UNITED STATES
SECURITIESANDEXCHANGECOMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
ofTheSecuritiesExchangeActof1934

Date of Report (Date of earliest event reported): **November 10, 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 November 10, 2022, Monopar Therapeutics Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 10, 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: November 10, 2022

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

EXHIBIT 99.1

Monopar Therapeutics Reports Third Quarter 2022 Financial Results and Recent Program Developments

Validive® Phase 2b/3 Interim Analysis on Track for Q1 2023
Camsirubicin Clinical Data at CTOS 2022 Next Week
MNPR-202 Preclinical Data at ASH 2022 in December

Wilmette, IL, November 10, 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 third quarter 2022 financial results and summarized recent program developments.

Recent Program Developments

Validive – International Phase 2b/3 Trial, Interim Go/No-go Analysis on Track for Q1 2023

- The VOICE trial continues to enroll patients and add additional clinical sites (now at 73 active sites and over 130 patients dosed across the U.S. and Europe).
- Enrollment for the Phase 2b portion of the trial has been completed. The trial recently expanded to include sites in Germany and Poland, and enrollment for the Phase 3 portion of the trial has commenced.
- The blinded interim analysis of clinical data from the Phase 2b patient cohort of the trial, to be performed by an independent data monitoring board, will be used to guide the Company as to whether or not to continue enrolling the Phase 3 portion of the trial. This analysis should be completed and reported out in Q1 2023.

Camsirubicin – Phase 1b Dose-Escalation Trial, Data to be Presented Next Week at CTOS 2022

- Monopar is currently dosing the fourth dose-level cohort, which is approximately double the highest dose of camsirubicin ever tested in a prior trial.
- Early results from the open-label camsirubicin Phase 1b clinical trial will be presented at the Connective Tissue Oncology Society (CTOS) Annual Meeting Conference being held on November 16-19, 2022 in Vancouver, BC.

MNPR-101 Radioimmunotherapeutic – Preclinical Studies Being Conducted to Support FIH Study

- Monopar is actively conducting preclinical studies to support a submission for a first-in-human (FIH) study with an MNPR-101-based radioimmunotherapeutic/radiodiagnostic that the Company has generated with its partner NorthStar Medical Radioisotopes, LLC.

MNPR-202: Preclinical Data to be Presented at ASH 2022 in December

- Monopar's collaborator, the Cancer Science Institute of Singapore at the National University of Singapore, has been testing MNPR-202 in preclinical cancer models with promising results.

- Monopar and Cancer Science Institute of Singapore will present a poster of MNPR-202 preclinical data at the American Society of Hematology (ASH) 64th Annual Meeting being held on December 10-13, 2022, in New Orleans, LA. The poster abstract can be found at the following link: https://ash.confex.com/ash/2022/webprogram/Paper168761.html

Results for the Third Quarter Ended September 30, 2022, Compared to the Third Quarter Ended September 30, 2021

Cash and Net Loss

Cash and cash equivalents as of September 30, 2022, were $14.3 million. Monopar anticipates that its current cash and cash equivalents will fund: the completion of 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 November 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 third quarter of 2022 was $2.4 million or $0.19 per share compared to net loss of $2.5 million or $0.20 per share for the third quarter of 2021.

Research and Development (R&D) Expenses

R&D expenses for the three months ended September 30, 2022, were $1,732,000, compared to $1,827,000 for the three months ended September 30, 2021. The decrease of $95,000 is attributed to (1) a decrease of $272,000 in R&D personnel expenses and (2) a $60,000 net decrease of other R&D expenses, partially offset by an increase of $237,000 in Validive clinical trial-related and clinical material manufacturing-related expenses.

General and Administrative (G&A) Expenses

G&A expenses for the three months ended September 30, 2022, were $675,000, compared to $632,000 for the three months ended September 30, 2021. The increase of $43,000 was primarily the result of 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 (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 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 enroll patients and add additional Validive clinical sites; that the VOICE trial interim analysis should be completed and reported out in Q1 2023; and that Monopar anticipates its current cash and cash equivalents will fund completion of 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 November 2023. The forward-looking statements involve risks and uncertainties including, but not limited to: not successfully recruiting patients and opening 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 preclinical studies will support a submission for a first-in-human study with an MNPR-101-based radioimmunotherapeutic/radiodiagnostic; whether the MNPR-202 preclinical study results can be repeated; 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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