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): **November 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 November 1, 2023, Monopar Therapeutics Inc. (Monopar) issued a press release announcing the presentation of data showing tumor reduction benefit from its ongoing Phase 1b open-label, dose-escalating clinical trial of camsirubicin in patients with advanced soft tissue sarcoma (ASTS) at the 2023 Connective Tissue Oncology Society (CTOS) Annual Meeting.

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 November 1, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

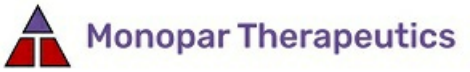
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Monopar Therapeutics Inc.

Date: November 1, 2023

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

Exhibit 99.1



Monopar Presents Data Showing Tumor Reduction Benefit of Camsirubicin from Ongoing Phase 1b at the 2023 Connective Tissue Oncology Society (CTOS) Annual Meeting

WILMETTE, Ill, November 1, 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, will present data from its ongoing Phase 1b open-label, dose-escalating clinical trial of camsirubicin in patients with advanced soft tissue sarcoma (ASTS) later today at the 2023 Connective Tissue Oncology Society (CTOS) Annual Meeting, which is bringing together the world's leading sarcoma specialists. Monopar's poster presentation can be found at the following link: https://www.monopartx.com/pipeline/Camsirubicin/mnpr-201-001-clinical-trial.

Clinical Trial Results To-Date

The Phase 1b clinical trial has enrolled 14 ASTS patients (9 female and 5 male) to-date ranging in age from 26 to 81 years (median = 52.5 years) across five dose cohorts. The trial is currently ongoing and is in the fifth dose level cohort (650 mg/m^2).

So far, 9 out of the 14 patients have had stable disease (SD, as defined by RECIST 1.1 criteria) after camsirubicin treatment. All patients in the fourth and fifth cohorts achieved stable disease, including the three most recently treated patients, each of whom also experienced an ~20% tumor size reduction at last study scan. One of these patients had unresectable cancer at study entry, but after the tumor size reduction, the patient became eligible for resection and underwent successful surgical removal of their cancer with clear margins.

No dose-limiting toxicity, as defined in the protocol, has been observed to-date. A medically complex patient in the 650 mg/m^2 dose cohort has an ongoing left ventricular ejection fraction (LVEF) decrease that is being monitored. This patient has a BMI of 42.5, one kidney, hypertension, a long standing heart murmur, and a maternal history of heart failure. No toxicities have occurred requiring expansion of a dose cohort, and the maximum tolerated dose (MTD) has not been reached.

Camsirubicin Background

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 was 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 to reduce cardiac damage could enable both higher and longer dosing, resulting in better efficacy and patient outcomes.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinicalstage 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 camsirubicin has been designed to retain the anti-cancer activity while avoiding the irreversible heart damage that is seen with doxorubicin; 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. 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; 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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