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): **June 1, 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**
(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 June 1, 2023, Monopar Therapeutics Inc. (Monopar) issued a press release announcing an update from its currently enrolling multi-center open-label Phase 1b clinical trial of camsirubicin 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 June 1, 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: June 1, 2023

By: /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Chief Financial Officer and Director

EXHIBIT 99.1

Monopar Announces Encouraging Camsirubicin Phase 1b Trial Update

Patient in 520 mg/m^2 cohort, previously unresectable, experienced tumor shrinkage and had tumor resected following camsirubicin treatment

3 of 3 patients in the 520 mg/m^2 cohort achieved stable disease

WILMETTE, Ill, June 1, 2023 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer, today announced an update from its currently enrolling multi-center open-label Phase 1b clinical trial of camsirubicin in patients with advanced soft tissue sarcoma (ASTS).

Background on ASTS and Camsirubicin

ASTS is a diverse type of cancer that typically develops in the connective tissue of the body and which has metastasized (spread) or is not amenable to surgery. The average life expectancy from time of diagnosis for patients with ASTS is about 12 to 15 months. Currently, doxorubicin is the first-line standard of care treatment for most types of ASTS.

Doxorubicin is one of the most widely used cancer drugs worldwide with FDA approval in ASTS and 13 additional cancer indications. Unfortunately, although higher doses of doxorubicin are known to be more effective at treating cancer, the risk of irreversible heart damage increases with the cumulative dose and limits the lifetime amount that a patient can receive. As a result, even if patients are responding, they discontinue doxorubicin treatment typically after only 6 to 8 cycles (~6 months or less).

Camsirubicin has been designed to retain the anti-cancer activity while avoiding the irreversible heart damage that is seen with doxorubicin. The hypothesis for camsirubicin is straightforward: modifying doxorubicin in order to reduce cardiac damage could enable higher and longer dosing, resulting in better efficacy and patient outcomes.

Updates from Currently Enrolling Phase 1b Clinical Trial

- One patient at the 520 mg/m^2 dose level, unresectable at study entry, was deemed eligible for tumor resection after several cycles of camsirubicin treatment and a corresponding 21% reduction in tumor dimensions. This patient recently underwent surgical resection of the cancer.
- 100% of patients (3 of 3) at the fourth dose-level (520mg/m^2) achieved stable disease, and had either a net reduction or no overall change in tumor size per RECIST 1.1 while on study drug.

- Phase 1b data continue to show an improvement in median progression free survival from what was observed in the prior camsirubicin Phase 2 trial (265 mg/m^2). This is supportive of our dose-response hypothesis with camsirubicin.
- Two patients are currently enrolled in the fifth dose-level cohort (650 mg/m^2), which is nearly 2.5x the highest dose evaluated in any prior camsirubicin clinical trial (265mg/m^2).
- No drug-related cardiotoxicity has been observed in this trial to-date as evaluated by the industry standard left ventricular ejection fraction (LVEF).
- As previously reported, this trial continues to show less frequent and less severe hair loss and oral mucositis with camsirubicin compared to what has been seen in recent ASTS clinical trials with doxorubicin.
- No dose limiting toxicity (DLT) has been experienced by any patient in the trial to-date.

Camsirubicin Clinical Trial Design and GEIS Collaboration

The purpose of this 3+3 dose escalation Phase 1b trial is to determine the maximum tolerated dose (MTD) of camsirubicin. Once the MTD is reached, Monopar has a clinical collaboration agreement in place with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas, or GEIS) to conduct a multi-country randomized Phase 2 clinical trial. The Phase 2 plan is to evaluate camsirubicin head-to-head against doxorubicin in patients with ASTS, with GEIS as the study sponsor with support from Monopar.

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 Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients. Monopar's pipeline consists of camsirubicin (Phase 1b) for the treatment of advanced soft tissue sarcoma; MNPR-101, a late-stage preclinical antibody for radiopharmaceutical use in advanced cancers; and MNPR-202, an early-stage camsirubicin analog 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 modifying doxorubicin to create camsirubicin in order to reduce cardiac damage could enable higher and longer dosing, resulting in better efficacy and patient outcomes; and plans to conduct a multi-country randomized Phase 2 clinical trial once the MTD is reached evaluating camsirubicin head-to-head against doxorubicin in patients with ASTS, with GEIS as the study sponsor with support from Monopar. The forward-looking statements involve risks and uncertainties including, but not limited to: the camsirubicin Phase 1b trial not proving safety and efficacy at higher doses; not successfully recruiting additional patients and initiating additional clinical trial sites for 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 continue the camsirubicin clinical program beyond the Phase 1b clinical trial; GEIS not conducting the camsirubicin Phase 2 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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