

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): **April 16, 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 April 16, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing it has filed a provisional patent application pertaining to the recent advancements and optimizations Monopar has achieved with its MNPR-101 radiopharmaceutical program.

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 April 16, 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: April 16, 2024

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



Monopar Announces Filing of Patent Protecting MNPR-101 Radiopharma Optimization Findings

WILMETTE, Ill, April 16, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced that it has filed a provisional patent application pertaining to the recent advancements and optimizations Monopar has achieved with its MNPR-101 radiopharmaceutical program.

The provisional patent titled “Antibody Radioisotope Constructs” that was filed with the United States Patent and Trademark Office (USPTO) outlines the MNPR-101-Zr construct, including variations on the radioisotopes, linkers, and antibody which could enhance the clinical profile of the construct, including properties such as its stability and biodistribution. It also covers the formulations and uses of MNPR-101-Zr, a zirconium-89 imaging radioisotope labeled version of MNPR-101, Monopar’s proprietary first-in-class humanized monoclonal antibody that is highly-selective against the urokinase plasminogen activator receptor (uPAR).

Monopar expects this provisional patent application to further strengthen its intellectual property around the MNPR-101 radiopharma program, under which the Company is aiming to develop therapies for numerous hard-to-treat advanced cancers that express uPAR. Monopar recently announced the initiation of its Phase 1 dosimetry clinical trial for MNPR-101-Zr in patients with advanced cancers.

“Filing of this provisional patent application is aimed at further protecting our novel MNPR-101 radiopharmaceutical program,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer. “This patent filing along with our earlier patent filings helps to create a broad portfolio of intellectual property around this program and potential future programs.”

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 1-stage MNPR-101 for radiopharmaceutical use in various advanced cancers; Phase 1b-stage camsirubicin for the treatment of advanced soft tissue sarcoma; and an early-stage camsirubicin analog, MNPR-202. For more information, visit: www.monopartrx.com and ir.monopartrx.com/presentations.

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 patent application outlines the MNPR-101-Zr construct, including variations with the radioisotopes, linkers and antibody which could enhance the clinical profile of the construct, including properties such as its stability and biodistribution; that Monopar expects this provisional patent application to further strengthen its intellectual property to protect the MNPR-101 radiopharma program; and that Monopar is aiming to develop therapies for numerous hard-to-treat advanced cancers that express uPAR. The forward-looking statements involve risks and uncertainties including, but not limited to: that patent applications may not result in allowed patents; that if allowed, the patents may be too narrow in scope to provide protection needed to successfully develop the radiopharma program; that we may expend available funds sooner than anticipated or require additional funding due to change in circumstances or unanticipated events; that future preclinical or clinical data will not be as promising as the data to date; not successfully enrolling the MNPR-101-Zr Phase 1 clinical trial if at all; that MNPR-101-Zr and/or MNPR-101 conjugated to a therapeutic radioisotope 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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