

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): **October 5, 2022**

**MONOPAR THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-39070</u> (Commission File Number)	<u>32-0463781</u> (I.R.S. Employer Identification No.)
<u>1000 Skokie Blvd., Suite 350, Wilmette, IL 60091</u> (Address of principal executive offices)		<u>60091</u> (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:**

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<b>Common Stock, \$0.001 par value</b>	<b>MNPR</b>	<b>The Nasdaq Stock Market LLC (Nasdaq Capital Market)</b>

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 October 5, 2022, Monopar Therapeutics Inc. issued a press release announcing completion of the Phase 2b enrollment and commencement of the Phase 3 enrollment in its VOICE clinical trial for severe oral mucositis (SOM) and the anticipated interim analysis planned for the first quarter of 2023.

The press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference

**Item 9.01 Financial Statements and Exhibits Description**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release Dated October 5, 2022</a>

**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: October 5, 2022

By: /s/ Kim R. Tsuchimoto

Name: Kim R. Tsuchimoto

Title: Chief Financial Officer, Secretary and Treasurer



**Monopar Announces Completion of Phase 2b Enrollment and  
Commencement of Phase 3 Enrollment in its VOICE Trial  
for Severe Oral Mucositis**

**Interim Analysis Planned for Q1 2023**

**WILMETTE, III, October 5, 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 announced an update on its actively enrolling Validive Phase 2b/3 VOICE clinical trial for the prevention of severe oral mucositis (SOM) in patients undergoing chemoradiotherapy (CRT) for oropharyngeal cancer. This is an indication for which there is currently no FDA-approved preventative or treatment.

Monopar announced it has enrolled greater than 130 patients, has completed enrollment for the Phase 2b portion of the trial, has activated a total of 68 sites, has recently expanded the trial to include sites in Germany and Poland, and has commenced enrollment for the Phase 3 portion of the trial. The blinded interim analysis of clinical data from the Phase 2b patient cohort of the trial, to be performed by an independent data monitoring board, will be used to guide the Company as to whether or not to continue enrolling the Phase 3 portion of the trial. This analysis should be complete with interim results announced during Q1 2023.

“In planning for success for a potential positive go/no-go outcome from the upcoming Q1 2023 interim analysis, we have been actively enrolling patients and adding clinical sites to the VOICE trial and expect to continue doing so,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer. “Expanding to include additional sites outside of the U.S. will dramatically increase the number of patients available for enrollment in the study.”

**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](http://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 the VOICE trial’s interim analysis is currently anticipated to be reached in the first quarter of 2023; that Monopar will continue to enroll patients and add sites to the VOICE trial; and that Monopar will activate additional clinical sites outside of the U.S. The forward-looking statements involve risks and uncertainties including, but not limited to: not successfully recruiting additional patients and initiating additional clinical trial sites for the VOICE clinical trial within expected timeframes, if at all; that the VOICE clinical trial may not reach interim analysis by the first quarter of 2023, if at all; the Company’s inability to raise sufficient funds or engage a partner to complete the Phase 3 portion of the VOICE clinical trial; 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:

### Monopar Therapeutics Inc.

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