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): **December 12, 2022**

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 12, 2022, Monopar Therapeutics Inc. issued a press release announcing promising data with MNPR-202 from its ongoing collaboration with the Cancer Science Institute of Singapore at the National University of Singapore. The data are displayed in a poster at the 64th American Society of Hematology Annual Meeting & Exposition.

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 12, 2022

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 12, 2022

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

Monopar Announces Promising MNPR-202 Data
from Ongoing National University of Singapore Collaboration

WILMETTE, Ill, December 12, 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 released promising data with MNPR-202 from its ongoing collaboration with the Cancer Science Institute of Singapore (CSI Singapore) at the National University of Singapore (NUS). The data are displayed in the poster that NUS and Monopar will be presenting this Sunday at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition (ASH 2022). Monopar has made the poster available on its website at the following link: https://www.monopartx.com/pipeline/mnpr-202.

MNPR-202 is a promising DNA Damaging Response (DDR) drug candidate, and analog of doxorubicin. It has the same potentially non-cardiotoxic backbone as camsirubicin, Monopar's clinical stage drug candidate that has shown a favorable heart toxicity profile to-date across three trials, but MNPR-202 is modified at additional sites with the intention of evading certain tumors' resistance mechanisms to doxorubicin.

Prior exploratory preclinical studies in solid tumors have shown MNPR-202 to have a similar cytotoxic potency to doxorubicin while retaining that potency even in doxorubicin-resistant cancers. The present preclinical work by Dr. Anand Jeyasekharan, MD PhD, of CSI Singapore, which was highlighted by the Gates Cambridge in a recent article: https://www.gatescambridge.org/about/news/scholars-join-forces-on-anti-cancer-drug/, corroborates MNPR-202's similar cytotoxic potency to doxorubicin even in blood cancers, while expanding the research in several exciting new directions, including a comparison to doxorubicin on DNA damage response, immune activation, apoptosis, gene expression, and synergy with other cancer compounds for combination usage.

Preclinical Results To-Date

Data from blood cancer preclinical studies to date show that MNPR-202:

- has a similar cytotoxic potency to doxorubicin
- generates increased DNA damage compared to doxorubicin
- has a unique immune activation profile versus doxorubicin
- demonstrates increased apoptosis compared to doxorubicin
- causes a distinct set of genes to be upregulated and downregulated versus doxorubicin; and

- may be superior to doxorubicin in certain combination treatment regimens. A combination drug screen with 183 compounds was performed, revealing distinct differences in the synergy profile between doxorubicin and MNPR-202 with other compounds. As example, MNPR-202 demonstrated a more favorable synergy profile with volasertib compared to doxorubicin.

The results generated to date suggest doxorubicin and MNPR-202 have a similar cytotoxic potency, but likely work through distinct cellular pathways and cause a different ancillary innate immune activation. These intracellular differences also influence drug synergies observed with the two compounds, implying that in the context of certain combinatorial regimens, MNPR-202 may be superior to doxorubicin. MNPR-202 also shows the potential to work in cancers resistant to doxorubicin. Taken together, we believe MNPR-202 has potential to disrupt the current chemotherapy landscape and impact a broad range of cancers.

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 MNPR-202 is a promising DNA Damaging Response (DDR) drug candidate that has the same potentially non-cardiotoxic backbone as camsirubicin; that MNPR-202 has the intention of evading certain tumors' drug resistance mechanisms to doxorubicin; that the collaboration plans to expand the research in several exciting new directions, including a comparison to doxorubicin on DNA damage response, immune activation, apoptosis, gene expression, and synergy with other cancer compounds for combination usage; that the results generated to-date suggest doxorubicin and MNPR-202 overall have a similar cytotoxic potency, but likely work through distinct cellular pathways and cause a different ancillary innate immune activation; that the preclinical data imply that in the context of certain combinatorial regimens, MNPR-202 may be superior to doxorubicin; that MNPR-202 also shows the potential to work in cancers resistant to doxorubicin; and that taken together, we believe MNPR-202 shows the potential to disrupt the current chemotherapy landscape and impact a broad range of cancers. The forward-looking statements involve risks and uncertainties including, but not limited to: that MNPR-202 may not yield positive results in future preclinical and clinical studies; if MNPR-202 generates positive data, Monopar may not have the funds to continue the development of MNPR-202; 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

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