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): **May 12, 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 May 12, 2022, Monopar Therapeutics Inc. issued a press release announcing its financial results for the first quarter ended March 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

Exhibit No.	Description
99.1	Press Release Dated May 12, 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: May 12, 2022

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

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

Validive® Phase 2b/3 VOICE Trial Continues Enrolling Patients Toward Interim
Camsirubicin Phase 1b Dose-Escalation Trial Clears 3rd Dose Level, Now Enrolling 4th

Wilmette, IL, May 12, 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 first quarter 2022 financial results and summarized recent program developments.

Recent Program Developments

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

- The VOICE trial continues to enroll patients and add additional clinical sites, with the interim analysis anticipated to occur in 2H-2022.

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

- Monopar has cleared the third dose-level and is currently enrolling the fourth dose-level cohort. The fourth dose-level is approximately double the highest dose of camsirubicin ever tested in a prior trial.
- Early signs of clinical benefit have been observed with camsirubicin in this Phase 1b trial.

*MNPR-101 Radioimmunotherapeutic ("*RIT*")*

- Monopar is currently evaluating pathways to initiate a first-in-human study with the MNPR-101-PCTA radioimmunotherapeutic/radiodiagnostic candidate that Monopar generated with its partner NorthStar Medical Radioisotopes, LLC.

MNPR-202

- Monopar's collaborator, the Cancer Science Institute of Singapore at the National University of Singapore, is testing MNPR-202 in preclinical cancer models and the Company is awaiting initial results.

Results for the First Quarter Ended March 31, 2022, Compared to the First Quarter Ended March 31, 2021

Cash and Net Loss

Cash and cash equivalents as of March 31, 2022 were $17.8 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 June 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 first quarter of 2022 was $2.5 million or $0.19 per share compared to net loss of $1.9 million or $0.16 per share for the first quarter of 2021.

Research and Development (R&D) Expenses

R&D expenses for the three months ended March 31, 2022 were $1,678,000, compared to $1,207,000 for the three months ended March 31, 2021. The increase of $471,000 is attributed to (1) an increase of $244,000 in Validive clinical trial-related and clinical material manufacturing-related expenses, (2) an increase of $193,000 in R&D personnel expenses and (3) a $34,000 net increase of other R&D expenses.

General and Administrative (G&A) Expenses

G&A expenses for the three months ended March 31, 2022 were $779,000, compared to $688,000 for the three months ended March 31, 2021. The increase of $91,000 is primarily attributed 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 enroll patients and add additional Validive clinical sites; that the VOICE trial is on track for reaching interim in 2H-2022; 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 June 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 early signs of clinical benefit observed with camsirubicin in this Phase 1b trial will continue; 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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