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): **August 12, 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 2.02 Results of Operations and Financial Condition

On August 12, 2026, Monopar Therapeutics Inc. ("Monopar" or the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2026. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the exhibit hereto are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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 August 12, 2026
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: August 12, 2026

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

Exhibit 99.1

Monopar Therapeutics Reports Second Quarter 2026 Financial Results and Provides Business Updates

Wilmette, IL, August 12, 2026 – 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 second quarter 2026 financial results and provided business updates.

Recent Program Developments

ALXN1840 for Wilson Disease – Rolling NDA Submission Initiated

On July 22, 2026, Monopar announced it had initiated the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for ALXN1840. The FDA authorized Monopar to submit the NDA on a rolling basis, allowing completed sections of the application to be submitted and reviewed while the Company finalizes the remaining sections. The Company anticipates completing the NDA submission within the next few months.

On June 30, 2026, the FDA granted Rare Pediatric Disease (RPD) designation to ALXN1840. The FDA grants RPD designation to therapies intended to treat serious or life-threatening diseases that primarily affect children from birth to 18 years of age. The designation provides the Company with the potential at the time of NDA approval to receive a pediatric Priority Review Voucher (PRV), which can be used to obtain priority review of a subsequent marketing application or sold or transferred to another sponsor.

On June 28, 2026, Monopar presented new analyses from the Phase 3 FoCus randomized controlled clinical trial of ALXN1840 (tiomolibdate choline, TMC) at the 12th Congress of the European Academy of Neurology (EAN 2026). The poster presentation, titled "Greater clinical benefit with tiomolibdate choline versus standard-of-care in neurologic Wilson disease patients in the Phase 3 FoCus Trial," showed significant neurologic improvement over time and greater global clinical improvement versus standard-of-care therapy in Wilson disease patients with neurologic symptoms at baseline. An oral late-breaker presentation on April 19, 2026, at the American Academy of Neurology (AAN) Annual Meeting also highlighted new analyses from the Phase 3 FoCus trial demonstrating greater neurologic benefit with ALXN1840 compared with standard of care (SoC) in Wilson patients with neurologic symptoms.

On May 29, 2026, Monopar presented Phase 2 ALXN1840-WD-205 data at the European Association for the Study of the Liver (EASL) Congress 2026. The oral presentation, titled "ALXN1840 (tiomolibdate choline) stabilizes liver disease and improves neurological symptoms as well as quality-of-life in treatment-experienced Wilson disease patients," demonstrated that, in a heavily pre-treated Wilson disease population, ALXN1840 can stabilize liver disease and provide clinically meaningful improvements in neurologic symptoms and quality of life. These findings complement the increased copper mobilization and clinical improvement shown in the completed Phase 3 pivotal trial (Study WTX101-301).

On May 19, 2026, *Hepatology Communications* published the manuscript titled "Effect of tiomolibdate choline on copper balance in patients with Wilson disease: an open-label Phase 2 trial." This peer-reviewed publication reported results from the Phase 2 ALXN1840-WD-204 study (NCT04573309) and demonstrated that ALXN1840 produced a rapid, statistically significant, and sustained improvement in daily copper balance in patients with Wilson disease, driven by increased fecal copper excretion.

Susan Rodriguez, who joined as Chief Commercial and Strategy Officer in March 2026, is leading preparations for a potential commercial launch. Commercial readiness has been further strengthened by the appointment of Nicole Sweeny, former Chief Commercial Officer of KalVista Pharmaceuticals, to the Board of Directors and the additions of Sharon Funk as Senior Vice President of Sales and Marketing, and Daniel Olmstead as Senior Vice President of Market Access, Distribution and Patient Services.

Financial Results for the Second Quarter Ended June 30, 2026, Compared to the Second Quarter Ended June 30, 2025

Cash and Net Loss

Cash, cash equivalents and investments as of June 30, 2026, were $134.3 million. Monopar expects its current funds to support operations through at least December 31, 2027, including: (1) regulatory and potential commercial activities for ALXN1840; (2) continued development of MNPR-101 programs; and (3) internal research and development.

Net loss for the second quarter of 2026 was $5.3 million, or $0.62 per share, compared to net loss of $2.5 million, or $0.35 per share, for the second quarter of 2025.

Research and Development ("R&D") Expenses

R&D expenses for the second quarter of 2026 were $4,766,832 compared to $1,730,000 for the second quarter of 2025. This represents an increase of $3,036,831 primarily attributed to (1) a $2,026,851 increase in R&D contractor and consulting expenses, (2) a $721,228 increase in R&D personnel expenses including stock-based compensation and (3) a net increase of $288,752 in other R&D expenses.

General and Administrative ("G&A") Expenses

G&A expenses for the second quarter of 2026 were $1,877,831 compared to $1,504,295 for the second quarter of 2025. This represents an increase of $373,536 primarily attributed to (1) a $234,113 increase in G&A personnel expenses including stock-based compensation, (2) a $198,988 increase in G&A contractor and consulting expenses and (3) a net decrease of $59,565 in other G&A expenses.

Other Income (Loss)

Other income for the second quarter of 2026 was $32,158 compared to $0 for the second quarter of 2025. The increase is primarily attributable to an adjustment to a vendor invoice recognized during the current period.

Interest Income (Loss)

Interest income for the second quarter of 2026 was $1,299,205 compared to $780,769 for the second quarter of 2025. The increase is attributed to interest earned on U.S. Treasury securities and commercial paper and to higher bank balances in 2026 due to the net proceeds of approximately $91.9 million from the September 2025 capital raise.

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 stable ATCs, suppressing copper's redox reactivity, limiting oxidative damage, and blocking its transport across the blood–brain barrier. Clinical data have also demonstrated that ALXN1840 improves copper balance by increasing fecal copper excretion.

In the pivotal Phase 3 trial, ALXN1840 met its primary endpoint, demonstrating rapid and sustained copper mobilization that was significantly greater than standard of care over 48 weeks in both previously treated and treatment-naïve patients. Across the ALXN1840 clinical development program, durable clinical improvement and favorable tolerability were observed across 645 patient-years of follow-up in 266 patients, with a well-characterized safety profile.

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, and links to SEC filings that contain detailed financial information, visit: https://ir.monopartx.com/quarterly-reports.

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 the following: that the Company anticipates completing the NDA submission within the next few months; that the RPD designation provides the Company with the potential at the time of NDA approval to receive a pediatric Priority Review Voucher (PRV), which can be used to obtain priority review of a subsequent marketing application or sold or transferred to another sponsor; that Susan Rodriguez is leading preparations for a potential commercial launch; and that Monopar expects its current funds to support operations through at least December 31, 2027. The forward-looking statements involve risks and uncertainties including, but not limited to: uncertainties related to the regulatory process that Monopar has initiated related to ALXN1840, including whether the FDA will accept the NDA for filing and the outcome of any review thereof; uncertainties related to whether the ALXN1840 marketing application will receive marketing approval and, if approved, whether Monopar will be awarded a Priority Review Voucher; whether, if awarded, the Priority Review Voucher can be used to obtain priority review of a subsequent marketing application or sold or transferred to another sponsor; the continued authorization and availability of the Rare Pediatric Disease Priority Review Voucher program; 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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