

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 22, 2024**

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-39070</u> (Commission File Number)	<u>32-0463781</u> (I.R.S. Employer Identification No.)
<u>1000 Skokie Blvd., Suite 350, Wilmette, IL</u> (Address of principal executive offices)		<u>60091</u> (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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 22, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing that it is presenting human clinical dosimetry data at the European Association of Nuclear Medicine.

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 22, 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 22, 2024

By: /s/ Karthik Radhakrishnan

Name: Karthik Radhakrishnan

Title: Chief Financial Officer



Monopar Presents Encouraging Human Clinical Dosimetry Data on its uPAR Program at EANM 2024

WILMETTE, Ill, October 22, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage radiopharmaceutical company focused on developing innovative treatments for cancer patients, is presenting today data from the clinical and preclinical development of its novel first-in-class lead radiopharma program based on MNPR-101 at the European Association of Nuclear Medicine (EANM) 2024 Annual Congress held in Hamburg, Germany. MNPR-101-Lu radiation dosimetry analytics using human data from MNPR-101-Zr show a favorable organ safety profile at high Lu-177 therapeutic dose levels. The slides for Monopar’s oral presentation can be found at the following link: <https://www.monopartx.com/pipeline/mnpr-101/eanm24-ppt>.

Monopar’s presentation, accepted as a “Top-Rated Oral Presentation” within the Scientific Program, illustrates the potential of the urokinase plasminogen activator receptor (uPAR) as a promising radiopharma target in solid tumors. Preclinical and clinical data show favorable biodistribution, tumor uptake, and low off-target binding of Monopar’s uPAR-targeted radiopharmaceuticals MNPR-101-Zr and MNPR-101-Lu. “We were able to optimize our uPAR-targeted radiopharmaceuticals in preclinical studies, and the data show these efforts have translated directly into humans with encouraging tumor uptake. Even at the highest Lu-177 therapeutic antibody dose we are aware of in the clinic, we estimate a favorable radiation dosimetry safety profile for off-target effects such as bone marrow exposure,” said Andrew Cittadine, Monopar’s Chief Operating Officer.

Further information about the MNPR-101-Lu Phase 1a trial is available at www.ClinicalTrials.gov under study identifier **NCT06617169**. Further information about the 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 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: MNPR-101-Lu radiation dosimetry analytics using human data from MNPR-101-Zr show a favorable organ safety profile at high Lu-177 therapeutic dose levels; Monopar’s presentation illustrates the potential of the urokinase plasminogen activator receptor (uPAR) as a promising radiopharma target in solid tumors; preclinical and clinical data show favorable biodistribution, tumor uptake, and low off-target binding of Monopar’s uPAR-targeted radiopharmaceuticals MNPR-101-Zr and MNPR-101-Lu; optimization of uPAR-targeted radiopharmaceuticals in preclinical studies show translation in humans with encouraging tumor uptake; and even the highest Lu-177 therapeutic antibody dose in the clinic presents a favorable radiation dosimetry safety profile for off-target effects such as bone marrow exposure. The forward-looking statements involve risks and uncertainties including, but not limited to: that radiation dosimetry analytics in the future may not be consistent with the estimated data generated thus far; Monopar may not find patients to enroll 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 the trials could result in a clinical hold should there be a Serious Adverse Event; 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.

CONTACT:

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Investor Relations

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Follow Monopar on social media for updates:

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