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): **July 9, 2024**

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 7.01 Regulation FD Disclosure.

On July 9, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing the enrollment of the first patient in its first-in-human Phase 1 dosimetry and imaging clinical trial of MNPR-101-Zr.

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 July 9, 2024
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: July 9, 2024

By: /s/ Karthik Radhakrishnan
Name: Karthik Radhakrishnan
Title: Chief Financial Officer

Exhibit 99.1

Monopar Announces First Patient Enrolled in First-in-Human Phase 1 Trial for Its Novel Radiopharmaceutical MNPR-101-Zr

WILMETTE, Ill., July 9, 2024 — Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage radiopharma company focused on developing innovative treatments for cancer patients, today announced the enrollment of the first patient in its first-in-human Phase 1 dosimetry and imaging clinical trial of MNPR-101-Zr. This novel radiopharmaceutical imaging agent combines MNPR-101, Monopar's antibody that selectively targets the urokinase plasminogen activator receptor (uPAR), with the radioisotope zirconium-89.

Monopar's Phase 1 clinical trial, led by internationally recognized nuclear medicine physician Professor Rodney Hicks at the Melbourne Theranostic Innovation Centre, aims to assess the safety and dosimetry of MNPR-101-Zr in up to 12 patients with advanced cancers. This is the first human study to evaluate a radiolabeled monoclonal antibody targeting uPAR.

"uPAR is a well-credentialed cancer target found in some of the most aggressive, deadly cancers, including pancreatic, triple negative breast, and colorectal cancers. We are very much looking forward to seeing the biodistribution and dosimetry data from this study," said Chandler Robinson, MD, Monopar's Chief Executive Officer.

"We are pleased to enroll our inaugural patient. Encouraging preclinical results in several challenging cancers underscore the potential of uPAR as a promising target to battle some of the most lethal cancers," added Andrew Cittadine, Monopar's Chief Operating Officer.

Further information about this clinical trial is available at www.ClinicalTrials.gov under study identifier**NCT06337084**.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage radiopharmaceutical company focused on developing innovative treatments for cancer patients, including Phase 1-stage MNPR-101-Zr for imaging advanced cancers and late preclinical-stage MNPR-101 radio-immuno-therapeutic (RIT) for the treatment of advanced cancers, as well as early development programs against solid cancers. For more information, visit: www.monopartx.com.

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 Company's Phase 1 trial aims to assess the safety and dosimetry of MNPR-101-Zr in up to 12 patients with advanced cancers; Monopar is very much looking forward to seeing the biodistribution and dosimetry data from this Phase-1 trial; and that encouraging preclinical results in several challenging cancers underscore the potential of uPAR as a promising target to battle some of the most lethal cancers. The forward-looking statements involve risks and uncertainties including, but not limited to: the enrolled patient may not receive the scheduled dose of MNPR-101-Zr; the Phase 1 imaging and dosimetry clinical trial in advanced cancer patients with MNPR-101-Zr may not yield satisfactory results, if at all; that future preclinical or clinical data will not be as promising as the data to date; that MNPR-101-Zr may cause unexpected serious adverse effects in humans; that Monopar may expend available funds sooner than anticipated or require additional funding due to change in circumstances or unanticipated events; 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:

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Investor Relations

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