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 5, 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 5, 2021, Monopar Therapeutics Inc. issued a press release announcing they have successfully reached its target of 20 activated clinical trial sites in the Phase 2b portion of the VOICE trial.

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 5, 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 5, 2021

By: /s/ Kim R. Tsuchimoto

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

Exhibit 99.1

Monopar Reaches Target Number of Clinical Sites in Phase 2b Portion of 2b/3 Validive® VOICE Trial

WILMETTE, Ill., August 5, 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 it has successfully reached its target of 20 activated clinical trial sites in the Phase 2b portion of the VOICE trial.

Validive® is a small, easy-to-use mucobuccal tablet that can be self-administered in the patient's home setting. The VOICE study evaluates Validive® for the prevention of severe oral mucositis (SOM) in oropharyngeal cancer patients. SOM results from the chemoradiation used to treat oropharyngeal cancer (OPC). There is no FDA-approved preventative or treatment option for the estimated >40,000 OPC patients in the US annually who are at-risk of developing SOM.

"We are very pleased to reach this clinical milestone and to achieve clinical site enrollment rates that have exceeded our base case projections to date," said Octavio Costa, MD, Monopar's Chief Medical Officer. "We are proud of our clinical team's efforts and grateful for the support from participating patients and staff at our clinical sites, who are joining us in our focus to prevent this painful debilitating condition that results in patients losing the ability to drink and/or eat."

"In planning for success and the Phase 3 portion of the VOICE trial, and as a result of strong interest from sites in joining the trial, we are going to expand the number of sites beyond the original 20 targeted," said Chandler Robinson, MD, Monopar's Chief Executive Officer. "Because of interest outside the US, we are also looking at activating sites in additional countries, potentially later this year."

Monopar anticipates reaching the interim analysis of the Phase 2b/3 Validive® VOICE trial in the first half of 2022. Further information about the trial is available at www.ClinicalTrials.gov under study identifier **NCT 04648020**.

About Severe Oral Mucositis

Severe oral mucositis (SOM) is a painful and debilitating inflammation and ulceration of the mucous membranes lining the oral cavity and oropharynx in response to insults such as chemoradiation treatment (CRT). SOM is the most frequent major side effect experienced by oropharyngeal cancer patients, experienced by a majority of those undergoing CRT. SOM impacts both quality of life and clinical outcomes for these patients. SOM prevents patients from drinking and/or eating, and can lead to severe weight loss, opiate usage, and the use of feeding tubes as well as intravenous supplementation to keep alive. Patients who develop SOM can become hospitalized, and symptoms can force patients to prematurely stop cancer treatment, reducing treatment efficacy and long-term survival.

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 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: Monopar’s plan to expand the number of sites beyond the original 20 targeted, including the Company’s plan to activate sites in additional countries, potentially later this year; and that Monopar anticipates reaching the interim analysis of the Phase 2b/3 Validive VOICE trial in the first half of 2022. The forward-looking statements involve risks and uncertainties including, but not limited to: Monopar’s inability to enroll the VOICE trial as planned; Monopar not reaching the interim analysis of the Phase 2b/3 Validive VOICE trial within the anticipated timeframe, if at all; the Company’s inability to complete the VOICE trial; that Validive 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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