

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): **February 27, 2024**

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 February 27, 2024, Monopar Therapeutics Inc. issued a press release announcing the internationally recognized radiopharmaceutical physician, Professor Rodney Hicks, will be the lead investigator for Monopar's MNPR-101-Zr Phase 1 dosimetry clinical trial in advanced cancer patients.

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 February 27, 2024
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.

Monopar Therapeutics Inc.

Date: February 27, 2024

By: /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Chief Financial Officer and Director



Monopar Provides Update on MNPR-101-Zr Radiopharma Clinical Trial

WILMETTE, Ill., February 27, 2024— Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients, today announced that the internationally recognized radiopharmaceutical physician, Professor Rodney Hicks, will be the lead investigator for Monopar's MNPR-101-Zr Phase 1 dosimetry clinical trial in advanced cancer patients. Professor Hicks will enroll patients at the Melbourne Theranostic Innovation Centre (MTIC) and will use one of the world's most sensitive clinical total-body PET/CT (positron emission tomography–computed tomography) scanners, the Siemens Biograph Vision Quadra, to image the targeting ability of MNPR-101-Zr in cancer patients.

"We are very excited to have Professor Hicks as the lead investigator for our MNPR-101-Zr clinical trial," said Chandler Robinson, MD, Monopar's Chief Executive Officer. "He is a true pioneer in the radiopharma space, having helped introduce radiopharma agents into the clinic which are now approved globally for neuroendocrine tumors and prostate cancer, and having installed the first PET/CT in Australia and one of the first in the world."

Professor Rodney Hicks, MBBS(Hons), MD, FRACP, FICIS, FAAHMS is the Founder, Chief Medical Officer, and Board Chair of Precision Molecular Imaging & Theranostics Pty Ltd, the company that operates MTIC. He is the former Director of Cancer Imaging at Peter MacCallum Centre in Melbourne, one of Australia's largest cancer research centers, and has published over 650 research articles, reviews, and commentaries. In 2023, Professor Hicks received the Saul Hertz Award from the Society of Nuclear Medicine and Molecular Imaging for his lifetime contribution to radionuclide therapy.

"The preclinical data that Monopar announced on this past Thursday encourages us to translate this class of agents into the clinical domain. MNPR-101-Zr is being developed for cancers with very high unmet medical need, such as pancreatic cancer and triple negative breast cancer," said Professor Hicks. "I founded MTIC in part to help patients gain access to promising new radiopharmaceuticals, and the entire MTIC team is looking forward to activating the MNPR-101-Zr trial shortly and enrolling patients."

Additional information about the MNPR-101-Zr Phase 1 dosimetry clinical trial for advanced cancer patients as well as the recently announced associated preclinical data can be found at the following links: [MNPR-101-Zr Phase 1](#) and [Preclinical Data](#).

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 Phase 1b-stage camsirubicin for the treatment of advanced soft tissue sarcoma; Phase 1-stage MNPR-101 for radiopharmaceutical use in advanced cancers; and an early-stage camsirubicin analog, MNPR-202. For more information, visit: www.monopar.tx.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: that Professor Rodney Hicks will be the lead investigator on Monopar's MNPR-101-Zr Phase 1 dosimetry clinical trial in advanced cancer patients; that Professor Hicks will be enrolling patients at the Melbourne Theranostic Innovation Centre (MTIC) and will utilize one of the world's most sensitive PET/CT; and that the MTIC team is looking forward to activating the MNPR-101-Zr trial shortly and enrolling patients. The forward-looking statements involve risks and uncertainties including, but not limited to: that future preclinical or clinical data will not be as promising as the data to date; not initiating and enrolling the Phase 1 clinical trial; that MNPR-101-Zr may cause unexpected serious adverse effects or fail to image or be effective against the cancer tumors in humans; the potential for the HREC to put the Phase 1 trial on clinical hold at any time; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of imaging agents 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.

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