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): **September 16, 2021**

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 September 16, 2021, Monopar Therapeutics Inc. issued a press release announcing its Phase 1b open-label dose-escalation clinical trial of camsirubicin in the US is active and recruiting patients. The trial is evaluating the safety and anti-tumor activity of increasing doses of camsirubicin in combination with growth factor support (pegfilgrastim/G-CSF) for the treatment of 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 September 16, 2021

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: September 16, 2021

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

EXHIBIT 99.1

Monopar Initiates Open-Label Phase 1b Clinical Trial Evaluating Camsirubicin in Patients with Advanced Soft Tissue Sarcoma

WILMETTE, Ill, September 16, 2021 – 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 its Phase 1b open-label dose-escalation clinical trial of camsirubicin in the US is active and recruiting patients. The trial is evaluating the safety and anti-tumor activity of increasing doses of camsirubicin in combination with growth factor support (pegfilgrastim/G-CSF) for the treatment of advanced soft tissue sarcoma (ASTS).

“This trial initiation marks a pivotal moment in the development of camsirubicin. The goal is to determine whether escalating doses of camsirubicin result in an increased anti-cancer effect in patients with ASTS, while also maintaining an appropriate safety profile,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer.

“We are very pleased with the positive response and dedication from physicians and clinical sites interested in participating in this clinical trial, enabling us to initiate the study in the US faster than we anticipated,” said Octavio Costa, MD, Monopar’s Chief Medical Officer.

Currently, ASTS patients receive doxorubicin, a widely used cancer drug that becomes more effective in higher doses. Unfortunately, patients are forced to stop treatment once a cumulative lifetime dose limit is reached, as higher dosing causes severe irreversible heart damage.

“Camsirubicin has already shown anti-tumor activity comparable to doxorubicin in a pilot study in ASTS patients, without any signs of irreversible heart damage,” said Andrew Mazar, PhD, Monopar’s Chief Scientific Officer. “We are excited, as the previous study’s dose of camsirubicin will be the first dose level in this Phase 1b clinical trial. From there the dose will increase, hopefully with corresponding increases in anti-cancer effect, to identify a recommended Phase 2 dose (RP2D) of camsirubicin when given with concomitant pegfilgrastim.”

Further information about the camsirubicin 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 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 through the use of prophylactic G-CSF. Based on encouraging clinical results to date, the Phase 1b trial is designed to test camsirubicin at even 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 will be diagnosed in the US 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® for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin 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: the dose level of the Phase 1b clinical trial increasing to identify a recommended Phase 2 dose (RP2D) for camsirubicin when given with concomitant pegfilgrastim; and whether escalating doses of camsirubicin result in an increased anti-cancer effect in patients with ASTS, while also maintaining an appropriate safety profile. The forward-looking statements involve risks and uncertainties including, but not limited to: whether the Phase 1b camsirubicin trial will successfully enroll patients, if at all; 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; 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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