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 3, 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 August 3, 2021, Monopar Therapeutics Inc. issued a press release announcing clearance from the US Food and Drug Administration to proceed under its IND with an open-label Phase 1b dose-escalation trial evaluating camsirubicin plus growth factor support (pegfilgrastim) in patients with advanced soft tissue sarcoma.

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 3, 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: August 3, 2021

By: /s/ Kim R. Tsuchimoto

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

Exhibit 99.1

Monopar Announces FDA Clearance to Proceed with Camsirubicin Clinical Trial Targeting Advanced Soft Tissue Sarcoma

WILMETTE, Ill., August 3, 2021 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company primarily focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients, today announced clearance from the US Food and Drug Administration (FDA) to proceed under its IND with an open-label Phase 1b dose-escalation trial evaluating camsirubicin plus growth factor support (pegfilgrastim) in patients with advanced soft tissue sarcoma (ASTS). The Company anticipates dosing the first patient in the trial in the fourth quarter of this year.

“By giving concomitant growth factor support to overcome the dose-limiting toxicity of this class of drug, we hypothesize camsirubicin could be dosed even higher and longer than doxorubicin, yielding the chance to demonstrate efficacy superiority over doxorubicin,” said Octavio Costa, MD, Monopar’s Chief Medical Officer.

“We eagerly await reaching each higher dose level in this trial,” said Andrew Mazar, PhD, Monopar’s Chief Scientific Officer. “Camsirubicin is a novel analog of doxorubicin, and doxorubicin is known to work through a dose-dependent mechanism, where higher quantities yield more anti-cancer effect.”

“If successful in ASTS, there are 13 other potential cancer indications for camsirubicin where doxorubicin is already FDA-approved,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company primarily focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients. Monopar's pipeline consists of Phase 2b/3-stage Validive® for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; Phase 1b-stage 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: the Company anticipating dosing the first patient in the fourth quarter of this year; that camsirubicin could be dosed even higher and longer than doxorubicin, yielding the chance to demonstrate efficacy superiority over doxorubicin; and if successful in ASTS, there are 13 other potential cancer indications for camsirubicin where doxorubicin is already FDA approved. The forward-looking statements involve risks and uncertainties including, but not limited to: not dosing the first patient in the Phase 1b clinical trial in the fourth quarter of this year, if at all; that camsirubicin may cause unexpected serious adverse effects or lacks meaningful efficacy; the potential for the FDA to put the Phase 1b trial on clinical hold at any time; whether giving concomitant growth factor support will overcome the dose-limiting toxicity of this class of drug and whether camsirubicin will be able to safely achieve any dose level higher than the starting dose level for this Phase 1b trial; camsirubicin not being superior to or as effective as doxorubicin; if successful, camsirubicin not being effective in 13 other cancer indications; 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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