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): December 8, 2020

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 December 8, 2020, Monopar Therapeutics Inc. (“Monopar”) issued a press release announcing itsPhase 2b/3 clinical trial ofValidive (VOICE trial, study identifier NCT 04648020 on ClinicalTrials.gov) for the prevention of chemoradiotherapy-induced severe oral mucositis in patients with oropharyngeal canceris active and recruiting 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 December 8, 2020

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: December 8, 2020

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

Monopar Announces Initiation of its Phase 2b/3 (VOICE) Trial to Evaluate Validive ® for the Prevention of Chemoradiotherapy-Induced Severe Oral Mucositis (SOM) in Oropharyngeal Cancer (OPC)

There are currently no FDA-approved drugs to prevent or treat chemoradiotherapy-induced SOM

WILMETTE, Ill., December 8, 2020 – 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 that its Phase 2b/3 clinical trial of Validive® for the prevention of chemoradiotherapy-induced se**v**ere **o**ral mucositis in pat**i**ents with oropharyngeal **c**anc**e**r (VOICE) is active and recruiting patients.

"We are pleased to have multiple clinical sites activated," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar, "and are looking forward to dosing the first patients shortly."

"The commencement of our Phase 2b/3 VOICE trial is a significant milestone for Monopar and, it represents a key step in the development of a therapy that could benefit many OPC patients," said Chandler Robinson, MD, Chief Executive Officer of Monopar. "This trial builds on the foundation of the completed Phase 2, and is designed to confirm Validive reduces the incidence of SOM in OPC patients undergoing chemoradiotherapy." The completed Phase 2 trial showed the incidence of SOM in OPC patients receiving Validive 100 µg to be 40% lower compared to those receiving placebo.

It is estimated there will be greater than 40,000 new OPC patients in the U.S. alone in 2021, the majority of whom will be treated with chemoradiation and run substantial risk of developing SOM. Currently, there is no FDA approved preventive or treatment for SOM in these patients, emphasizing the clear unmet medical need in this patient population.

Up to approximately 260 patients will be enrolled in this multi-center, randomized, double-blind, placebo-controlled, Phase 2b/3 clinical trial. The trial includes an interim analysis, which is anticipated to be reached approximately twelve months after the first patient is dosed.

Further information about the Validive Phase 2b/3 VOICE trial is available at www.ClinicalTrials.gov under study identifier **NCT 04648020.**

About Validive

Validive (clonidine mucobuccal tablet; clonidine MBT) is a novel mucobuccal tablet (MBT) formulation of clonidine which provides for prolonged and enhanced local delivery of clonidine to the regions of mucosal radiation damage in OPC patients. The tablet is self-administered once daily in the patient's home setting with the patient placing it under the upper lip where it adheres to the gums and dissolves over several hours, continuously releasing the clonidine into the saliva. Clonidine agonizes the alpha-2 adrenergic receptor on macrophages (white blood cells present in the immune tissues of the oropharynx), decreasing the macrophages' expression of destructive cytokines they tend to release in response to radiotherapy. A completed double-blind, randomized, placebo-controlled Phase 2 clinical trial of Validive showed reduced incidence (absolute decrease of 26%, relative decrease of 40%) in OPC patients treated with Validive 100 µg (a meaningful trend in the Phase 2, which the Phase 2b/3 is designed to confirm with a larger trial in OPC for potential statistical significance), a safety profile similar to the placebo, and a high rate of treatment compliance (over 90%).

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 insult 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; and a late-stage preclinical antibody, MNPR-101, for advanced cancers and severe COVID-19. 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 whether Monopar will successfully enroll its Validive Phase 2b/3 VOICE clinical trial, if at all; whether Validive will benefit OPC patients in the VOICE trial; whether the VOICE trial will yield results similar to the Phase 2 clinical trial in OPC patients and that are statistically significant; and whether the VOICE trial will reach the interim analysis approximately twelve months from the first patient dosed, if at al. The forward-looking statements involve risks and uncertainties for Monopar including, but not limited to, the requirement for additional capital to complete the VOICE trial beyond the interim analysis and for potential commercialization; not being able to ensure volumes of Validive can be manufactured and scaled up to meet potential demand; uncertainties about levels of demand if and when a treatment is available for commercialization; 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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Monopar Therapeutics