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): **April 10, 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 April 10, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing that its Phase 1 dosimetry clinical trial for its novel radiopharmaceutical imaging agent MNPR-101-Zr (MNPR-101 conjugated to zirconium-89) 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 April 10, 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: April 10, 2024

By: /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Chief Financial Officer and Director

Exhibit 99.1

Monopar Initiates Radiopharma Phase 1 Clinical Trial for MNPR-101-Zr in Advanced Cancer Patients

WILMETTE, Ill, April 10, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced that its Phase 1 dosimetry clinical trial for its novel radiopharmaceutical imaging agent MNPR-101-Zr (MNPR-101 conjugated to zirconium-89) is now active and recruiting patients with advanced cancers. The antibody MNPR-101 targets the urokinase plasminogen activator receptor (uPAR), which is expressed on numerous tumor types including pancreatic, breast, colorectal, and bladder.

The study is now open for enrollment at the Melbourne Theranostic Innovation Centre (MTIC) in Australia, and is being led by Professor Rodney Hicks, an internationally recognized physician and pioneer in the radiopharma space. MTIC will use one of the world's most sensitive, state-of-the-art, clinical total-body PET/CT (positron emission tomography–computed tomography) scanners, the Siemens Biograph Vision Quadra, to image the tumor targeting ability of MNPR-101-Zr in advanced cancer patients.

The Phase 1 dosimetry trial is evaluating the safety and dosimetry of MNPR-101-Zr in up to 12 patients with advanced cancer. Preclinical data to date have shown highly specific and durable tumor uptake of MNPR-101-Zr in human cancer xenograft models. Moreover, Monopar recently shared positive preclinical efficacy data showing potent and durable anti-tumor activity of MNPR-101 bound to therapeutic radioisotopes. If the tumor uptake, biodistribution, and safety look encouraging in this Phase 1 clinical trial for MNPR-101-Zr, the Company plans to expand the study or initiate a new study to test the potential efficacy of MNPR-101 bound to a therapeutic radioisotope such as Ac-225 in patients with advanced cancers.

“The Monopar team is quite excited about this trial initiation,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer. “The preclinical results to date in hard-to-treat cancers such as pancreatic and triple negative breast have impressed us, with our radiopharma program demonstrating a promising ability to selectively target and destroy uPAR expressing tumors. We are very much looking forward to seeing the biodistribution and dosimetry data from this first-in-human study in advanced cancer patients.”

Further information about the MNPR-101-Zr trial is available at www.ClinicalTrials.gov under study identifier**NCT06337084.**

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients. Monopar's pipeline consists of Phase 1-stage MNPR-101 for radiopharmaceutical use in various advanced cancers; Phase 1b-stage camsirubicin for the treatment of advanced soft tissue sarcoma; and an early-stage camsirubicin analog, MNPR-202. For more information, visit: www.monopartx.com and ir.monopartx.com/presentations.

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 the MTIC will use one of the world's most sensitive, state-of-the-art, clinical total-body PET/CT (positron emission tomography–computed tomography) scanners, the Siemens Biograph Vision Quadra, to image the tumor targeting ability of MNPR-101-Zr in advanced cancer patients; that if the tumor uptake, biodistribution, and safety look encouraging in this Phase 1, the Company plans to test the efficacy of MNPR-101 bound to a therapeutic radioisotope such as Ac-225 in patients with advanced cancers; and that Monopar is very much looking forward to seeing the biodistribution and dosimetry data from this first-in-human study in advanced cancer patients. The forward-looking statements involve risks and uncertainties including, but not limited to: that future preclinical or clinical data will not be as promising as the data to date; not enrolling the Phase 1 clinical trial; that MNPR-101-Zr, MNPR-101-Ac225 and/or other radiopharmaceuticals we may develop may cause unexpected serious adverse effects or fail to image or be effective against the cancer tumors in humans; the potential for the HREC to put the Phase 1 trial on clinical hold at any time; 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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