2026, in Geneva, Switzerland. These analyses build upon the previously reported Phase 3 FoCus results demonstrating ALXN1840 met its primary endpoint of superior copper mobilization versus standard of care.

In an encore poster presentation titled "Greater clinical benefit with tiomolibdate choline versus standard of care in neurologic Wilson disease patients in the Phase 3 FoCus Trial," Aurélia Poujois, MD, PhD, Department of Neurology, Adolphe de Rothschild Foundation Hospital, Paris, France, will present results showing that ALXN1840 produced significant neurologic improvement over time and greater global clinical improvement compared to standard-of-care (SoC) therapy in Wilson disease (WD) patients with neurologic symptoms at baseline. ALXN1840 also demonstrated similar or better outcomes compared to SoC across a range of psychiatric and hepatic measures during the 48-week study.

Key findings presented at EAN 2026:

In the subset of patients with neurologic symptoms at baseline from the 2:1 randomized Phase 3 FoCus clinical trial (NCT03403205; n=207), ALXN1840 demonstrated improved outcomes compared to SoC across multiple clinical measures:

- Neurologic improvement on the rater-blinded, physician-assessed Unified Wilson Disease Rating Scale (UWDRS) Part III was significant and continued over time with ALXN1840 ($p=0.006$) but not with SoC ($p=0.435$).
- Global clinical improvement as assessed by the Clinical Global Impressions – Improvement (CGI-I) scale at Week 48 was significantly greater with ALXN1840 than with SoC ($p<0.001$).
- A greater proportion of patients treated with ALXN1840 achieved improvement on the rater-blinded UWDRS Part III at Week 48 compared with SoC, with consistent results observed across multiple improvement thresholds.
- ALXN1840 also produced similar or greater improvement than SoC at Week 48 across psychiatric and hepatic measures.

Across Phase 2 and Phase 3 studies, ALXN1840 has demonstrated a well-characterized and favorable safety profile in 266 patients, with a median treatment duration of 2.58 years and maximum exposure of more than 8 years. Drug-related serious adverse events (SAEs) occurred in 4.9% of patients, including neurologic SAEs in less than 1% and no treatment-related deaths.

"For Wilson disease patients with neurologic symptoms, meaningful improvement can be difficult to achieve with existing therapies, and some patients experience severe paradoxical worsening," said Dr. Poujois. "These new analyses from the Phase 3 FoCus trial are encouraging because they show that ALXN1840 treatment was associated with continued neurologic improvement over time and greater global clinical benefit compared with standard of care."

The poster is available on Monopar's website (https://www.monopartx.com/pipeline/alxn1840/ean-poster-june-2026).

These findings further support Monopar's planned New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for ALXN1840 in mid-2026.

About Wilson Disease

Wilson disease (WD) is a rare genetic disorder that affects approximately 1 in 30,000 people worldwide. It is caused by mutations in the ATP7B gene, which impairs the body's ability to excrete copper. It is characterized by toxic accumulation of copper in the liver, brain, and other organs, leading to progressive and potentially fatal outcomes if untreated.

About ALXN1840

ALXN1840 (tiomolibdate choline, TMC) is a novel first-in-class albumin tripartite complex (ATC) activator under investigation for the treatment of Wilson disease. ALXN1840 rapidly mobilizes and tightly sequesters excess copper in ATCs, suppressing its redox reactivity, limiting oxidative damage, and blocking transport across the blood–brain barrier. Clinical data demonstrate that ALXN1840 improves copper balance by increasing fecal copper excretion. In the Phase 3 pivotal trial, ALXN1840 met the primary endpoint by demonstrating rapid and sustained copper mobilization significantly greater than standard of care over 48 weeks in both previously treated and untreated patients. Durable clinical improvement and a favorable safety and tolerability profile were observed across 645 patient-years of follow-up in 266 patients.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company with late-stage ALXN1840 for Wilson disease, and radiopharmaceutical programs including MNPR-101-Zr (Phase 1) for imaging advanced cancers along with MNPR-101-Lu (Phase 1a) and MNPR-101-Ac (late preclinical) 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. An example of a forward-looking statement includes the statement concerning: that these findings (the Phase 3 FoCus data) further support Monopar's planned New Drug Application (NDA) submission to the FDA for ALXN1840 in mid-2026. 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.

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Source: Monopar Therapeutics Inc.

