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): **March 31, 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 March 31, 2025, Monopar Therapeutics Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2024. 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 March 31, 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: March 31, 2025

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

EXHIBIT 99.1

Monopar Reports Fourth Quarter and Full-Year 2024 Financial Results and Recent Developments

WILMETTE, Ill., March 31, 2025 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for patients with unmet medical needs, today announced fourth quarter and full-year 2024 financial results and summarized recent developments.

"2024 was a productive year for Monopar, with the in-licensing of ALXN1840, the initiation of two first-in-human radiopharma Phase 1 clinical trials, and the strengthening of our balance sheet with net proceeds of over $55 million from financings," said Chandler Robinson, MD, Chief Executive Officer of Monopar. "We are especially grateful to the Wilson disease patients. Their testimonies and support are what provided the opportunity for Monopar to progress ALXN1840 toward an NDA filing."

Recent Program Developments

ALXN1840 – Plan to Submit NDA with FDA for Wilson Disease in Early 2026

Wilson disease is a rare and progressive genetic condition in which the body's pathway for removing excess copper is compromised, leading to damage from toxic copper build-up in tissues and organs such as the liver and brain. ALXN1840 is a potent binder and mobilizer of copper, as demonstrated in a Phase 3 clinical trial that met its primary endpoint. In October 2024, Monopar announced the execution of a worldwide exclusive license to ALXN1840 with Alexion, AstraZeneca Rare Disease ("AZ"). As part of this transaction, AZ received a total cash payment of $4.0 million, was issued 9.9% ownership of Monopar's outstanding common stock, and is entitled to receive regulatory approval and sales milestones along with a tiered royalty based on net sales.

MNPR-101 – Currently Enrolling Phase 1 Imaging and Therapeutic Oncology Trials

Imaging agent MNPR-101-Zr (MNPR-101 conjugated to zirconium-89) and therapeutic agent MNPR-101-Lu (MNPR-101 conjugated to lutetium-177) target the urokinase plasminogen activator receptor ("uPAR"), which is expressed in numerous aggressive cancers such as triple-negative breast, colorectal, and pancreatic cancers.

- Initiated Phase 1a clinical trial for novel therapeutic radiopharmaceutical MNPR-101-Lu in patients with advanced cancers
- Dosed first patient with MNPR-101-Lu in December 2024
- Presented encouraging human clinical imaging and dosimetry data of MNPR-101-Zr at the European Association of Nuclear Medicine ("EANM") 2024 Annual Congress
- uPAR expression, as detected by MNPR-101-Zr, has been seen to date in breast, colorectal, pancreatic, adrenocortical carcinoma, and ovarian cancer patients
- Filed a patent application covering new therapeutic radiopharmaceuticals based on a novel family of linkers used to connect radioisotopes with targeting agents, including Monopar's uPAR targeting antibody MNPR-101

Recent Financings

In Q4 2024, we raised net proceeds of over $55 million from the following financings:

- On October 30, 2024, pursuant to a placement agent agreement with Rodman & Renshaw LLC, we sold 1,181,540 shares of our common stock at $16.25 in a public offering, yielding net proceeds of approximately $17.8 million.

- On December 23, 2024, pursuant to an underwriting agreement with Piper Sandler & Co., we sold 798,655 shares of our common stock at $23.79 per share in a public offering. Concurrently with the public offering, we completed a private placement of 882,761 pre-funded warrants to purchase shares of common stock to an institutional investor at a purchase price of $23.789 per pre-funded warrant. The net proceeds of the December 23, 2024, public offering and private placement were approximately $37.4 million.

Results for the Fourth Quarter and Year Ended December 31, 2024, Compared to the Fourth Quarter and Year Ended December 31, 2023

Cash and Net Loss

Cash, cash equivalents and short-term investments as of December 31, 2024, were $60.2 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 radiopharma and rare disease pipeline.

Net loss for the fourth quarter of 2024 was $10.9 million or $2.23 per share compared to $1.8 million or $0.60 per share for the fourth quarter of 2023. Net loss for the year ended December 31, 2024, was $15.6 million or $4.11 per share compared to $8.4 million or $3.04 per share for the year ended December 31, 2023.

Research and Development ("R&D") Expenses

R&D expenses for the fourth quarter of 2024 were $9.9 million compared to $1.0 million for the fourth quarter of 2023. This increase of $8.9 million was primarily due to: (1) an increase of $8.6 million related to the in-licensing of ALXN1840 and (2) an increase of $0.4 million in R&D salaries, partially offset by a net decrease of $0.1 million in other R&D expenses.

R&D expenses for the year ended December 31, 2024, were $13.0 million compared to $5.6 million for the year ended December 31, 2023. This increase of $7.4 million was primarily due to: (1) an increase of $8.6 million related to the in-licensing of ALXN1840; (2) an increase of $0.3 million in R&D personnel expenses; and (3) a net increase of $0.1 million in other R&D expenses, partially offset by a decrease of $1.6 million in trial closure related expenses.

General and Administrative ("G&A") Expenses

G&A expenses for the fourth quarter of 2024 were $1.2 million, compared to $0.9 million for the fourth quarter of 2023. This increase of $0.3 million was primarily due to: (1) an increase of $0.1 million in G&A personnel salaries; (2) an increase of $0.1 million in G&A consulting fees; and (3) an increase of $0.1 million in Delaware franchise taxes.

G&A expenses for the year ended December 31, 2024, were $3.2 million, compared to $3.2 million for the year ended December 31, 2023.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biotechnology company with late-stage ALXN1840 for Wilson disease, and radiopharma 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, and links to SEC filings that contain detailed financial information, visit: https://ir.monopartx.com/annual-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: that Monopar plans to submit an NDA for Wilson disease in early 2026; 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 discussions that Monopar intends to initiate related to ALXN1840 and the outcome thereof; that radiation dosimetry analytics in the future may not be consistent with the estimated data generated thus far; that Monopar may not find enough patients to successfully enroll its MNPR-101-Lu therapeutic study; that the Phase 1 imaging and dosimetry clinical trial in advanced cancer patients with MNPR-101-Zr may not yield consistently satisfactory results; that future preclinical, including MNPR-101-Ac, or clinical data may not be as promising as the data to date; that MNPR-101-Zr and/or MNPR-101-Lu may cause unexpected serious adverse effects or fail to be effective against the cancer tumors in humans; that the trials could result in a clinical hold should there be a serious adverse event; 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.

CONTACT:

Monopar Therapeutics Inc.
Investor Relations
Quan Vu
Chief Financial Officer
vu@monopartx.com

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X: @MonoparTx LinkedIn: Monopar Therapeutics