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): **March 27, 2023**

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**
(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 March 27, 2023, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing completion of a pre-specified interim analysis for its Validive Phase 2b/3 VOICE trial for the prevention of severe oral mucositis ("SOM") in patients undergoing chemoradiotherapy for oropharyngeal cancer.

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

Item 8.01 Other Events.

The pre-specified interim analysis for Monopar's Validive Phase 2b/3 VOICE trial included the first approximately 50% of the total planned patients to be enrolled. It was conducted by an independent Data Safety Monitoring Board ("DSMB"), which informed Monopar that the trial did not meet the pre-defined threshold for efficacy of a 15% absolute difference in SOM prevention between Validive and placebo. The DSMB also reported that there were no safety concerns attributed to Validive. Based on not meeting the pre-specified efficacy threshold, Monopar announced today that it will be discontinuing the study along with the active development of Validive. Monopar expects to now focus on re-deploying the financial and human resources previously dedicated to Validive in order to advance its Phase 1b camsirubicin clinical trial and MNPR-101 radiopharmaceutical program partnered with NorthStar Medical Radioisotopes.

Based on the discontinuation of the study and active development of Validive, Monopar believes it has sufficient funds to support its currently planned activities further beyond the first quarter of 2024.

Forward-Looking Statements

Statements contained in this report 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 Monopar remains focused on re-deploying the financial and human resources previously dedicated to Validive to advance its Phase 1b camsirubicin clinical trial and its MNPR-101 radiopharmaceutical program; and that Monopar also noted it has sufficient funds to support its currently planned activities further beyond the first quarter of 2024. The forward-looking statements involve risks and uncertainties including, but not limited to: not successfully recruiting patients in Monopar's Phase 1b camsirubicin clinical trial within expected timeframes, if at all; the Phase 1b camsirubicin clinical trial does not provide safety or efficacy data; MNPR-101 radiopharmaceutical program partnered with NorthStar does not prove safe or efficacious; Monopar does not have sufficient resources to support its currently planned activities further beyond the first quarter of 2024 and is unable to raise funds; 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.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release Dated March 27, 2023

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: March 27, 2023

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

EXHIBIT 99.1

Monopar Announces Result of Interim Analysis of Phase 2b/3 VOICE Trial Evaluating Validive for Severe Oral Mucositis

WILMETTE, Ill, March 27, 2023 – 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 completion of a pre-specified interim analysis for its Validive Phase 2b/3 VOICE trial for the prevention of severe oral mucositis (SOM) in patients undergoing chemoradiotherapy (CRT) for oropharyngeal cancer (OPC). This is an indication for which there is currently no FDA-approved preventative or treatment.

The interim analysis included the first approximately 50% of the total planned patients to be enrolled. It was conducted by an independent Data Safety Monitoring Board (DSMB), which informed the Company that the trial did not meet the pre-defined threshold for efficacy of a 15% absolute difference in SOM prevention between Validive and placebo. The DSMB also reported that there were no safety concerns attributed to Validive. Based on not meeting the pre-specified efficacy threshold, Monopar announced today that it will be discontinuing the study along with the active development of Validive.

“We are very grateful to the patients and investigators who participated in the VOICE trial. The Phase 2b/3 VOICE trial was intended to further evaluate a novel treatment for SOM following the promising signals observed in a prior randomized, double-blinded Phase 2 study with OPC patients. While we are disappointed with the outcome of this study, we are now focused on re-deploying the financial and human resources previously dedicated to Validive in order to advance our Phase 1b camsirubicin clinical trial and our MNPR-101 radiopharmaceutical program partnered with NorthStar Medical Radioisotopes,” said Chandler Robinson, MD, Monopar’s Chief Executive Officer.

Monopar also noted today that it has sufficient funds to support its currently planned activities further beyond the first quarter of 2024.

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 camsirubicin (Phase 1b) for the treatment of advanced soft tissue sarcoma; a late-stage preclinical antibody, MNPR-101, for radiopharmaceutical use in advanced cancers; 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: that Monopar remains focused on re-deploying the financial and human resources previously dedicated to Validive to advance its Phase 1b camsirubicin clinical trial and its MNPR-101 radiopharmaceutical program; and that Monopar also noted it has sufficient funds to support its currently planned activities further beyond the first quarter of 2024. The forward-looking statements involve risks and uncertainties including, but not limited to: not successfully recruiting patients in Monopar’s Phase 1b camsirubicin clinical trial within expected timeframes, if at all; the Phase 1b camsirubicin clinical trial does not provide safety or efficacy data; MNPR-101 radiopharmaceutical program partnered with NorthStar does not prove safe or efficacious; Monopar does not have sufficient resources to support its currently planned activities further beyond the first quarter of 2024 and is unable to raise funds; 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.
Investor Relations
Kim R. Tsuchimoto
Chief Financial Officer
kimtsu@monopartx.com

Follow Monopar on social media for updates:
Twitter: @MonoparTx LinkedIn: Monopar Therapeutics