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 24, 2022**

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	**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 24, 2022, Monopar Therapeutics Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2021. 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 24, 2022

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 24, 2022

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

Monopar Therapeutics Reports
Fourth Quarter and Full-Year 2021
Financial Results and Recent Program Developments

Validive® Phase 2b/3 VOICE Trial Continues Adding Sites in the U.S. and Europe
Camsirubicin Phase 1b Dose-Esclation Trial Clears 2nd Dose Level and is Now Enrolling 3rd Dose-Level Cohort

Wilmette, IL, March 24, 2022 – 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 2021 financial results and summarized recent program developments.

Recent Program Developments and Highlights

Validive – International Phase 2b/3 VOICE Clinical Trial, Actively Recruiting

- Validive is a novel mucobuccal tablet formulation for clonidine that has been designed to provide for prolonged and enhanced local delivery of clonidine to the regions of oral mucosal radiation damage in patients being treated for oropharyngeal cancer.
- Monopar received clearance in the U.S. and multiple European countries to conduct its Phase 2b/3 VOICE clinical trial of Validive (clonidine HCl mucobuccal tablet) (NCT04648020 / EudraCT No. 2021-000999-11) for the prevention of severe oral mucositis (SOM) in patients undergoing chemoradiotherapy (CRT) for oropharyngeal cancer.
- The VOICE trial now has 44 active clinical trial sites in the U.S. and Europe, continues to open additional sites globally, and is on track to reach the interim analysis in mid-2022. Based on findings extracted from public reporting of recently completed SOM trials, Monopar is presently evaluating potential enhancements to and exact timing of the interim analysis.
- There is no FDA-approved prevention or treatment for CRT-induced SOM.

Camsirubicin – Phase 1b Dose-Escalation Trial, Actively Recruiting

- Camsirubicin, a propriety doxorubicin analog, has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing the toxic effects on the heart.
- In August 2021, Monopar received clearance from the U.S. Food and Drug Administration to proceed under an Investigational New Drug (IND) application with an open-label Phase 1b dose-escalation clinical trial evaluating camsirubicin plus growth factor support (pegfilgrastim/G-CSF) in patients with advanced soft tissue sarcoma (ASTS) (NCT 05043649).
- First patient was dosed in October 2021.
- Monopar is currently enrolling the third dose-level, which is a higher dose level of camsirubicin than tested in any previous clinical trial.
- Early signs of clinical benefit have been observed with camsirubicin in this Phase 1b trial.

MNPR-101 and Related Compounds

- MNPR-101 is a preclinical stage uPAR-targeted antibody being developed as a radioimmunotherapeutic and companion diagnostic for advanced cancers and severe COVID-19.
- In collaboration with NorthStar Medical Radioisotopes, Monopar filed a provisional patent describing antibody conjugates of the metal binding agent PCTA, based on the unexpected observation of nearly 100% binding of Ac-225 to the PCTA-antibody conjugates.
- A provisional patent was also filed covering a radiotherapeutic consisting of Monopar's proprietary antibody MNPR-101 bound to Actinium-225 (Ac-225) via the metal binding agent PCTA (MNPR-101-PCTA-Ac-225).
- Currently evaluating pathways to initiating a first-in-human study.

MNPR-202

- MNPR-202 is a novel analog of camsirubicin, modified to potentially enable it to evade doxorubicin drug resistance mechanisms.
- Monopar entered into a collaboration and commenced work with Cancer Science Institute of Singapore to evaluate activity of MNPR-202 in preclinical models of multiple cancers.
- Composition of matter patent covering MNPR-202 has been allowed in the U.S.

Results for the Fourth Quarter and Year Ended December 31, 2021, Compared to the Fourth Quarter and Year Ended December 31, 2020

Cash and Net Loss

Cash and cash equivalents as of December 31, 2021, were $20.3 million. Monopar anticipates that its current cash and cash equivalents will fund: the Phase 2b portion of the VOICE clinical trial; the commencement of the Phase 3 portion of the VOICE clinical trial; and the Phase 1b camsirubicin clinical trial through at least March 2023. The Company plans to raise additional funds and/or engage a partner within the next 12 months to complete the VOICE clinical program and continue camsirubicin clinical development through and beyond the ongoing open-label, dose escalation Phase 1b clinical trial.

Net loss for the fourth quarter of 2021 was $2.7 million or $0.21 per share compared to net loss of $2.1 million or $0.19 per share for the fourth quarter of 2020. Net loss for the year ended December 31, 2021 was $9.1 million or $0.73 per share compared to net loss of $6.3 million or $0.58 per share for the year ended December 31, 2020.

Research and Development (R&D) Expenses

R&D expenses for the fourth quarter of 2021 were $2.0 million compared to $1.6 million for the fourth quarter of 2020. This increase of $0.4 million was primarily due to increases of $0.5 million for R&D personnel expenses and $0.4 million for VOICE clinical trial expenses offset by a decrease of $0.5 million for Phase 1b camsirubicin clinical material manufacturing and other clinical trial planning expenses.

R&D expenses for the year ended December 31, 2021 were $6.5 million compared to $4.1 million for the year ended December 31, 2020. This increase of $2.4 million was primarily due to increases in expenses of $1.4 million for VOICE clinical trial expenses and $1.2 million for R&D personnel expenses offset by a decrease of $0.2 million for Phase 1b camsirubicin clinical material manufacturing expenses.

General and Administrative (G&A) Expenses

G&A expenses for the fourth quarter of 2021 were $0.7 million, compared to $0.6 million for the fourth quarter of 2020. 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, 2021 were $2.6 million, compared to $2.4 million for the year ended December 31, 2020. This increase of $0.2 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. The Company's pipeline consists of Validive for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin for the treatment of advanced soft tissue sarcoma; a late-stage preclinical antibody, MNPR-101, for advanced cancers and severe COVID-19; 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 is on track for reaching interim in mid- 2022; that Monopar continues to activate additional clinical sites and recruit additional patients in the U.S. for the camsirubicin Phase 1b clinical trial; and that Monopar anticipates its current cash and cash equivalents will fund the Phase 2b portion of the VOICE clinical trial, the commencement of the Phase 3 portion of the VOICE clinical trial, and the Phase 1b camsirubicin clinical trial at least through March 2023. 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 VOICE clinical trial or the camsirubicin Phase 1b clinical trial within expected timeframes, if at all; 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; whether early signs of clinical benefit observed with camsirubicin in this Phase 1b trial will continue; whether Monopar and its collaborators will be able to successfully conduct preclinical or clinical studies of MNPR-101 and MNPR-202; 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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