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 22, 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 22, 2024, Monopar Therapeutics Inc. issued a press release announcing promising preclinical imaging and therapeutic efficacy data for its MNPR-101 radiopharmaceutical program targeting advanced cancers.

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 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: February 22, 2024

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

Monopar Therapeutics

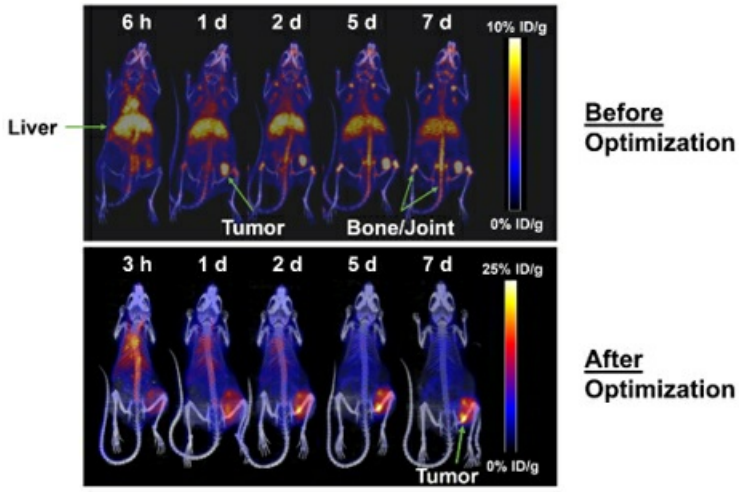
Monopar Announces Promising Preclinical Data for its MNPR-101 Radiopharma Program Targeting Advanced Cancers

WILMETTE, Ill., February 22, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced promising preclinical imaging and therapeutic efficacy data for its MNPR-101 radiopharmaceutical program. This novel first-in-class radiopharma program targets cancers expressing the urokinase plasminogen activator receptor (uPAR), which include a majority of all triple-negative breast, colorectal, and pancreatic cancers.

MNPR-101 Conjugated to Imaging Radioisotope

Maximizing the dose delivered to the tumor relative to normal tissue is of paramount importance in radiopharmaceutical therapy. Figure 1 below shows the before and after optimization of MNPR-101-Zr, Monopar's radiopharmaceutical imaging agent for advanced solid tumors expressing uPAR. Monopar's in-house radiopharmaceutical development team was able to significantly increase tumor uptake of MNPR-101-Zr while minimizing uptake in healthy tissue, as shown in this preclinical positron emission tomography (PET) sequential imaging time-series. The high specificity and durable tumor uptake are evident in the After Optimization panel below.

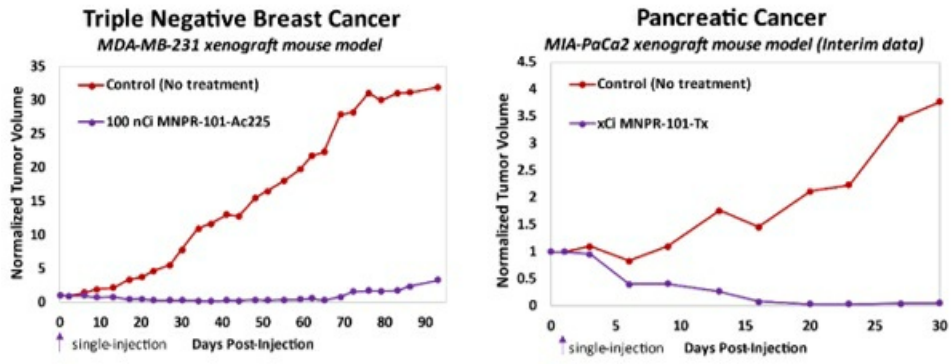
Figure 1. Pancreatic Cancer (MIA PaCa-2) Tumor Xenograft



MNPR-101 Conjugated to Therapeutic Radioisotopes

Preclinical data to date demonstrate compelling and durable anti-tumor benefits with MNPR-101 conjugated to therapeutic radioisotopes. Figure 2 below shows preclinical efficacy data in a triple negative breast cancer as well as a pancreatic cancer human tumor xenograft mouse model utilizing two different therapeutic radioisotopes conjugated to MNPR-101; one of these radioisotopes has already been disclosed as being actinium-225 (Ac-225). The results in both show near complete elimination of the tumor after a single injection of the radiopharmaceutical agent. These studies demonstrate the potential of a MNPR-101 based radiopharmaceutical to provide a very meaningful clinical benefit to patients.

Figure 2. Tumor Efficacy Studies



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. "As we prepare to launch this clinical trial, we are encouraged by the significant, precise, and durable accumulation we are seeing in tumors and the corresponding therapeutic benefit in preclinical human tumor xenograft models," said Andrew Cittadine, Monopar's Chief Operating Officer. "We are aiming to present these promising preclinical results at an upcoming scientific meeting."

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 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 these studies demonstrate the potential of an MNPR-101 based radiopharmaceutical to provide a very meaningful clinical benefit to patients; and that we are aiming to present these promising preclinical results at an upcoming scientific meeting. 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 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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