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): **September 12, 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 September 12, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing positive early human clinical data from its ongoing open-label MNPR-101-Zr Phase 1 imaging and dosimetry clinical trial validating MNPR-101-Zr's tumor targeting ability.

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 September 12, 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: September 12, 2024

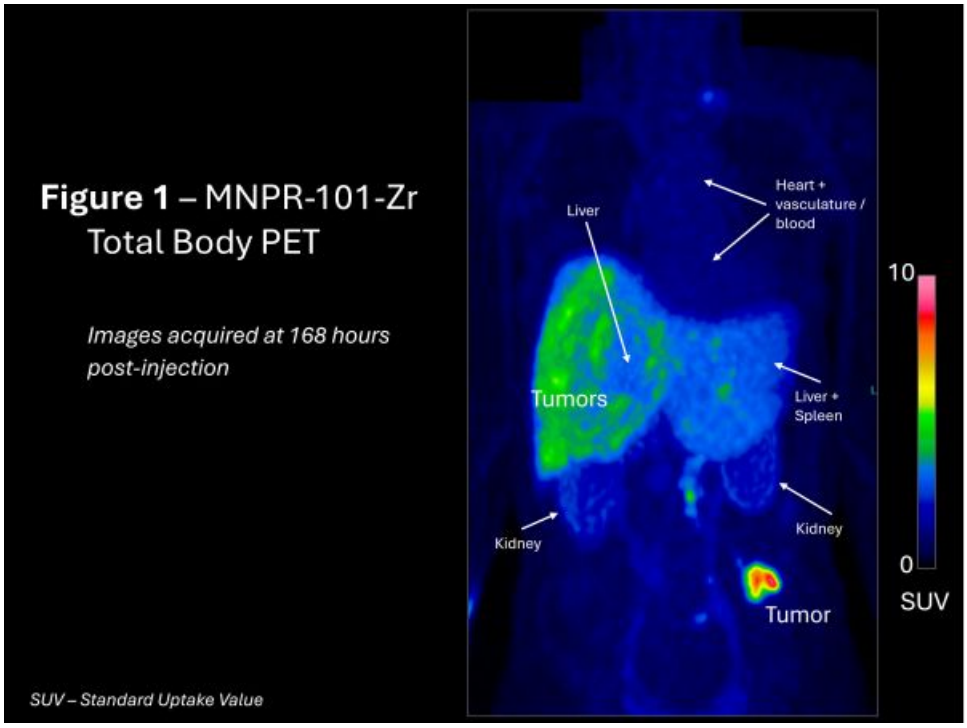
By: /s/ Karthik Radhakrishnan
Name: Karthik Radhakrishnan
Title: Chief Financial Officer

Monopar Announces Positive Early Human Clinical Data Validating the Tumor Targeting Ability of MNPR-101-Zr

WILMETTE, Ill., September 12, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage radiopharma company focused on developing innovative treatments for cancer patients, today announced positive early data from its ongoing open-label MNPR-101-Zr Phase 1 imaging and dosimetry clinical trial confirming MNPR-101-Zr's tumor targeting ability in humans.

