UNITED STATES
SECURITIESANDEXCHANGECOMMISSION
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): **January 18, 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	**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 7.01 Regulation FD Disclosure

On January 18, 2023, Monopar Therapeutics Inc. issued a press release announcing the positive recommendation from its safety review committee to advance to the fifth dose level (650 mg/m^2) in its camsirubicin Phase 1b trial in patients with advanced soft tissue sarcoma (ASTS).

The press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release Dated January 18, 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: January 18, 2023

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

Monopar Announces Successful Advancement of Camsirubicin Phase 1b Clinical Trial Past Fourth Cohort, Escalates Next to 650mg/m^2

WILMETTE, Ill, January 18, 2023 - Monopar Therapeutics Inc. (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 the positive recommendation from its safety review committee to advance to the fifth dose level (650 mg/m^2) in its camsirubicin Phase 1b trial in patients with advanced soft tissue sarcoma (ASTS). This decision was made following a review of safety data from the patients in the first four dose cohorts.

"Clearance to go to this higher dose level is an important milestone for the trial as this class of drugs is known to have dose-dependent anti-tumor activity," said Chandler Robinson, MD, Monopar's Chief Executive Officer. "We continue to see a favorable safety profile compared to doxorubicin, and the Phase 1b data to-date shows an improvement in median progression free survival from what was observed in the prior camsirubicin Phase 2 trial (265mg/m^2). We are looking forward to evaluating the 650 mg/m^2 dose level, which is nearly 2.5x higher than the highest dose evaluated in any prior camsirubicin clinical trial."

Further information about this actively enrolling, open-label, dose-escalation Phase 1b clinical trial is available at www.ClinicalTrials.gov under study identifier **NCT 05043649**.

About Camsirubicin

Camsirubicin is a novel, proprietary analog of the widely used cancer drug doxorubicin. It has been previously investigated in ASTS patients in a Phase 1 and a single-arm Phase 2 clinical trial. In these studies, no camsirubicin-treated patients developed the irreversible cardiotoxicity common to doxorubicin at higher cumulative doses. The most frequent adverse event observed in the Phase 1 study was neutropenia, which was mitigated in the Phase 2 study using prophylactic G-CSF. Based on encouraging clinical results from prior clinical trials, the current Phase 1b trial is designed to test camsirubicin at progressively higher doses than previously administered while using concomitant prophylactic G-CSF to prevent neutropenia.

About Soft Tissue Sarcoma

Soft tissue sarcomas (STS) are a diverse type of cancer that typically develop in the connective tissue of the body. According to the American Cancer Society, in 2021, an estimated 13,460 new STS cases were diagnosed in the U.S. alone, and about 5,350 people will not survive their disease. These tend to be the advanced cases; those with sarcomas that are unresectable and/or have metastasized. The average life expectancy from time of diagnosis for those patients with advanced disease (ASTS) is about 12 to 15 months. Doxorubicin is the current standard of care in the 1st-line setting for ASTS, and has been for decades, since there have been no 1st-line therapeutic advancements that have improved overall survival for this patient population.

About Monopar Therapeutics Inc.

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 advanced cancers and severe COVID-19; and an early-stage camsirubicin analog, MNPR-202, for various cancers. For more information, visit: www.monopartx.com.

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: that Monopar will advance to the fifth dose level (650 mg/m^2) in its camsirubicin Phase 1b clinical trial in patients with advanced soft tissue sarcoma (ASTS); that Monopar continues to see a favorable safety profile compared to doxorubicin; and that Monopar is looking forward to evaluating the 650 mg/m^2 dose level. The forward-looking statements involve risks and uncertainties including, but not limited to: whether the Phase 1b camsirubicin clinical trial will successfully enroll sufficient patients to accomplish trial goals; whether camsirubicin will show comparable anti-tumor activity to doxorubicin without any signs of irreversible heart damage; that camsirubicin may not prove to be clinically efficacious; that the Company will need to raise additional funds to develop camsirubicin beyond Phase 1b; 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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