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 11, 2023**

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 11, 2023, Monopar Therapeutics Inc. issued a press release announcing its financial results for the first quarter ended March 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 May 11, 2023

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 11, 2023

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

Monopar Therapeutics Reports First Quarter 2023
Financial Results and Recent Developments

Camsirubicin Phase 1b Dose-Escalation Trial Enrolling 5th Dose-Level Cohort (650 mg/m^2)
MNPR-101 RIT Shows Promising Imaging and Therapeutic Preclinical Study Results

Wilmette, IL, May 11, 2023 – Monopar Therapeutics Inc. (Monopar or the Company) (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients, today announced first quarter 2023 financial results and summarized recent developments.

Recent Developments

Camsirubicin – Phase 1b Dose-Escalation Trial, Currently Enrolling Fifth Dose-Level Cohort

- Phase 1b data to date show an improvement in median progression free survival in patients with advanced soft tissue sarcoma (ASTS) from what was observed in the prior camsirubicin Phase 2 trial (265 mg/m^2). This is supportive of our dose-response hypothesis with camsirubicin. Additionally, one of the three patients in the 520 mg/m^2 dose-level cohort recently went from having what was initially determined to be an unresectable cancer to, after several cycles of camsirubicin treatment and a corresponding 21% reduction in tumor dimensions, being determined to be resectable. This changed the course of treatment for this patient, who recently did undergo surgical resection of the cancer.

- Monopar is currently enrolling patients into the fifth dose-level cohort (650 mg/m^2), which is nearly 2.5x the highest dose evaluated in any prior camsirubicin clinical trial (265mg/m^2).

- To date, no drug-related cardiotoxicity has been observed with camsirubicin treatment as evaluated by the industry standard left ventricular ejection fraction (LVEF). This compares favorably to the well-documented dose-restricting cardiotoxicity experienced with doxorubicin, the current first-line treatment for ASTS.

- 75% of camsirubicin patients in this trial have experienced no hair loss. Of the 25% with any hair loss, only 8% experienced >50% hair loss and only 17% experienced low grade hair loss. This compares favorably to the approximately 50% of doxorubicin treated patients in recent ASTS clinical trials reporting some amount of hair loss, with the majority of these patients experiencing >50% hair loss.

- Only 8% of camsirubicin patients in the trial have experienced low grade, mild oral mucositis. This compares favorably to the roughly 35-40% of doxorubicin treated patients in recent ASTS clinical trials that experienced mild-to-severe oral mucositis.

MNPR-101 for Radiopharmaceutical Use – Promising Preclinical Studies Support FIH Study

- Based on promising preclinical imaging results with MNPR-101-Zr showing high uptake across multiple tumor types, and with preclinical therapeutic efficacy and biodistribution studies utilizing the radioisotopes Ac-225 and Lu-177, Monopar and its collaborator, NorthStar Medical Radioisotopes, committed to additional funding with the aim of initiating a first-in-human (FIH) imaging study with MNPR-101-Zr as early as end of this year.

- MNPR-101-Zr is a zirconium-89 labeled version of MNPR-101 (a highly selective antibody against the urokinase plasminogen activator receptor, also known as uPAR). Positron emission tomography (PET) imaging of preclinical mouse models for triple-negative breast, colorectal, and pancreatic tumors displayed high and selective uptake of MNPR-101-Zr in these uPAR-expressing tumors.

- Preclinical triple negative breast cancer mouse model studies with Ac-225 and Lu-177 radiolabeled MNPR-101 showed a promising dose-dependent-anti-cancer-effect and favorable biodistribution profile. The imaging and therapeutic preclinical results to date demonstrate the potential utility of MNPR-101 as a precision targeting agent for both imaging and treatment in multiple cancer indications.

MNPR-202 - Promising Preclinical Data Ignites Further Research

- MNPR-202 is designed to retain the same potentially non-cardiotoxic backbone as camsirubicin but is modified at other positions which may enable it to work in certain cancers that are resistant to camsirubicin and doxorubicin.

