

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): July 11, 2023

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</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>
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 July 11, 2023, Monopar Therapeutics Inc. (Monopar) issued a press release announcing a collaboration with the Cancer Science Institute of Singapore (CSI Singapore) at the National University of Singapore (NUS) to evaluate radiopharmaceutical versions of MNPR-101 in several aggressive cancers.

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 July 11, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: July 11, 2023

Monopar Therapeutics Inc.

By: /s/ Kim R. Tsuchimoto

Name: Kim R. Tsuchimoto

Title: Chief Financial Officer and Director



Monopar Announces MNPR-101 Radiopharma Collaboration Agreement with National University of Singapore

WILMETTE, Ill, July 11, 2023 – Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer, today announced a collaboration with the Cancer Science Institute of Singapore (CSI Singapore) at the National University of Singapore (NUS) to evaluate radiopharmaceutical versions of MNPR-101 in several aggressive cancers. MNPR-101 is a novel, first-in-class humanized monoclonal antibody to the urokinase Plasminogen Activator Receptor (uPAR).

Dr. Anand Jeyasekharan, MBBS MRCP (UK) PhD, of CSI Singapore, NUS, will be the Principal Investigator on the collaboration. Dr. Jeyasekharan is a physician-scientist who runs a research laboratory investigating the molecular and biological responses of cancer cells to oncology drugs, as well as treats cancer patients and leads early phase oncology clinical trials at NUS.

In this collaboration, Dr. Jeyasekharan will initially investigate uPAR expression levels in tissue samples from patients with various subtypes of advanced soft tissue sarcoma (ASTS). Studies have shown uPAR to be a promising target for ASTS, which is a cancer Dr. Jeyasekharan specializes in treating. He plans to assess retrospective patient samples to identify which subtypes of ASTS have the highest expression of uPAR, thus making them the most promising to pursue in a human clinical trial.

“uPAR is an exciting target for ASTS, and a radiopharmaceutical approach using MNPR-101 has the potential to combine personalized medicine with precision oncology,” said Dr. Jeyasekharan. “We have the chance here to use immunohistochemistry on patient tissue samples to identify high uPAR expressing cancers, to then work with our colleagues in radiology and nuclear medicine to radiolabel MNPR-101 for a subsequent clinical imaging study. For patients with positive scans, a therapeutic isotope such as Lu-177 or Ac-225 may provide an interesting option for a clinical trial.”

“It is exciting what Dr. Jeyasekharan and NUS are aiming to do here,” said Chandler Robinson, MD, CEO of Monopar. “They are seeing if we can select patients most likely to respond at the time of tissue biopsy. And from there, if you can see it on PET/SPECT imaging with a radiopharmaceutical version of MNPR-101, you can treat it. Dr. Jeyasekharan is uniquely equipped to undertake this endeavor, too, as he can oversee both the preclinical work as well as the overall management of patients under standard Phase 1 protocols.”

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients. Monopar's pipeline consists of camsirubicin (Phase 1b) for the treatment of advanced soft tissue sarcoma; MNPR-101, a late-stage preclinical antibody for radiopharmaceutical use in advanced cancers; and MNPR-202, an early-stage camsirubicin analog for various cancers. For more information, visit: www.monopartx.com.

About the Cancer Science Institute of Singapore (CSI Singapore)

The Cancer Science Institute of Singapore (CSI) is one of only six Research Centres of Excellence established by the Government of Singapore with funding from the National Research Foundation and the Ministry of Education. Its mission is to better understand the causes of human cancer across Asia, and thereby improve its detection, treatment and prevention for the benefit of the patients. The CSI's outstanding researchers and excellent scientific facilities create an energetic environment for ground-breaking research and world-class training. The CSI is internationally recognized for its innovative research on the biology of cancers prevalent in Asia, and for taking new methods for cancer treatment from the laboratory to the clinic. Through its local and global partnerships, the CSI works with leading minds from multiple scientific and clinical disciplines in Singapore, the USA and Europe, both in academia and in industry.

For more information on CSI Singapore, visit <https://csi.nus.edu.sg/>

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 under the collaboration, Dr. Jeyasekharan will investigate uPAR expression levels in tissue samples from advanced soft tissue sarcoma (ASTS) patients; whether uPAR is a target for ASTS; that Dr. Jeyasekharan plans to use patient samples to see which subtypes of ASTS have the highest expression of uPAR, thus making them the most ideal for pursuing in a human clinical trial; that a radiopharmaceutical approach using MNPR-101 has the potential to combine personalized medicine with precision oncology; whether radiolabeled MNPR-101 will be used to image ASTS patients, and whether a therapeutic isotope such as Lu-177 or Ac-225 will be used to treat ASTS patients. The forward-looking statements involve risks and uncertainties including, but not limited to: Monopar's inability to raise additional capital to complete future preclinical and clinical development; negative or inconclusive data from the studies of MNPR-101 and related radiopharmaceuticals conducted in the collaboration with CSI at the NUS; if successful, the potential for commercialization, including uncertainties about levels of demand of MNPR-101 and related radiopharmaceuticals; and the significant general risks and uncertainties surrounding the research, development, regulatory approval and commercialization of diagnostics and 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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