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 13, 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 2.02 Results of Operations and Financial Condition

On May 13, 2025, Monopar Therapeutics Inc. (Monopar) issued a press release announcing its financial results for the first quarter ended March 31, 2025. 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.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release Dated May 13, 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 13, 2025

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

Monopar Therapeutics Reports First Quarter 2025 Financial Results and Recent Developments

Wilmette, IL, May 13, 2025 – Monopar Therapeutics Inc. ("Monopar" or the "Company") (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for patients with unmet medical needs, today announced first quarter 2025 financial results and recent developments.

Recent Developments

ALXN1840 for Wilson Disease

On May 7, 2025, Monopar presented long-term efficacy and safety data for ALXN1840 (tiomolybdate choline) at the **European Association for the Study of the Liver ("EASL") International Liver Congress 2025**, a leading global conference in liver disease.

The data support ALXN1840 as a potential treatment for **Wilson disease**, a rare genetic disorder that causes toxic copper buildup in organs like the liver and brain. Pooled results from three clinical trials (n=255) showed **sustained clinical benefits** over a median treatment duration of 2.63 years. Safety data, which included an additional Phase 2 study (n=266), confirmed a **favorable safety profile** with fewer than 5% of patients experiencing a drug-related serious adverse event ("SAE") and **no renal or urinary system SAEs**.

Sustained neurological improvement as assessed by the physician as well as the patient using the Unified Wilson Disease Rating Scale ("UWDRS") was observed, as was sustained increased copper mobilization. Patients reported greater convenience and effectiveness when treated with ALXN1840 compared to standard of care, and improvement in the New Wilson Index (a prognostic indicator of the status of the liver) was also observed.

The Company is preparing to submit a **New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") in early 2026**.

MNPR-101 for Radiopharmaceutical Use

The Company's MNPR-101-Zr Phase 1 (imaging and dosimetry) and MNPR-101-Lu (therapeutic) Phase 1a clinical trials in advanced cancers are active and enrolling in Australia. Monopar continues its preclinical work with MNPR-101-Ac (therapeutic) with plans to enter the clinic in the future.

Financial Results for the First Quarter Ended March 31, 2025, Compared to the First Quarter Ended March 31, 2024

Cash and Net Loss

Cash, cash equivalents and investments as of March 31, 2025, were $54.6 million. Monopar expects that its current funds will be sufficient to continue operations at least through December 31, 2026, in order to: (1) assemble a regulatory package and file an NDA for ALXN1840; (2) continue to conduct and conclude its first-in-human imaging and dosimetry clinical trial with MNPR-101-Zr; (3) continue to conduct its first-in-human therapeutic clinical trial of MNPR-101-Lu; (4) advance its preclinical MNPR-101-Ac program into the clinic; and (5) invest in internal research and development projects to expand its radiopharmaceutical and rare disease pipeline.

Net loss for the first quarter of 2025 was $2.6 million or $0.38 per share compared to net loss of $1.6 million or $0.51 per share for the first quarter of 2024.

Research and Development ("R&D") Expenses

R&D expenses for the first quarter of 2025 were $1,643,000, compared to $966,000 for the first quarter of 2024. This represents an increase of $677,000 attributed to (1) a $611,000 increase in R&D personnel expenses including stock-based compensation and (2) a $69,000 increase in clinical trial site activity related to MNPR-101 for radiopharmaceutical use, partially offset by (3) a net decrease of $3,000 in other R&D expenses.

General and Administrative ("G&A") Expenses

G&A expenses for the first quarter of 2025 were $1,578,000, compared to $757,000 for the first quarter of 2024. This represents an increase of $821,000 primarily attributed to (1) a $416,000 increase in Board compensation resulting from the grant of stock options during the quarter ended March 31, 2025 (no stock options were granted during the quarter ended March 31, 2024), (2) a $291,000 increase in G&A personnel expenses including stock-based compensation, (3) a $73,000 increase in legal fees and (4) a $41,000 increase in insurance expenses.

Interest Income

Interest income for the first quarter of 2025 increased by $515,000, compared to the first quarter of 2024. The increase is attributed to interest earned on U.S. Treasury securities and higher bank balances in 2025, resulting from over $55 million of funds raised in the fourth quarter of 2024.

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-Ac 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: that Monopar's data support ALXN1840 as a potential treatment for Wilson disease; that Monopar is preparing to submit an NDA to the FDA in early 2026; that Monopar continues its preclinical work with MNPR-101-Ac with the plan to enter the clinic in the future; and that Monopar expects that its current funds will be sufficient to continue operations at least through December 31, 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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