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): **April 19, 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 April 19, 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 benefit versus standard of care in Wilson disease patients with neurologic symptoms at baseline. Monopar presented the analyses at the American Academy of Neurology (AAN) Annual Meeting, which takes place April 18-22, 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 April 19, 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: April 20, 2026

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

Exhibit 99.1

Monopar Presents Phase 3 Data Showing Greater Neurologic Benefit with ALXN1840 vs SoC in Wilson Disease Patients with Neurologic Symptoms at AAN 2026

WILMETTE, Ill., April 19, 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, announced new analyses from the randomized controlled Phase 3 FoCus trial of ALXN1840 (tiomolibdate choline, TMC) showing greater neurologic benefit versus standard of care (SoC) in Wilson disease patients with neurologic symptoms at baseline. The data will be presented today at the American Academy of Neurology (AAN) Annual Meeting 2026, taking place April 18-22, 2026.

In a late-breaker oral and poster presentation titled "Greater clinical benefit with tiomolibdate choline versus standard-of-care in neurologic Wilson disease patients in the Phase 3 FoCus Trial," Dr. Peter Hedera, MD, PhD, Department of Neurology, University of Louisville School of Medicine, will present results showing that ALXN1840 provided greater neurologic improvement and significantly less worsening than standard of care through Week 48, with durable neurologic benefit observed over multiple years of treatment.

- In the randomized FoCus trial, analysis of patients with neurologic symptoms at baseline (TMC: n=77; SoC: n=35) demonstrated that treatment with ALXN1840 resulted in both higher rates of improvement and lower rates of worsening, addressing a critical unmet need in the neurologic management of Wilson disease.
    - Clinically meaningful neurologic worsening at Week 48 was observed in 25% of patients treated with standard of care vs 9% of ALXN1840-treated patients (p=0.038)
    - Clinically meaningful neurologic improvement at Week 48 was observed in 45% of ALXN1840-treated patients vs 32% on standard of care
    - CGI-S improvement from baseline to Week 48 was greater with ALXN1840 vs standard of care (61% vs 17%; p=0.008)
    - CGI-I improvement at Week 48 was greater with ALXN1840 vs standard of care (47% vs 19%; p=0.003)
- Durable neurologic benefit in the ALXN1840-treated group continued to increase during long-term follow-up on treatment and was sustained over approximately 3 years
- Neurologic benefit was consistent across both treatment-naïve and treatment-experienced patients with neurologic symptoms at baseline, supporting ALXN1840's potential as a novel treatment option for Wilson disease
- ALXN1840 has demonstrated a well-characterized and favorable safety profile across Phase 2 and Phase 3 studies (266 patients; median 2.58 years on treatment; max >8 years), with drug-related serious adverse events (SAEs) limited to 4.9% of patients — including neurologic SAEs in < 1% — and no treatment-related deaths

"These data highlight the potential of ALXN1840 to meaningfully change the treatment landscape for Wilson disease patients with neurologic symptoms by delivering both improved clinical outcomes and a lower likelihood of neurologic deterioration compared to standard of care," said Dr. Hedera.

The presentation is available at https://www.monopartx.com/AAN-Presentation-April-2026, and the poster is available at https://www.monopartx.com/AAN-Poster-April-2026.

These findings support the continued advancement of ALXN1840 toward the planned New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) in mid-2026.

About Wilson Disease

Wilson disease 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 demonstrated rapid and sustained copper mobilization (primary endpoint) that was 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 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 the neurologic benefit supports ALXN1840’s potential as a novel treatment option for Wilson disease; that ALXN1840 has the potential to meaningfully change the treatment landscape for Wilson disease patients with neurologic symptoms by delivering both improved clinical outcomes and a lower likelihood of neurologic deterioration compared to standard of care; that these findings support the continued advancement of ALXN1840 toward the planned submission of an NDA to the FDA 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, pre-commercial 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 therapeutics and imaging agents. 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.

Greater clinical benefit with tiomolibdate choline versus standard of care in neurologic WD patients in the Phase 3 FoCus Trial

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Presenter
Peter Hedera, MD, PhD
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AAN Annual Meeting
April 18-22, 2026

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. All analyses conducted on patients with data available.

Significantly Less Neurologic Worsening on TMC vs. SoC

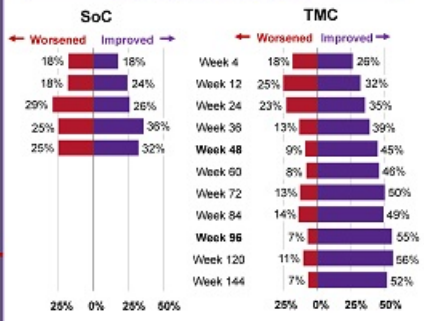
UWDRS Part III
Responder rates at Week 48

SoC	TMC
32% improved	45% improved
25% worsened*	9% worsened*

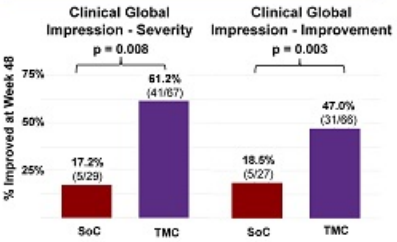
* = p < 0.05 for TMC vs. SoC

Results

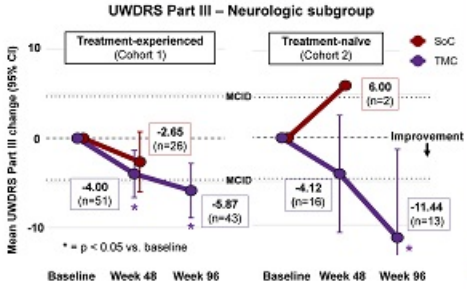
More Neurologic Improvement over Time on TMC vs SoC



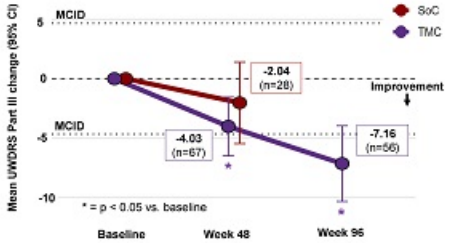
Greater Clinical Improvement on TMC vs. SoC at Week 48



Neurologic Benefit Increases over Time on TMC Regardless of Cohort



UWDRS Part III – Cohort 1 and 2 Combined



Safety

TMC showed a favorable safety profile across all treated patients with WD in Phase 2 & Phase 3 studies. Very few patients (~1%) experienced a neurologic or psychiatric SAE related to TMC. No deaths occurred that were deemed related to TMC.

Serious Adverse Events (SAEs) on TMC	
Number of patients	266
Median time on treatment (years)	2.58
Total patient-years (PYs)	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 regardless of WD treatment history. Continued improvement was sustained through long-term follow-up. These findings demonstrate that TMC improves neurologic outcomes in patients with WD presenting with neurologic symptoms.

References & Acknowledgements

The authors would like to thank the patients and their families for their participation in the studies, as well as all participating sites