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 28, 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 March 28, 2024, Monopar Therapeutics Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2023. 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 March 28, 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 28, 2024

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

Monopar Reports Fourth Quarter and Full-Year 2023 Financial Results and Recent Developments

WILMETTE, Ill., March 28, 2024 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced fourth quarter and full-year 2023 financial results and summarized recent developments.

Recent Developments

Novel MNPR-101 Radiopharmaceutical Program targeting uPAR – Phase 1 dosimetry clinical trial to commence in the coming weeks

- MNPR-101-Zr Phase 1 dosimetry clinical trial has Human Research Ethics Committee (HREC) clearance in Australia and is on track to initiate at the Melbourne Theranostic Innovation Centre (MTIC) within the next few weeks.
    - Will enroll patients with advanced cancers, aiming for those most likely to have uPAR expression, which include a majority of all triple-negative breast, colorectal, and pancreatic cancers.
    - Will utilize state-of-the-art positron emission tomography (PET) imaging to assess tumor uptake, normal organ biodistribution, and safety.
    - Internationally recognized radiopharmaceutical physician, Professor Rodney Hicks, will be the lead investigator for the trial.
- Positive preclinical data support the potential of a MNPR-101 based radiopharmaceutical to provide a very meaningful clinical benefit to patients.
    - In February 2024, Monopar shared preclinical biodistribution and efficacy data using imaging and therapeutic radioisotopes conjugated to MNPR-101. Imaging with MNPR-101-Zr in a pancreatic cancer human tumor xenograft mouse model showed high specificity and durable tumor uptake. With the therapeutic radioisotope actinium-225 (Ac-225) conjugated to MNPR-101, near complete elimination of tumor was achieved after a single injection in a triple negative breast human tumor xenograft mouse model.
    - In March 2024, Monopar shared biodistribution data using the therapeutic radioisotope Lutetium-177 (Lu-177) conjugated to MNPR-101. The images show highly preferential uptake in tumor, helping explain the near complete elimination of tumors observed after a single injection of therapeutic radioisotopes bound to MNPR-101.

Camsirubicin – Phase 1b Dose-Escalation Trial, Currently enrolling the Fifth Dose-Level Cohort (650 mg/m²)

- Monopar is presently enrolling patients at the fifth dose level, which is over twice the highest dose reached in any prior camsirubicin clinical trial (650 mg/m^2 versus 265 mg/m^2).

Results for the Fourth Quarter and Year Ended December 31, 2023, Compared to the Fourth Quarter and Year Ended December 31, 2022

Cash and Net Loss

Cash, cash equivalents and short-term investments as of December 31, 2023, were $7.3 million. Monopar expects that its current funds, which include an additional $3.2 million from the net proceeds of its at-the-market facility in Q1 2024, will be sufficient for Monopar to continue operations at least through June 30, 2025, to conduct and conclude its first-in-human clinical trial with Monopar's MNPR-101-Zr radiopharma program and continue the Company's other pipeline programs.

Net loss for the fourth quarter of 2023 was $1.8 million or $0.12 per share compared to $2.9 million or $0.22 per share for the fourth quarter of 2022. Net loss for the year ended December 31, 2023 was $8.4 million or $0.61 per share compared to $10.5 million or $0.83 per share for the year ended December 31, 2022.

Research and Development (R&D) Expenses

R&D expenses for the fourth quarter of 2023 were $1.0 million compared to $2.1 million for the fourth quarter of 2022. This decrease of $1.1 million was primarily due to (1) a decrease of $0.9 million for Validive clinical trial expense, (2) a decrease of $0.2 million in camsirubicin manufacturing costs, and (3) a decrease of $0.1 million in R&D salaries, partially offset by an increase of $0.1 million in MNPR-101 radiopharmaceutical program development activities.

R&D expenses for the year ended December 31, 2023 were $5.6 million compared to $7.6 million for the year ended December 31, 2022. This decrease of $2.0 million was primarily due to (1) a decrease of $1.4 million for Validive clinical trial and manufacturing costs, (2) a decrease of $0.9 million in camsirubicin clinical trial and manufacturing costs, (3) a decrease of $0.1 million in R&D salaries, partially offset by an increase of $0.4 million in MNPR-101 radiopharma activity.

General and Administrative (G&A) Expenses

G&A expenses for the fourth quarter of 2023 were $0.9 million, compared to $0.8 million for the fourth quarter of 2022. This increase of $0.1 million was primarily due to an increase in G&A personnel expenses.

G&A expenses for the year ended December 31, 2023 were $3.2 million, compared to $2.9 million for the year ended December 31, 2022. This increase of $0.3 million was primarily due to an increase in G&A personnel expenses.

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 Monopar’s Phase 1 dosimetry clinical trial will commence in the coming weeks; that Professor Rodney Hicks, will be the lead investigator for Monopar’s MNPR-101-Zr Phase 1 dosimetry clinical trial; that Professor Hicks will enroll patients at MTIC in Australia; that positive preclinical data to date support the potential of a MNPR-101 based radiopharmaceutical (MNPR-101-RIT) to provide a very meaningful clinical benefit to patients and that Monopar expects that its current funds, including the net proceeds from its at-the-market facility in Q1 2024, will be sufficient for Monopar to continue operations beyond June 30, 2025. 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 initiating and enrolling the MNPR-101-Zr Phase 1 clinical trial in the coming weeks 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.

CONTACT:

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

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Twitter: @MonoparTx LinkedIn: Monopar Therapeutics