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): **November 16, 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 7.01 Regulation FD Disclosure

On November 16, 2022, Monopar Therapeutics Inc. issued a press release announcing encouraging clinical data from its ongoing Phase 1b open-label clinical trial of camsirubicin in advanced soft tissue sarcoma (ASTS) patients.

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 16, 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: November 16, 2022

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

Monopar Announces Encouraging Clinical Data from Ongoing Camsirubicin Phase 1b Trial

WILMETTE, Ill, November 16, 2022 – 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 released encouraging data from its ongoing Phase 1b open-label clinical trial of camsirubicin in advanced soft tissue sarcoma patients. The data is displayed in the poster Monopar will be presenting later today at the 2022 Connective Tissue Oncology Society (CTOS) Annual Meeting, which is bringing together the world's leading sarcoma specialists. Monopar has made the poster available on its website at the following link:
https://www.monopartx.com/pipeline/Camsirubicin/mnpr-201-001-clinical-trial.

Camsirubicin Background

Doxorubicin is one of the most widely used cancer drugs worldwide. 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). The hypothesis behind camsirubicin is straightforward: molecularly modifying doxorubicin in order to reduce cardiac damage could enable higher and longer dosing, resulting in better patient outcomes.

The prior exploratory clinical studies of camsirubicin in cancer patients showed the potential to treat patients with high doses for a year or longer. The preclinical and exploratory clinical studies also showed no irreversible heart toxicity with camsirubicin. The current Phase 1b study is designed to evaluate whether camsirubicin can be dosed even higher than previously achieved and continue for longer than doxorubicin.

Camsirubicin Phase 1b Clinical Trial Design

The Phase 1b trial is an open label dose escalation design to determine the maximum tolerated dose of camsirubicin in advanced soft tissue sarcoma (ASTS) patients. The average life expectancy of ASTS patients at diagnosis is about 12 to 15 months, and doxorubicin is the current first-line standard of care treatment for most types of ASTS.

The starting dose for the first three patients was set at 265 mg/m^2, the highest dose previously tested in the exploratory clinical trials. With a positive recommendation from the trial safety review committee at the completion of each dose level, the trial is allowed to then treat at least three new patients at the next dose level, which is 25% higher.

Clinical Trial Results To-Date

The Phase 1b clinical trial has enrolled 11 patients (8 female and 3 male) to-date ranging in age from 26 to 81 years (median = 49 years). 5 of 10 patients have exhibited stable disease (SD, as defined by RECIST 1.1 criteria) at 12 weeks. 1 patient met the criteria for SD at the first CT scan (6 weeks) but unfortunately died due to COVID-19 and was not evaluable at the 12-week CT scan. The ASTS subtype patients achieving stable disease on camsirubicin are in line with those also more likely to respond to doxorubicin.

These encouraging results are in the face of all patients in the trial, at the time of enrollment, having had an Eastern Cooperative Oncology Group (ECOG) performance score of 1, or “strenuous physical activity restricted”. This suggests that the patients enrolled in this Phase 1b trial are more medically complex and challenging than those in other recent ASTS studies. The majority of patients enrolled in first-line ASTS trials of the past few years have had no physical activity impairments, with only a minority having an ECOG score of 1 or worse. Worse ECOG scores at the time of enrollment for advanced cancer patients are associated with reduced patient survival.

The trial is presently at the fourth dose-level cohort (520mg/m^2), almost twice the trial’s starting dose. No drug-related clinical cardiotoxicity has been observed in any patient, as tracked by left ventricular ejection fraction, an industry standard measure of cardiotoxicity. In line with the hypothesis of reaching a higher dose, the trial is continuing to enroll and dose-escalate, as there have been no signs of having yet hit the maximum tolerated dose.

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 molecularly modifying doxorubicin in order to reduce cardiac damage could enable higher and longer dosing, resulting in better patient outcomes. The forward-looking statements involve risks and uncertainties including, but not limited to: whether the Phase 1b camsirubicin 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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