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): **February 20, 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 February 20, 2024, Monopar Therapeutics Inc. issued a press release announcing it has received Human Research Ethics Committee (HREC) clearance in Australia to commence a Phase 1 dosimetry trial of its novel radiopharmaceutical 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 February 20, 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: February 20, 2024

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

Monopar Receives Clearance to Proceed with First-in-Human Phase 1 Trial of Novel Radiopharmaceutical MNPR-101-Zr in Advanced Cancers

WILMETTE, Ill., February 20, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced it has received Human Research Ethics Committee (HREC) clearance in Australia to commence a Phase 1 dosimetry trial of its novel radiopharmaceutical MNPR-101-Zr.

The MNPR-101-Zr Phase 1 dosimetry clinical trial will enroll patients with advanced cancers and will utilize positron emission tomography (PET) imaging to assess tumor uptake, normal organ biodistribution, and safety.

MNPR-101-Zr is a zirconium-89 (imaging radioisotope) labeled version of MNPR-101, Monopar's proprietary first-in-class humanized monoclonal antibody that is highly selective against the urokinase plasminogen activator receptor (uPAR). PET imaging studies in preclinical xenograft models of triple-negative breast, colorectal, and pancreatic cancers displayed high and selective uptake of MNPR-101-Zr in these uPAR-expressing tumors. The imaging results, along with corresponding *in vivo* efficacy studies with actinium-225 (Ac-225, a powerful alpha-emitting therapeutic radioisotope) bound to MNPR-101 in preclinical xenograft tumor models, support the development MNPR-101 as a targeted radiopharmaceutical for multiple advanced cancer indications.

"This is a significant milestone for Monopar," said Chandler Robinson, MD, Monopar's Chief Executive Officer. "Following more than 18 months of extensive preclinical development, we believe we are well-positioned in this space. This is our first human clinical trial using our uPAR targeting agent. There has been quite impressive clinical data generated in the radiopharma sector of late, such as against PSMA and SSTR2 expressing cancers, and we believe this to be just the beginning."

If the tumor uptake, biodistribution, and safety look encouraging in this Phase 1 clinical trial, which is anticipated to enroll around 12 patients and to initiate in the near future, the plan is to evaluate the efficacy in humans of a therapeutically radio-labeled version of MNPR-101 bound to an isotope such as Ac-225.

About Monopar Therapeutics Inc.
Monopar Therapeutics is a clinical-stage biopharmaceutical company primarily focused on developing innovative treatments for cancer patients. Monopar's pipeline consists of Phase 1b-stage camsirubicin for the treatment of advanced soft tissue sarcoma; Phase 1-stage MNPR-101 for radiopharmaceutical use in advance cancers; and an early-stage camsirubicin analog, MNPR-202. 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 MNPR-101-Zr Phase 1 dosimetry clinical trial will enroll patients with advanced cancers and will utilize positron emission tomography (PET) imaging to assess tumor uptake, normal organ biodistribution, and safety; that the Phase 1 clinical trial is anticipated to enroll around 12 patients in the near future; and that the plan is to evaluate the efficacy in humans of a therapeutically radio-labeled version of MNPR-101 bound to an isotope such as Ac-225. The forward-looking statements involve risks and uncertainties including, but not limited to: not initiating and enrolling the Phase 1 clinical trial in 2024, if at all; that MNPR-101-Zr may cause unexpected serious adverse effects or fails to image 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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