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 27, 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 March 27, 2026, Monopar Therapeutics Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 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 March 27, 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: March 27, 2026

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

Exhibit 99.1

Monopar Reports Fourth Quarter and Full-Year 2025 Financial Results and Provides Business Update

Wilmette, Ill., March 27, 2026 – Monopar Therapeutics Inc. ("Monopar," the "Company," "we") (Nasdaq: MNPR), a clinical-stage biopharmaceutical company developing innovative treatments for patients with unmet medical needs, today announced the fourth quarter and full-year 2025 financial results and provided a summary of recent developments.

"2025 was a productive year for Monopar, marked by multiple ALXN1840 data presentations, an important publication, a strengthened balance sheet and continued progress toward a planned New Drug Application submission for ALXN1840 in Wilson disease," said Chandler Robinson, MD, Chief Executive Officer of Monopar. "We also recently strengthened our leadership team with the addition of Susan Rodriguez as Chief Commercial and Strategy Officer as we prepare for the potential launch of ALXN1840. We are grateful to the Wilson disease patients and their families whose experiences have informed our efforts to advance ALXN1840."

Recent Program Developments

ALXN1840 – NDA Submission Planned for Mid-2026 for Wilson Disease

Wilson disease is a rare genetic disorder characterized by impaired copper elimination, resulting in toxic accumulation in organs such as the liver and brain. ALXN1840 binds and mobilizes copper and has a novel mechanism of action as an albumin tripartite complex ("ATC") activator that differentiates it from currently available first-line therapies.

Based on recent interactions with the U.S. Food and Drug Administration ("FDA"), Monopar plans to submit a New Drug Application ("NDA") for ALXN1840 in mid-2026.

ALXN1840 updates:

- **EASL 2025:** Presented pooled long-term efficacy and safety data (n=255; median treatment duration 2.63 years), with additional safety data (n=266) supporting a favorable safety profile, as a late-breaking abstract
- **ANA 2025:** Presented data demonstrating long-term neurological benefit; the abstract was selected for oral and poster presentation and designated an "Abstract of Distinction"
- **Journal of Hepatology / AASLD 2025:** Reported statistically significant improvement in copper balance, with sustained improvement in daily copper balance driven by increased fecal copper excretion
- **EL-PFDD:** Attended externally led patient-focused drug development ("EL-PFDD") meeting with the FDA on January 29, 2026. During the meeting, patients and caregivers described the burden of Wilson disease, shared their experience with the currently available treatments, and highlighted the urgent need for additional treatment options
- **Upcoming 2026 presentations:** Abstracts accepted for presentation at EASL 2026 and the American Academy of Neurology ("AAN") 2026 Annual Meeting, including:
    - *Tiomolybdate choline stabilizes liver disease and improves neurological symptoms as well as quality of life in treatment-experienced Wilson disease patients* (EASL 2026 oral presentation)
    - *Greater clinical benefit with tiomolybdate choline versus standard-of-care in neurologic Wilson disease patients in the Phase 3 FoCus Trial* (AAN 2026 late-breaking oral and poster presentation)

MNPR-101 Radiopharmaceutical Programs

MNPR-101-Zr (zirconium-89), MNPR-101-Lu (lutetium-177), and MNPR-101-Ac (actinium-225) target the urokinase plasminogen activator receptor ("uPAR"), which is expressed in multiple aggressive cancers, including triple-negative breast, colorectal, and pancreatic cancers.

MNPR-101 platform update:

- Ongoing Phase 1 clinical activity in Australia for MNPR-101-Zr and MNPR-101-Lu
- Investigational new drug ("IND") clearance received for MNPR-101-Lu to initiate a Phase 1 clinical trial in the US
- FDA-authorized physician-sponsored Expanded Access Program at Excel Diagnostics and Nuclear Oncology Center ("EDNOC") in Houston, Texas
- Preclinical development of MNPR-101-Ac

Financings

In 2025, Monopar strengthened its balance sheet through the following financing activities:

- Completed an underwritten public offering generating approximately $91.9 million, after a concurrent repurchase of common stock but before offering expenses

Results for the Fourth Quarter and Year Ended December 31, 2025, Compared to the Fourth Quarter and Year Ended December 31, 2024

Cash and Net Loss

Cash, cash equivalents and short-term investments as of December 31, 2025, were $140.4 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 fourth quarter of 2025 was $5.2 million, or $0.61 per share, compared to $10.9 million, or $2.23 per share, for the fourth quarter of 2024.

Net loss for the year ended December 31, 2025, was $13.7 million, or $1.85 per share, compared to $15.6 million, or $4.11 per share, for the year ended December 31, 2024.

Research and Development ("R&D") Expenses

R&D expenses for the fourth quarter of 2025 were $3.9 million compared to $9.9 million for the fourth quarter of 2024. The decrease was primarily due to the absence of one-time expenses incurred in connection with the in-licensing of ALXN1840 in 2024, partially offset by higher R&D personnel expenses (driven by increased headcount and compensation), increased clinical material and manufacturing costs for the ALXN1840 program, and higher other R&D expenses.

R&D expenses for the year ended December 31, 2025, were $9.9 million compared to $13.0 million for the year ended December 31, 2024. The decrease was primarily due to the absence of one-time expenses incurred in connection with the in-licensing of ALXN1840 in 2024, as well as lower radiopharmaceutical clinical trial costs reflecting a shift in focus following the in-licensing, partially offset by higher R&D personnel expenses (driven by increased headcount and compensation), increased clinical material and manufacturing costs for the ALXN1840 program, and higher other R&D expenses.

General and Administrative ("G&A") Expenses

G&A expenses for the fourth quarter of 2025 were $2.2 million compared to $1.2 million for the fourth quarter of 2024. The increase was primarily due to higher Board of Directors (the "Board") and G&A personnel expenses (including stock-based compensation and bonuses), higher patent legal fees, and other increases in G&A expenses.

G&A expenses for the year ended December 31, 2025, were $6.8 million compared to $3.2 million for the year ended December 31, 2024. The increase was primarily due to higher Board and G&A personnel expenses (including stock-based compensation and bonuses), higher patent legal fees, and other increases in G&A expenses.

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, including links to SEC filings containing detailed financial information, please 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 statements concerning: that Monopar is making continued progress toward a planned New Drug Application (“NDA”) submission for ALXN1840 in Wilson disease; that Monopar is preparing for the potential launch of ALXN1840; that Monopar plans to submit an NDA for ALXN1840 to the FDA in mid-2026; 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 intends to initiate related to ALXN1840, including the submission of the NDA to the FDA, 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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Follow Monopar on social media for updates:

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