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MONOPAR THERAPEUTICS

FORM 8-K
(Current report filing)

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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 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 November 12, 2026, Monopar Therapeutics Inc. ("Monopar" or the "Company") issued a press release announcing its financial results for the third quarter ended September 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 November 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: November 12, 2026

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

Exhibit 99.1



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

Wilmette, IL, November 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 third quarter 2026 financial results and provided business updates.

Recent Program Developments

ALXN1840 for Wilson Disease

On November 8, 2026, Monopar presented baseline findings from the Phase 3 FoCus study of ALXN1840 (tiomolibdate choline, TMC), the largest randomized controlled trial ever conducted in Wilson disease, characterizing residual disease burden in treatment-experienced patients at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2026. Baseline rates in treatment-experienced and treatment-naïve patients were 39% and 30% for cirrhosis, 79% and 83% for neurologic symptoms, and 75% and 70% for psychiatric symptoms, respectively. Among evaluable patients, 73% had at least two of these manifestations. Only 47% of treatment-experienced patients were within the guideline-recommended copper target range. Among patients receiving standard-of-care therapy for more than 12 months, 31% had 24-hour urinary copper excretion above that range.

On November 5, 2026, Monopar presented a poster at AASLD reporting neutral molybdenum balance and lack of molybdenum toxicity in subjects treated with ALXN1840, with serum uric acid remaining within normal limits over six years of treatment. These findings are consistent with ALXN1840's known albumin tripartite complex (ATC) mechanism and provide further evidence supporting its long-term safety profile.

On August 19, 2026, Monopar announced the appointment of Jeffrey D. Kent, M.D., FACP, FACG, as Executive Vice President, Head of Medical Affairs. Dr. Kent is leading the Company's medical affairs organization as Monopar prepares for potential U.S. Food and Drug Administration (FDA) approval of the New Drug Application (NDA) for ALXN1840, its first-in-class ATC activator drug candidate for the treatment of Wilson disease. Dr. Kent brings more than 20 years of biopharmaceutical leadership experience across medical affairs, clinical development and regulatory strategy, with expertise spanning rare diseases, hepatology and gastroenterology, immunology and specialty therapeutics.

On July 22, 2026, Monopar announced it had initiated the rolling submission of an NDA to the 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 is on track to complete the NDA submission within the next several weeks.

Financial Results for the Third Quarter Ended September 30, 2026, Compared to the Third Quarter Ended September 30, 2025

Cash and Net Loss

Cash, cash equivalents and investments as of September 30, 2026, were $129.4 million. Monopar expects its current funds to support operations through at least March 31, 2028, 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 third quarter of 2026 was $6.2 million, or $0.72 per share, compared to net loss of $3.4 million, or $0.48 per share, for the third quarter of 2025.

Research and Development ("R&D") Expenses

R&D expenses for the third quarter of 2026 were $4,436,543 compared to $2,589,749 for the third quarter of 2025. This represents an increase of $1,846,794 primarily attributed to (1) a $1,772,461 increase in R&D contractor and consulting expenses, (2) a $909,699 increase in R&D personnel expenses including stock-based compensation, (3) a decrease of $709,250 in manufacturing activities related to ALXN1840, and (4) a net decrease of $126,116 in other R&D expenses.

General and Administrative ("G&A") Expenses

G&A expenses for the third quarter of 2026 were $3,031,302 compared to $1,503,326 for the third quarter of 2025. This represents an increase of $1,527,976 primarily attributed to (1) a $973,753 increase in G&A personnel expenses including stock-based compensation, (2) a $353,963 increase in G&A contractor and consulting expenses, and (3) a net increase of $200,260 in other G&A expenses.

Interest Income (Loss)

Interest income for the third quarter of 2026 was $1,271,370 compared to $655,473 for the third 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 Dr. Kent is leading the Company’s medical affairs organization as Monopar prepares for potential U.S. Food and Drug Administration (FDA) approval of the New Drug Application (NDA) for ALXN1840; that the Company is on track to complete the NDA submission within the next several weeks; and that Monopar expects its current funds to support operations through at least March 31, 2028. The forward-looking statements involve risks and uncertainties including, but not limited to, uncertainties related to the Company’s ability to complete the NDA submission within the anticipated timeframe; whether the FDA will accept the NDA for filing, require additional information or studies, or approve ALXN1840; the timing of FDA review; the risk that changes in operating plans, development or commercialization costs, or the timing and amount of contractual milestone payments could shorten the Company’s expected cash runway; 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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