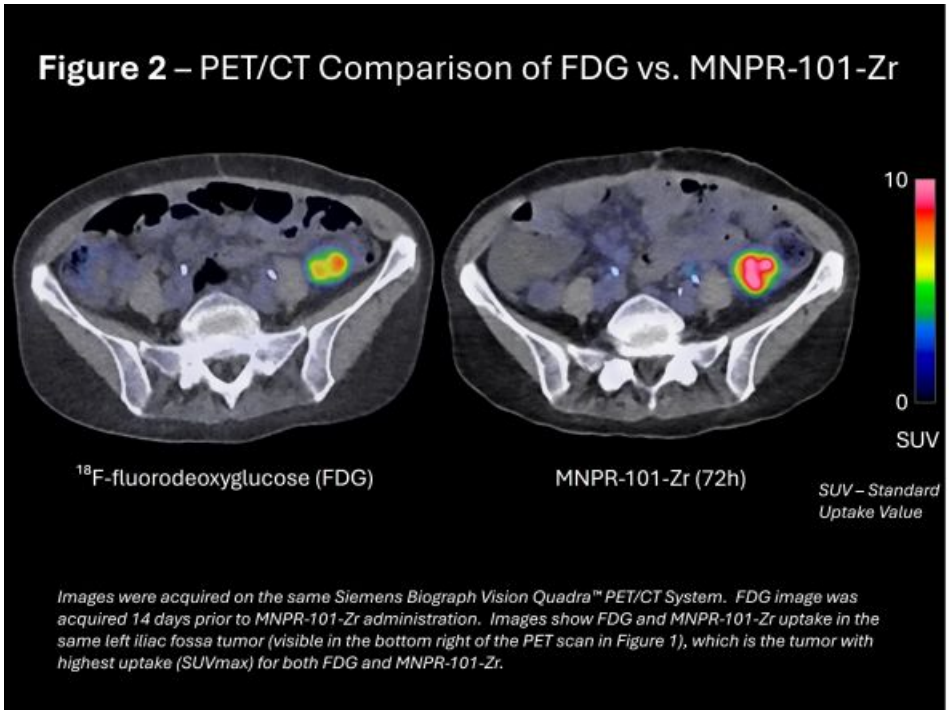
MNPR-101 is Monopar's proprietary first-in-class humanized monoclonal antibody that targets cancers expressing the urokinase plasminogen activator receptor (uPAR). These include a majority of all triple-negative breast, colorectal, bladder, ovarian, gastric, and pancreatic cancers.

A total-body positron emission tomography (PET) image was taken at 168 hours (7 days) post administration of MNPR-101-Zr (a zirconium-89 imaging radioisotope conjugated to MNPR-101) of the first cancer patient in the trial with one of the known high uPAR-expressing cancer types. The results, seen in Figure 1, demonstrate the specificity, durability, and uptake of MNPR-101-Zr in the metastatic tumors relative to normal tissue. The regions of higher uptake also align with the locations of the previously observed metastatic tumors on conventional FDG PET imaging.



“This is exactly what we had hoped to see – highly preferential uptake in the tumor,” said Andrew Cittadine, Monopar’s Chief Operating Officer.

MNPR-101-Zr was evaluated against FDG, the gold standard for detecting metastatic tumors.
Figure 2 shows FDG uptake in its highest-uptake tumor compared to MNPR-101-Zr uptake in the same tumor imaged on the same Siemens Biograph Vision Quadra™ PET/CT scanner.



“At the Melbourne Theranostic Innovation Centre, we utilize one of the world's most sensitive PET/CT scanners. Using the same scanner for FDG and MNPR-101-Zr, the results show MNPR-101-Zr achieved uptake at sites of known disease with retention out to late points, which is promising for future therapeutic translation,” said Professor Rodney Hicks, MBBS(Hons), MD, FRACP, FICIS, FAAHMS, lead investigator on the MNPR-101-Zr Phase 1 imaging and dosimetry clinical trial.

Monopar recently received clearance in Australia to initiate an MNPR-101-Lu Phase 1 therapeutic clinical trial [link] which is currently scheduled to launch in the fourth quarter of this calendar year.

“We are looking forward to sharing additional data at the upcoming European Association of Nuclear Medicine 2024 Annual Congress to be held in Hamburg, Germany on October 19-23, 2024, where our abstract has been accepted as a 'Top-Rated Oral Presentation' within the Scientific Program,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer.

Further information about the ongoing MNPR-101-Zr Phase 1 imaging and dosimetry 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, Phase 1-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac225 for the treatment of advanced cancers, as well as early development stage 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: the results show MNPR-101-Zr achieved uptake at sites of known disease with retention out to late points, which is promising for future therapeutic translation; and that an MNPR-101-Lu Phase 1 therapeutic clinical trial is currently scheduled to launch in the fourth quarter of this calendar year. The forward-looking statements involve risks and uncertainties including, but not limited to: that Monopar may not launch its MNPR-101-Lu therapeutic study in the fourth quarter of 2024, if at all; 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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