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 23, 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 March 23, 2023, Monopar Therapeutics Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2022. 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 23, 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: March 23, 2023

By: /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Chief Financial Officer, Secretary and Treasurer

EXHIBIT 99.1

Monopar Therapeutics Reports
Fourth Quarter and Full-Year 2022
Financial Results and Recent Developments

Validive® Phase 2b/3 VOICE Trial Anticipates Go/No-Go Interim Readout by End of Next Week
Camsirubicin Phase 1b Dose-Escalation Trial Now Enrolling 5th Dose-Level Cohort (650 mg/m^2)

Wilmette, IL, March 23, 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 fourth quarter and full-year 2022 financial results and summarized recent developments.

Recent Developments

Validive – International Phase 2b/3 Trial, Interim Go/No-go Analysis on Track for End of Next Week

- The VOICE trial, in planning for a potential positive go/no-go outcome from the interim analysis, continues to enroll patients in the Phase 3 portion of the VOICE trial and add additional clinical sites (now at 81 active sites across the U.S. and Europe).
- The blinded interim analysis of clinical data from the Phase 2b patient cohort of the trial, to be performed by an independent data monitoring committee, will be used to recommend the Company either continue enrolling the Phase 3 portion of the trial or to stop the trial. This analysis should be completed and reported out by the end of next week.

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

- 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).
- Phase 1b data to date show an improvement in median progression free survival 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.
- 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 advanced soft tissue sarcoma (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

- MNPR-101-Zr is a zirconium-89 labeled version of MNPR-101, a highly selective antibody against the urokinase plasminogen activator receptor (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.

- Based on the promising recently generated preclinical imaging results with MNPR-101-Zr, Monopar and its collaborator, NorthStar Medical Radioisotopes, LLC committed to additional funding with the aim of initiating a first-in-human (FIH) imaging study with MNPR-101-Zr as early as the end of this year.

- These proof-of-concept studies provide support for a FIH PET imaging study with MNPR-101-Zr and a future therapeutic study using the previously announced actinium-225 labeled radioimmunotherapeutic version of MNPR-101. Overall, the imaging results demonstrate the potential utility of MNPR-101 as a precision targeting agent for both imaging and therapy 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 and 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.

Kim R. Tsuchimoto Appointed as New Board Member

- On March 20, 2023, the Company increased its Board size from five to six members.

- Simultaneously, Monopar appointed Kim R. Tsuchimoto, the Company's Chief Financial Officer, to the Board to serve until the next annual stockholders' meeting.

- Ms. Tsuchimoto brings over 25 years of experience in the biopharma industry, which includes previously serving as Vice President at BioMarin Pharmaceutical and Chief Financial Officer at Raptor Pharmaceutical. She was involved in BioMarin's initial public offering onto Nasdaq in 1999, Raptor's reverse merger onto Nasdaq in 2009, and Monopar's initial public offering onto Nasdaq in 2019. She brings strong financial management, corporate governance and financial strategy experience to Monopar's Board.

Results for the Fourth Quarter and Year Ended December 31, 2022, Compared to the Fourth Quarter and Year Ended December 31, 2021

Cash and Net Loss

Cash, cash equivalents and short-term investments as of December 31, 2022, were $13.1 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) and the continued enrollment in the Phase 3 portion of the ongoing Validive Phase 2b/3 (VOICE) clinical program should the interim analysis yield a "go" decision. Monopar will require additional funding and/or a corporate partner to advance its clinical and preclinical programs and anticipates that it will seek to raise additional capital and/or engage a partner within the next 12 months to fund its future operations.

Net loss for the fourth quarter of 2022 was $2.9 million or $0.22 per share compared to net loss of $2.7 million or $0.21 per share for the fourth quarter of 2021. Net loss for the year ended December 31, 2022 was $10.5 million or $0.83 per share compared to net loss of $9.1 million or $0.73 per share for the year ended December 31, 2021.

Research and Development (R&D) Expenses

R&D expenses for the fourth quarter of 2022 were $2.1 million compared to $2.0 million for the fourth quarter of 2021. This increase of $0.1 million was primarily due to 1) an increase of $0.3 million for VOICE clinical trial expenses, and 2) an increase in $0.1 million in R&D consulting partially offset by a decrease of $0.3 million in R&D personnel expenses.

R&D expenses for the year ended December 31, 2022 were $7.6 million compared to $6.5 million for the year ended December 31, 2021. This increase of $1.1 million was primarily due to 1) an increase of $1.0 million for VOICE clinical trial expenses, 2) an increase of $0.5 million for camsirubicin Phase 1b clinical trial expenses, and 3) increase of $0.2 million in R&D consulting partially offset by 1) a decrease of $0.5 million in R&D personnel expenses and 2) a decrease of $0.1 million in preclinical program expenses.

General and Administrative (G&A) Expenses

G&A expenses for the fourth quarter of 2022 were $0.8 million, compared to $0.7 million for the fourth quarter of 2021. 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, 2022 were $2.9 million, compared to $2.6 million for the year ended December 31, 2021. This increase of $0.3 million was primarily due to an increase in G&A personnel expenses.

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 Validive® (Phase 2b/3) for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin (Phase 1b) for the treatment of advanced soft tissue sarcoma; a late-stage preclinical antibody, MNPR-101, for radiopharmaceutical use in advanced cancers; and an early-stage camsirubicin analog, MNPR-202, for various cancers. For more information, and links to SEC filings that contain detailed financial information, visit: https://ir.monopartx.com/annual-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: Monopar’s plans to continue to activate Validive clinical sites in both the U.S. and Europe; that the VOICE trial interim analysis should be completed and reported out by the end of next week; that Monopar and its collaborator, NorthStar Medical Radioisotopes, LLC are aiming to initiate a first-in-human imaging study with MNPR-101-Zr as early as the end of this year; and that 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) and the continued enrollment in the Phase 3 portion of the ongoing Validive Phase 2b/3 (VOICE) clinical program. The forward-looking statements involve risks and uncertainties including, but not limited to: not completing and reporting out the VOICE trial interim analysis by the end of next week; reaching a no-go decision based on the interim analysis; uncertainty of the continuation of the Validive program if the interim analysis is negative; if the interim analysis is positive, not successfully recruiting patients and initiating additional clinical trial sites for the Phase 3 portion of the VOICE trial or 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 complete the Phase 3 portion of the VOICE clinical trial and continue the camsirubicin clinical program through and beyond the Phase 1b clinical trial; 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.

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