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): **August 21, 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 August 21, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing that Monopar has received Human Research Ethics Committee (HREC) clearance in Australia to commence a Phase 1 therapeutic trial of its novel radiopharmaceutical MNPR-101-Lu.

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 August 21, 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: August 21, 2024

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

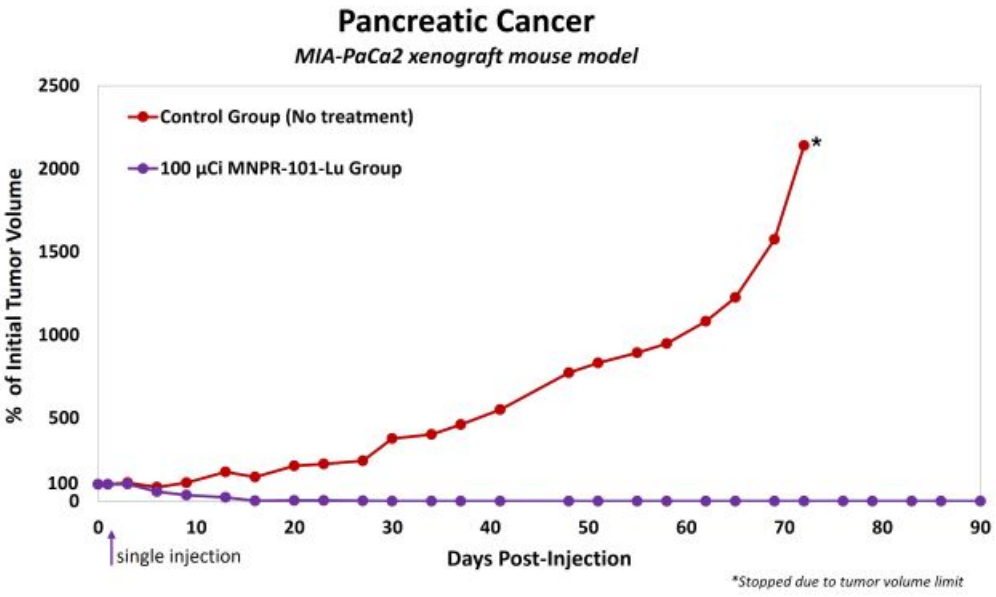
Monopar Receives Clearance to Proceed with Phase 1 Therapeutic Trial of Novel Radiopharmaceutical in Advanced Cancers

WILMETTE, Ill., August 21, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage radiopharma 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 therapeutic trial of its novel radiopharmaceutical MNPR-101-Lu.

MNPR-101-Lu combines the therapeutic radioisotope lutetium-177 (Lu-177) with Monopar's proprietary first-in-class humanized monoclonal antibody MNPR-101, which is highly selective against the urokinase plasminogen activator receptor (uPAR). The MNPR-101-Lu Phase 1 clinical trial will enroll patients with advanced solid cancers and will be a therapeutic follow-on study to the currently ongoing MNPR-101-Zr imaging and dosimetry clinical trial.

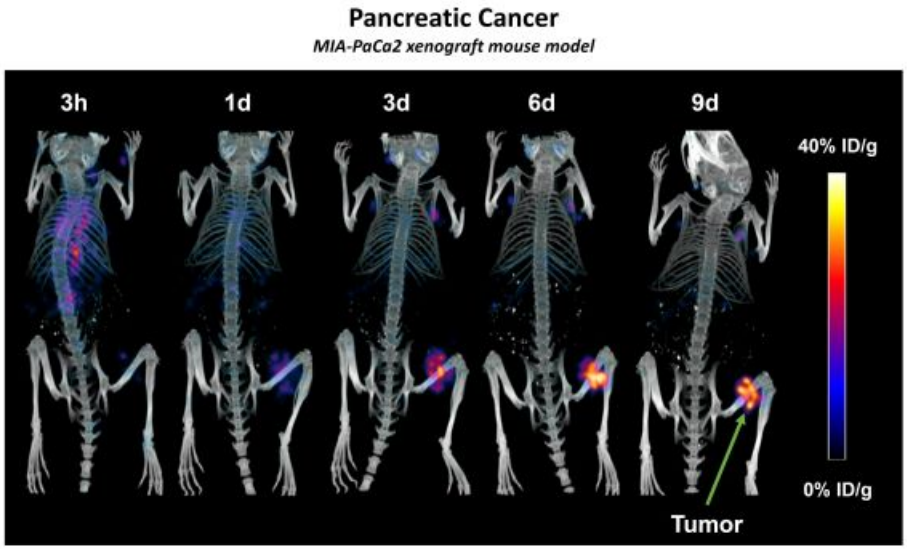
The results from preclinical studies of MNPR-101-Lu are promising. In a 90-day efficacy study in a human pancreatic cancer xenograft mouse model (Figure 1, below) as an example, MNPR-101-Lu demonstrated durable antitumor effects after a single injection, achieving complete elimination of tumors that lasted the duration of the study.

Figure 1. Tumor Efficacy Study



The MNPR-101-Lu imaging data in a human pancreatic cancer xenograft mouse model presented in March (link Figure 2 below) provides additional insight into the strong therapeutic effect observed after a single injection of MNPR-101-Lu. The imaging data demonstrates the high specificity and durable uptake of MNPR-101-Lu in the tumor relative to normal tissue.

Figure 2. Biodistribution of MNPR-101-Lu



“We are excited about the HREC clearance and encouraged by the potential of MNPR-101-Lu to provide a meaningful clinical benefit to patients with uPAR-positive tumors. Several of the most aggressive, deadly cancers express uPAR, including triple negative breast cancer and pancreatic cancer,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer. “We are looking forward to launching the trial as quickly as we can.”

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-Lu and MNPR-101-Ac225 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: that the MNPR-101-Lu Phase 1 clinical trial will enroll patients with advanced solid cancers, and will be a therapeutic follow-on to the currently ongoing MNPR-101-Zr imaging and dosimetry clinical trial; the results from preclinical studies of MNPR-101-Lu are promising; that these data support the potential of MNPR-101-Lu to provide a meaningful clinical benefit to patients with uPAR-positive tumors; and that Monopar is looking forward to launching the trial as quickly as it can. The forward-looking statements involve risks and uncertainties including, but not limited to: that Monopar may not launch its MNPR-101-Lu therapeutic study even after receiving regulatory clearance; that 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 and/or MNPR-101-Lu may cause unexpected serious adverse effects or fail to image or be effective against the cancer tumors in humans; 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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