Presenter:
Aurelia Poujois, MD, PhD
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Greater clinical benefit with tiomolibdate choline versus standard of care in neurologic WD patients in the Phase 3 FoCus Trial

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Disclosures:

AP, ML, PH: Travel grants from Monopar Therapeutics
CR, AC, DT: Employees of Monopar Therapeutics
JB, DB, PD, IM, TL: Nothing to disclose

Introduction

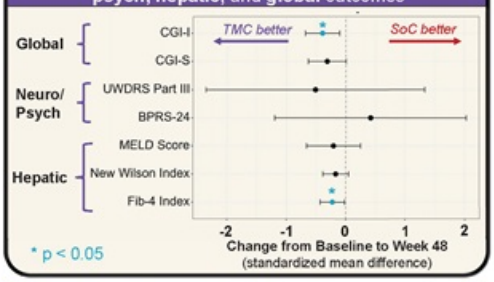
ALXN1840 (tiomolibdate choline, TMC), is a novel first-in-class Albumin Tripartite Complex (ATC) activator under investigation for the treatment of Wilson disease (WD). WD is a rare genetic disorder of copper overload. ALXN1840 rapidly mobilizes and tightly sequesters excess copper in ATCs, suppressing its redox reactivity, limiting oxidative damage, and blocking transport across the blood–brain barrier. Clinical data demonstrate that ALXN1840 improves copper balance by increasing fecal copper excretion. In the phase III pivotal trial, ALXN1840 demonstrated rapid and sustained copper mobilization significantly greater than standard of care (SoC) over 48 weeks in both previously treated and untreated patients. Durable clinical improvement and a favorable tolerability and safety profile were observed across > 6 years of treatment.

Methods

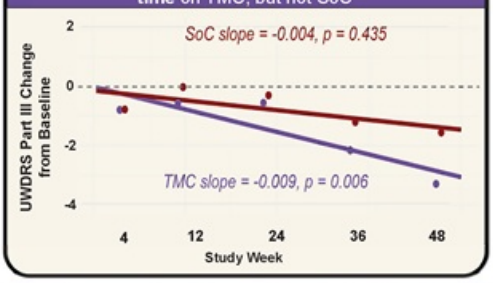
The Phase 3 FoCus RCT (NCT03403205) enrolled 207 patients with WD to TMC (n=137) or standard of care (SoC, n=70) for 48 weeks, with an optional 5-year extension on TMC. Over half of enrolled patients (TMC: n=77; SoC: n=35) demonstrated neurological symptoms at baseline, defined as baseline Unified WD Rating Scale (UWDRS) Part III score greater than the minimum clinically important difference (MCID) of 4.668. UWDRS Part III assessments during the trial were rater-blinded. Analyses were conducted on all patients with data available.

Results

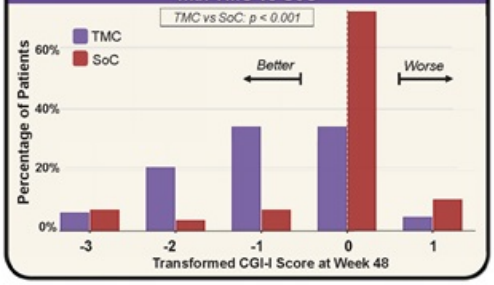
TMC was same or better than SoC across neuro, psych, hepatic, and global outcomes



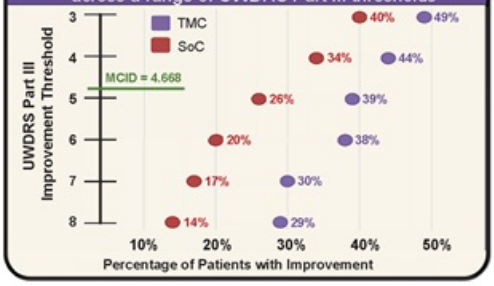
Significant continued neurologic improvement over time on TMC, but not SoC



Significantly greater global clinical improvement with TMC vs SoC



More neuro benefit on TMC vs SoC at Week 48, across a range of UWDRS Part III thresholds



Safety

TMC showed a favorable safety profile across all dosed patients with WD in Phase 2 & 3 studies.

Serious Adverse Events (SAEs) on TMC	
Number of patients	266
Median time on treatment (yrs)	2.58
Total **patient-years**	645.6
Patients with **any drug-related SAE**	13 (4.9%)
Neurologic	2 (0.8%)
Psychiatric	1 (0.4%)

Data through 01-Sep-2022.

Conclusions

In WD patients with neurologic symptoms at baseline, 48 weeks of treatment with TMC led to greater clinical and neurologic benefit and less worsening compared to SoC. Greater neurologic benefit was observed in the TMC group across both previously treated and treatment-naïve patient groups. Continued improvement was sustained through long-term follow-up. These findings demonstrate TMC improves outcomes in WD patients with neurologic symptoms and could serve as a valuable new treatment for this population in need.