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): **May 9, 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 2.02 Results of Operations and Financial Condition

On May 9, 2024, Monopar Therapeutics Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2024. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the exhibit hereto are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release Dated May 9, 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: May 9, 2024

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

Monopar Therapeutics Reports First Quarter 2024
Financial Results and Strategic Focus on its Radiopharma Pipeline

Initiated MNPR-101-Zr First-in-Human Phase 1 Radiopharma Clinical Trial
MNPR-101-RIT Phase 1 Clinical Trial Targeted for Launch as Early as Q4 2024 or Q1 2025

Wilmette, IL, May 9, 2024 – Monopar Therapeutics Inc. (Monopar or the Company) (Nasdaq: MNPR), a clinical--stage radiopharmaceutical company focused on developing innovative treatments for cancer patients, today announced first quarter 2024 financial results and summarized recent developments.

Recent Developments

The radiopharma space has had numerous positive recent developments and announcements, from acquisitions to clinical data to reimbursement rates to commercial demand. Since this past December alone, four significant acquisitions have been publicly announced or completed which have had upfront payments ranging from approximately $1 billion to over $4 billion (BMS/RayzeBio, AstraZeneca/Fusion Pharma, Eli Lilly/POINT BioPharma, and Novartis/ Mariana Oncology).

Monopar has been generating promising preclinical data, and recently entered the clinic with its novel, proprietary MNPR-101 radiopharma program targeting the urokinase plasminogen activator receptor (uPAR). Based on these advances, Monopar has made the strategic decision to focus its resources on the assets and capabilities it has been building up in the radiopharma space. As such, the Company is winding down its non-radiopharma programs, including camsirubicin (and its Phase 1b clinical trial) as well as MNPR-202. The Company is targeting launching its second radiopharma clinical trial as early as the end of this year or the first quarter of 2025.

MNPR--101 for Radiopharmaceutical Use – First-in-Human Study with MNPR-101-Zr is Now Active

- Received clearance and recently initiated a first-in-human Phase 1 imaging and dosimetry clinical trial with novel radiopharmaceutical MNPR-101-Zr in advanced cancer patients. Further information about the MNPR-101-Zr trial is available at www.ClinicalTrials.gov under study identifier **NCT06337084**. This study is being led by internationally recognized radiopharmaceutical physician Prof. Rodney Hicks, founder of the Melbourne Theranostic Innovation Centre (MTIC).
- Optimized imaging and therapeutic MNPR-101 radiopharma programs, significantly increasing tumor uptake while minimizing uptake in healthy tissue (link). This work led to *in vivo* efficacy studies demonstrating near complete elimination of the tumor after a single injection of the MNPR-101 radiopharmaceutical agent.
- Imaged the biodistribution of a therapeutic radioisotope bound to MNPR-101, and demonstrated highly preferential tumor uptake in the tumor consistent with what is seen with the Zr-89 imaging radioisotope (link).
- Filed a provisional patent application to protect the recent advancements and optimizations Monopar has achieved with its MNPR-101 radiopharma programs.
- Announced that Monopar's abstract on MNPR-101-Zr radiopharma program was selected for presentation at the Society of Nuclear Medicine and Molecular Imaging's Annual Meeting on June 8-11, 2024.
- Monopar is targeting initiating a Phase 1 clinical study in advanced cancers with its therapeutic radiopharmaceutical MNPR-101-RIT as soon as the end of this year or early next year.

Results for the First Quarter Ended March 31, 2024, Compared to the First Quarter Ended March 31, 2023

Cash and Net Loss

Cash, cash equivalents and short-term investments as of March 31, 2024, were $8.8 million. Monopar projects that its current funds will be sufficient to continue operations at least through June 30, 2025, to continue to conduct and conclude its first-in-human imaging and dosimetry clinical trial with MNPR-101-Zr, and to advance the preclinical MNPR-101-RIT therapeutic program into the clinic. Monopar will require additional funding to advance its preclinical and clinical programs beyond that, and anticipates seeking to raise additional capital within the next 12 months to fund its future operations.

Net loss for the first quarter of 2024 was $1.6 million or $0.10 per share compared to net loss of $2.4 million or $0.19 per share for the first quarter of 2023.

Research and Development (R&D) Expenses

R&D expenses for the first quarter of 2024 were $966,000 compared to $1,653,000 for the first quarter of 2023. This decrease of $687,000 was primarily due to a decrease of $716,000 in Validive clinical trial-related expenses due to the closure of the trial in March 2023, partially offset by a net increase of $29,000 in other R&D expenses.

General and Administrative (G&A) Expenses

G&A expenses for the first quarter of 2024 were $757,000, compared to $872,000 for the first quarter of 2023. This represents a decrease of $115,000 primarily attributed to (1) a decrease in stock-based compensation to the non-employee directors of $70,000 as no equity awards were issued in the first quarter of 2024 compared to the first quarter of 2023, (2) a reduction of $62,000 in patent expenses related to the closure of the Validive trial, and (3) a reduction of stock-based compensation expenses to employees of $16,000 due to the full vesting of the 2020 grants in the fourth quarter of 2023, partially offset by a net increase in consulting, tax services and other G&A expenses of $33,000.

About Monopar Therapeutics

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 and late preclinical-stage MNPR-101 radio-immuno-therapeutic (RIT) for the treatment of advanced cancers. For more information, and links to SEC filings that contain detailed financial information, visit: https://ir.monopartx.com/quarterly-reports.

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 and are not limited to: that Monopar is targeting initiating a Phase 1 clinical study in advanced cancers with its therapeutic radiopharmaceutical MNPR-101-RIT as soon as the end of this year or early next year; and that current funds will be sufficient for Monopar to continue operations at least through June 30, 2025, to continue to conduct and conclude its first-in-human clinical trial with Monopar's MNPR-101-Zr radiopharmaceutical

program, and to advance the preclinical MNPR-101-RIT therapeutic program into the clinic. The forward-looking statements involve risks and uncertainties including, but not limited to: 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 enrolling sufficient patients in the MNPR-101-Zr Phase 1 clinical trial or 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.

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