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): **November 12, 2021**

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 November 12, 2021, Monopar Therapeutics Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 12, 2021

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: November 12, 2021

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

Monopar Therapeutics Reports Third Quarter 2021 Financial Results and Recent Clinical Developments

First Patients Dosed in Camsirubicin Phase 1b Clinical Trial in U.S.
Validive® Phase 2b/3 VOICE Trial Cleared to Enroll in Europe and on Track for Reaching Interim in H1 2022

Wilmette, IL, November 12, 2021 – 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 third quarter 2021 financial results and summarized recent clinical developments.

Recent Clinical Developments

Validive

- Monopar received clearance in multiple European countries to conduct its Phase 2b/3 VOICE clinical trial of Validive (clonidine HCl mucobuccal tablet) for the prevention of severe oral mucositis (SOM) in patients undergoing chemoradiotherapy (CRT) for oropharyngeal cancer.
- Monopar continues to actively initiate additional clinical sites in both the U.S. and the EU for the Phase 2b clinical trial, which is on track to reach the interim in the first half of 2022.
- There remains no FDA-approved prevention or treatment for CRT-induced SOM.

Camsirubicin

- 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.
- In September 2021, Monopar initiated the Phase 1b clinical trial, and in October 2021, dosed the first patients.
- Monopar continues to work on activating additional clinical sites in the U.S. for the Phase 1b clinical trial.

Results for the Third Quarter Ended September 30, 2021, Compared to the Third Quarter Ended September 30, 2020

Cash and Net Loss

Cash and cash equivalents as of September 30, 2021, were $22.3 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 December 2022. 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 beyond the Phase 1b clinical trial.

Net loss for the third quarter of 2021 was $2.5 million or $0.20 per share compared to net loss of $1.6 million or $0.15 per share for the third quarter of 2020.

Research and Development (R&D) Expenses

R&D expenses for the third quarter of 2021 were $1.8 million compared to $1.2 million for the third quarter of 2020. This increase of $0.6 million was primarily due to increases of $0.5 million for VOICE clinical trial expenses and $0.2 million for R&D personnel expenses offset by a decrease of $0.1 million for Phase 1b camsirubicin clinical trial expenses.

General and Administrative (G&A) Expenses

G&A expenses for the third quarter of 2021 were $0.6 million, compared to $0.4 million for the third quarter of 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/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: Monopar’s plans to continue to activate Validive clinical sites in both the U.S. and the EU; that the VOICE trial is on track for reaching interim in the first half of 2022; that Monopar continues to activate additional clinical sites 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 through December 2022. 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 beyond the Phase 1b clinical trial; 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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