

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): **June 11, 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 June 11, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing an amendment and expansion to their existing collaboration with NorthStar Medical Radioisotopes, LLC.

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 June 11, 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: June 11, 2024

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



Monopar and NorthStar Amend & Extend Collaboration

Highlights:

- Builds on Companies' respective core strengths
- Aligns intellectual property rights
- Establishes a long-term supply agreement under which NorthStar provides actinium-225 for Monopar's development and potential future commercial programs

WILMETTE, IL and Beloit, WI, June 11, 2024— Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage radiopharma company, and NorthStar Medical Radioisotopes, LLC, a global innovator in development and commercial production of medical radioisotopes, today announced an amendment and expansion to their existing collaboration. Under terms of the revised collaboration, the Companies entered into a long-term, non-exclusive master supply agreement for NorthStar to provide Monopar with the powerful therapeutic radioisotope actinium-225 (Ac-225). The amendment builds on NorthStar's significant investment in Ac-225 manufacturing and Monopar's promising preclinical therapeutic results with Ac-225 in its lead MNPR-101 radiopharma program.

The amendment also clarifies certain economic terms and those related to jointly developed intellectual property rights for Monopar's MNPR-101 for radiopharmaceutical use. Monopar has acquired those rights from NorthStar, together with certain broad, jointly developed intellectual property pertaining to MNPR-101, giving Monopar full ownership and title to its lead MNPR-101 radiopharmaceutical platform. Both companies will share ownership of the filed patent application on the use of PCTA as a linker with Ac-225, which has shown superior binding and yield with Ac-225 over the current industry-leading linker, DOTA.

"We are excited about the evolution of our collaboration, the promising potential of the MNPR-101 radiopharma platform, and the long-term access to a high-quality source of Ac-225 that can support our current development programs and potential future commercial products," said Chandler Robinson, MD, Monopar's Chief Executive Officer.

"Using our proprietary electron accelerator technology, NorthStar is poised to be the first commercial-scale producer of non-carrier added (n.c.a.) Ac-225. We're delighted to continue and extend our collaboration with Monopar and support development of its exciting MNPR-101 radiopharma platform focused on therapeutic agents to treat aggressive cancers," said Frank Scholz, PhD, NorthStar's Chief Executive Officer.

About Monopar Therapeutics Inc. (Monopar)

Monopar Therapeutics is a clinical-stage radiopharmaceutical company focused on developing innovative treatments for cancer patients, including Phase 1-stage MNPR-101-Zr for imaging advanced cancers and late preclinical-stage MNPR-101 radio-immuno-therapeutic (RIT) for the treatment of advanced cancers. For more information, visit: www.monopartx.com.

About NorthStar Medical Radioisotopes, LLC (NorthStar)

NorthStar Medical Radioisotopes is a commercial-stage radiopharmaceutical company at the forefront of advancing patient care by utilizing novel technologies to produce commercial-scale radioisotopes that, once attached to a molecule, have the ability to detect and treat cancer and other serious diseases. NorthStar's expanding industry-leading position in the emerging field of radiopharmaceutical therapy is supported by its unique capabilities in the sophisticated production of radioisotopes, proven management team, and state-of-the-art, environmentally preferable technologies. NorthStar routinely produces copper-67 (Cu-67) and is poised to be the first commercial-scale producer of non-carrier-added (n.c.a.) actinium-225 (Ac-225). The Company's Radiopharmaceutical Contract Development and Manufacturing Organization (CDMO) services unit provides customized service offerings and specialized radiopharmaceutical expertise to help biopharmaceutical companies rapidly advance their development and commercial programs. For more information about NorthStar's comprehensive portfolio and patient-focused services, visit: www.northstarm.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 NorthStar will provide actinium-225 for Monopar's development and potential future commercial programs; the promising potential of Monopar's MNPR-101 radiopharma platform, and the long-term access to a high-quality source of Ac-225 that can support Monopar's current development programs and potential future commercial products; that NorthStar is poised to be the first commercial-scale producer of non-carrier added (n.c.a.) Ac-225; and that NorthStar will continue to support development of Monopar's exciting MNPR-101 radiopharma platform focused on therapeutic agents to treat aggressive cancers. The forward-looking statements involve risks and uncertainties including, but not limited to: that Monopar's and shared intellectual property may not result in allowed patents; that if allowed, the patents may be too narrow in scope to provide protection needed to successfully develop the radiopharma program; that NorthStar may not be able to supply Ac-225 at quantities needed, if at all; that NorthStar may not be the first commercial-scale producer of n.c.a. Ac-225; that Monopar may expend available funds sooner than anticipated or require additional funding due to change in circumstances or unanticipated events; that future preclinical or clinical data will not be as promising as the data to date; not successfully enrolling the MNPR-101-Zr Phase 1 clinical trial if at all; that MNPR-101-Zr and/or MNPR-101 conjugated to a therapeutic radioisotope may cause unexpected serious adverse effects or fail to image or be effective against the cancer tumors in humans; 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 and/or NorthStar's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

CONTACTS:

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