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): **August 8, 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 Disclosures.

On August 8, 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 August 8, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 8, 2023

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

Exhibit 99.1

Monopar Provides Encouraging Camsirubicin Clinical Data Update

WILMETTE, IL, August 8, 2023 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer, today provided an update from its currently enrolling multi-center open-label Phase 1b clinical trial of camsirubicin in patients with advanced soft tissue sarcoma (ASTS). Both patients treated to date at the 650 mg/m^2 dose level have experienced tumor size reductions – of 18% and 20% respectively – after the first two cycles of camsirubicin treatment. Both patients are set to receive additional cycles of camsirubicin treatment, as well, which may result in further tumor size reduction.

The Phase 1b clinical trial data is continuing to support Monopar's dose-response hypothesis with camsirubicin. The best response seen prior to the current 650 mg/m^2 dose level was at the immediately prior dose level (520 mg/m^2), which was a 21% reduction in tumor size in a patient after receiving six cycles of camsirubicin treatment. This patient's cancer was unresectable at study entry, but after the tumor size reduction, became eligible and the patient underwent successful surgical removal of their cancer with clear margins. Furthermore, all three patients at the 520 mg/m^2 dose level achieved stable disease and had either a net reduction or no overall change in tumor size per RECIST 1.1 while on study drug.

Additionally, no drug-related cardiotoxicity has been observed in the trial to date as evaluated by the industry standard left ventricular ejection fraction (LVEF), and no toxicities have been experienced by any patient that have required expanding the size of a dose cohort. Further, 71% of camsirubicin patients have experienced no hair loss, and only approximately 14% have experienced >50% hair loss, with the remainder having low grade hair loss. This compares favorably to the approximately 50% of doxorubicin treated patients in recent ASTS clinical trials reporting some amount of hair loss, with the majority of these patients experiencing >50% hair loss. Only 14% of camsirubicin patients in the Phase 1b trial have experienced mild-to-severe oral mucositis. This compares favorably to the roughly 35-40% of doxorubicin-treated patients in recent ASTS clinical trials that experienced mild-to-severe oral mucositis.

ASTS is a deadly cancer with inadequate treatment options. Doxorubicin is currently the first-line standard of care treatment for most types of ASTS, and the average life expectancy from time of diagnosis for these patients is only about 12 to 15 months. Because of the risk of irreversible heart damage, patients discontinue doxorubicin treatment after just 6 to 8 cycles. Camsirubicin has been designed to retain the anti-cancer activity while avoiding the irreversible heart damage that is seen with doxorubicin. The value-driving 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.

Camsirubicin Clinical Trial Design and GEIS Collaboration

The purpose of this 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; MNPR101, a late-stage preclinical antibody for radiopharmaceutical use in advanced cancers; and MNPR202, 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 additional cycles of camsirubicin treatment may result in further tumor size reduction; that 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; and Monopar's 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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