UNITED STATES
SECURITIESANDEXCHANGECOMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) ofTheSecuritiesExchangeActof1934

Date of Report (Date of earliest event reported): **January 26, 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	**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 January 26, 2023, Monopar Therapeutics Inc. issued a press release announcing it is planning to report over the next two months (1) the interim go/no-go analysis for its Validive Phase 2b/3 VOICE trial, (2) clinical data from its camsirubicin Phase 1b trial, and (3) a preclinical progress update on its MNPR-101 RIT program.

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 January 26, 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: January 26, 2023

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

EXHIBIT 99.1

Monopar Announces Projected Timeline of Upcoming Q1 2023 Data Events for Validive, Camsirubicin, and MNPR-101 RIT

WILMETTE, Ill, January 26, 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 it is planning to report over the next two months (1) the interim go/no-go analysis for its Validive Phase 2b/3 VOICE trial, (2) clinical data from its camsirubicin Phase 1b trial, and (3) a preclinical progress update on its MNPR-101 RIT program.

February 2023:

Camsirubicin Phase 1b Clinical Trial Data Update

In addition to the previously reported improvement in median progression free survival over the prior camsirubicin Phase 2 study, Monopar plans to provide details of the Phase 1b trial's improved toxicity and safety observed to date compared to doxorubicin.

MNPR-101 Radioimmunotherapeutic (RIT) Preclinical Data Update

Monopar plans to report an update on recently generated preclinical data and anticipated next steps with partner NorthStar Medical Radioisotopes.

March 2023:

Interim Go/no-go Analysis for Validive Phase 2b/3 VOICE Trial

Monopar expects to have the interim analysis completed and to report out the go/no-go decision during March 2023; in the intervening time, patient enrollment and addition of new sites continue in preparation for a potentially positive interim.

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® (Phase 2b/3) for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin (Phase 1b) 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: that Monopar is planning to report over the next two months various data events; that Monopar plans to provide details of the Phase 1b trial's improved toxicity and safety observed to-date compared to doxorubicin; that Monopar plans to report an update on recently generated data on MNPR-101 RIT; that the VOICE trial's interim analysis is anticipated to be reached during March 2023. The forward-looking statements involve risks and uncertainties including, but not limited to: unanticipated delays causing us not to report some or all of the data over the next two months on our expected timeline; not successfully recruiting additional patients and initiating additional clinical trial sites for the VOICE clinical trial or the camsirubicin Phase 1b clinical trial within expected timeframes, if at all; the VOICE clinical trial not reaching interim analysis by end of March 2023; negative or ambiguous data are generated by the clinical and preclinical programs; the Company's inability to raise sufficient funds or engage a partner to complete the Phase 3 portion of the VOICE clinical trial and continue the camsirubicin clinical program beyond the Phase 1b clinical trial; that MNPR-101 RIT may not find a pathway to initiating a first-in-human study; 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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