- Monopar's collaborator at the National University of Singapore, Cancer Science Institute, has reported data from blood cancer preclinical studies showing that MNPR-202:

  - has a similar cytotoxic potency to doxorubicin
  - generates increased DNA damage in the cancer cells compared to doxorubicin
  - has a unique immune activation profile versus doxorubicin
  - demonstrates increased apoptosis (programmed cell death) compared to doxorubicin
  - causes a distinct set of genes to be upregulated and downregulated versus doxorubicin and
  - may also be superior to doxorubicin in certain combination treatment regimens.

- A combination drug screen with 183 compounds was performed, revealing distinct differences in the synergy profile between doxorubicin versus MNPR-202 when used along with other compounds. For example, MNPR-202 demonstrated a more favorable synergy profile with the experimental anti-cancer agent volasertib compared to doxorubicin.

Validive Clinical Update

On March 27, 2023, the Company discontinued its Validive Phase 2b/3 VOICE trial based upon its independent Data Safety Monitoring Board's determination that the trial did not meet the pre-defined threshold for efficacy of a 15% absolute difference in severe oral mucositis prevention between Validive and placebo. Other than clinical site close-out related expenses to be incurred in Q2 2023, the Company will not incur any license or royalty obligations and is not anticipating any significant expenses beyond Q2 2023 related to Validive.

Results for the First Quarter Ended March 31, 2023, Compared to the First Quarter Ended March 31, 2022

Cash and Net Loss

Cash, cash equivalents and short-term investments as of March 31, 2023, were $11.7 million. Monopar expects that its current funds will be sufficient for Monopar to obtain topline results from its ongoing open-label Phase 1b camsirubicin clinical trial as planned by the end of 2023 (but this may not be the case if camsirubicin reaches even higher dose levels than anticipated and topline results are deferred as dosing continues beyond 2023), advance the Company's MNPR-101 radiopharmaceutical program into its first in human clinical trial and close out Monopar's terminated Validive Phase 2b/3 (VOICE) clinical program. The Company estimates its cash, cash equivalents and short-term investments will fund the Company's planned operations at least through June 2024. Monopar will require additional funding to advance its clinical and preclinical 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 2023 was $2.4 million or $0.19 per share compared to net loss of $2.5 million or $0.19 per share for the first quarter of 2022.

Research and Development (R&D) Expenses

R&D expenses for the first quarter of 2023 were $1,653,000 compared to $1,678,000 for the first quarter of 2022. This decrease of $25,000 was primarily due to a decrease of $120,000 in R&D personnel costs, partially offset by an increase of $79,000 in Validive and camsirubicin clinical trial-related and clinical material manufacturing-related expenses.

General and Administrative (G&A) Expenses

G&A expenses for the first quarter of 2023 were $872,000 compared to $779,000 for the first quarter of 2022. This increase of $93,000 was primarily due to (1) an increase in G&A salaries and benefits and (2) an increase in accounting and audit fees.

About Monopar Therapeutics

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients. Monopar's pipeline consists of camsirubicin (Phase 1b) for the treatment of advanced soft tissue sarcoma; MNPR-101, a late-stage preclinical antibody for radiopharmaceutical use in advanced cancers; and MNPR-202, an early-stage camsirubicin analog for various 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 statements concerning: that Monopar and its collaborator, NorthStar Medical Radioisotopes, are aiming to initiate a first-in-human imaging study with MNPR-101-Zr as early as end of this year; that preclinical results to date demonstrate the potential utility of MNPR-101 as a precision targeting agent for both imaging and treatment in multiple cancer indications; that MNPR-202 may be superior to doxorubicin in certain combination treatment regimens; that Monopar is not anticipating any significant expenses beyond Q2 2023 related to Validive; the timing and cost of the Phase 1b camsirubicin clinical trial; and that the Company's cash, cash equivalents and short-term investments will be sufficient to fund planned operations at least through June 2024. The forward-looking statements involve risks and uncertainties including, but not limited to: not successfully recruiting patients and initiating additional clinical trial sites for the camsirubicin Phase 1b clinical trial within expected timeframes, if at all; the camsirubicin trial data being inconclusive or negative; the Company's inability to raise sufficient funds or engage a partner to continue the camsirubicin clinical program through and beyond the Phase 1b clinical trial and to further develop MNPR-101-Zr with its collaboration partner if its first-in-human trial is successful; the effects of general economic and market conditions on Monopar's operations and ability to raise fundings, including potential ramifications due to recent instability in the banking industry; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of 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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