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): **October 7, 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 October 7, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing that the Phase 1a clinical trial for its novel therapeutic radiopharmaceutical MNPR-101-Lu (MNPR-101 conjugated to lutetium-177) is now active and recruiting patients with advanced cancers.

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 October 7, 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: October 7, 2024

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

Monopar Initiates Clinical Trial of Novel uPAR-Targeted Radiopharmaceutical Therapy in Advanced Cancers

WILMETTE, Ill., October 7, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage radiopharma company focused on developing innovative treatments for cancer patients, today announced that the Phase 1a clinical trial for its novel therapeutic radiopharmaceutical MNPR-101-Lu (MNPR-101 conjugated to lutetium-177) is now active and recruiting patients with advanced cancers.

The Phase 1a trial is an open-label dose-escalation study of MNPR-101-Lu in patients with solid tumors. The first clinical trial site activated for the study is the Melbourne Theranostic Innovation Centre (MTIC) in Australia. To help identify those patients most likely to benefit from MNPR-101-Lu, the trial will only be open to those participating in the ongoing MNPR-101-Zr Phase 1 imaging and dosimetry clinical trial.

MNPR-101 is Monopar's proprietary antibody that targets the urokinase plasminogen activator receptor (uPAR), which is expressed in numerous tumor types including pancreatic, breast, colorectal, ovarian, and bladder. By selectively targeting uPAR, Monopar aims to deliver a radiopharma therapy that kills cancer cells while minimizing damage to healthy tissue. Both clinical (link) and preclinical (link) data to date have demonstrated highly specific and durable tumor uptake of MNPR-101-Zr (MNPR-101 conjugated to zirconium-89).

"We are very encouraged by the recently released human clinical data and preclinical efficacy results (link), and are thrilled to be launching this therapeutic trial months ahead of our originally planned schedule," said Chandler Robinson, MD, Monopar's Chief Executive Officer.

"We believe this may be the world's first uPAR-targeted therapeutic radiopharma clinical trial," commented Andrew Cittadine, Monopar's Chief Operating Officer. "Our goal is to light up the tumors with MNPR-101-Zr and then treat them with MNPR-101-Lu."

Further information about the MNPR-101-Lu trial is available at www.ClinicalTrials.gov under study identifier**NCT06617169.** Details about the ongoing MNPR-101-Zr Phase 1 imaging and dosimetry clinical trial are 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, Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac225 for the treatment of advanced cancers, as well as early development-stage radiopharma 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: that by selectively targeting uPAR, Monopar aims to deliver a radiopharma therapy that kills cancer cells while minimizing damage to healthy tissue; that Monopar believes MNPR-101-Lu may be the world's first uPAR-targeted therapeutic radiopharma clinical trial; and that Monopar's goal is to light up the tumors with MNPR-101-Zr then treat it with targeted MNPR-101-Lu. The forward-looking statements involve risks and uncertainties including, but not limited to: that Monopar may not recruit and enroll patients in 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 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 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.

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