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): **March 5, 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 March 5, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing positive preclinical imaging data of a therapeutic radioisotope bound to its proprietary uPAR (urokinase plasminogen activator receptor) targeting agent MNPR-101.

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 March 5, 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: March 5, 2024

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

Exhibit 99.1

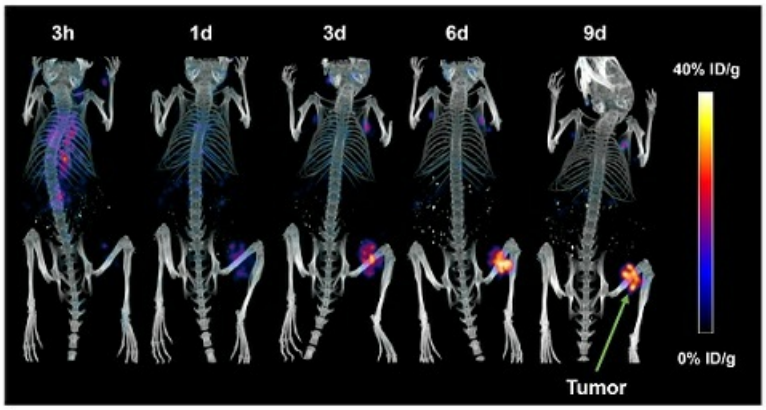
Monopar Announces Positive Preclinical Therapeutic Isotope Data for its MNPR-101 Radiopharma Program

WILMETTE, Ill., March 5, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced positive preclinical imaging data of a therapeutic radioisotope bound to its proprietary uPAR (urokinase plasminogen activator receptor) targeting agent MNPR-101. The data clearly demonstrate highly preferential uptake in the tumor. This is an extension of the tumor imaging and efficacy data Monopar released on February 22 (link), where Monopar disclosed biodistribution data with a diagnostic imaging radioisotope (Zirconium-89) as well as efficacy data with therapeutic radioisotopes (e.g., Actinium-225) bound to MNPR-101 in human tumor xenograft models. The new imaging data released today provide additional support for the tumor-targeting ability of MNPR-101 and help explain the near complete elimination of tumors (link) observed after a single injection of therapeutic radioisotopes bound to MNPR-101.

Biodistribution of a Therapeutic Radioisotope Conjugated to MNPR-101

Two of the most commercially successful radiopharmaceuticals, Pluvicto® and Lutathera™, use the therapeutic radioisotope Lutetium-177 (Lu-177). Beyond killing cancer cells, this radioisotope has the added advantage that its biodistribution can be visualized via SPECT (single-photon emission computed tomography) imaging. Monopar collected a sequential SPECT imaging time-series utilizing MNPR-101 conjugated to Lu-177 (MNPR-101-Lu) in a uPAR-expressing human pancreatic cancer xenograft model. The results can be seen in Figure 1. High specificity and durable uptake of MNPR-101-Lu in the tumor relative to normal tissue is readily apparent, and these results are consistent with the previously released data for Monopar's diagnostic imaging radiopharmaceutical MNPR-101-Zr.

Figure 1. Biodistribution of Therapeutic Radioisotope Lu-177 Conjugated to MNPR-101 in Pancreatic Cancer (MIA PaCa-2) Tumor Xenograft



“Delivering a high dose to the tumor relative to normal tissue is of central importance in radiopharmaceutical therapy,” said Andrew Cittadine, Monopar’s Chief Operating Officer. “These data help explain the compelling and durable anti-tumor benefits observed to-date in preclinical studies using MNPR-101 conjugated to therapeutic radioisotopes.”

Monopar recently announced it received Human Research Ethics Committee (HREC) clearance in Australia to commence a Phase 1 dosimetry clinical trial for MNPR-101-Zr in advanced cancer patients (link). The data disclosed today further support Monopar’s efforts to create a radiodiagnostic and radiotherapeutic pairing to image and treat uPAR-positive cancers.

“Some of the most aggressive, deadly cancers express uPAR, such as triple negative breast cancer and pancreatic cancer,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer. “These data further support the potential of a MNPR-101 based radiopharmaceutical to provide a very meaningful clinical benefit to patients with uPAR-positive tumors.”

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 1b-stage camsirubicin for the treatment of advanced soft tissue sarcoma; Phase 1-stage MNPR-101 for radiopharmaceutical use in various advanced 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 data disclosed today further support Monopar’s efforts to create a radiodiagnostic and radiotherapeutic pairing to image and treat uPAR-positive cancers; and that these data further support the potential of a MNPR-101 based radiopharmaceutical to provide a very meaningful clinical benefit to patients with uPAR-positive tumors. 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 initiating and enrolling the Phase 1 clinical trial; 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; 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:

Monopar Therapeutics Inc.
Investor Relations
Kim R. Tsuchimoto
Chief Financial Officer
kimtsu@monopartx.com

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