

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): May 26, 2021

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-39070
(Commission File Number)

32-0463781
(I.R.S. Employer Identification No.)

**1000 Skokie Blvd., Suite 350, Wilmette,
IL 60091**
(Address of principal executive offices)

60091
(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 May 26, 2021, Monopar Therapeutics Inc. issued a press release announcing the filing of a provisional composition of matter patent titled “Urokinase Plasminogen Activator Receptor-Targeted Radiopharmaceutical” covering a radiotherapeutic consisting of Monopar’s proprietary antibody MNPR-101 bound to Actinium-225 (Ac-225) via the metal binding agent PCTA in 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 May 26, 2021

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: May 26, 2021

By: /s/ Kim R. Tsuchimoto

Name: Kim R. Tsuchimoto

Title: Chief Financial Officer, Secretary
and Treasurer



Monopar and NorthStar Announce Filing of Composition of Matter Patent Protecting MNPR-101 Radiotherapeutic

WILMETTE, Ill. and BELOIT, Wis., May 26, 2021— Monopar Therapeutics Inc. (Nasdaq: MNPR) and NorthStar Medical Radioisotopes, LLC, today announced the filing of a provisional composition of matter patent titled “Urokinase Plasminogen Activator Receptor-Targeted Radiopharmaceutical” covering a radiotherapeutic consisting of Monopar’s proprietary antibody MNPR-101 bound to Actinium-225 (Ac-225) via the metal binding agent PCTA. This Radio-Immuno-Therapeutic (RIT) demonstrated a 98% radiochemical purity and has the potential to be a highly selective, potent treatment for a variety of cancers, severe COVID-19, and other diseases characterized by aberrant urokinase plasminogen activator receptor (uPAR) expression.

RITs are an emerging class of drugs formed by attaching a radioactive element to an antibody for the purpose of targeting and killing specific cells. Actinium is quickly becoming a premier radioisotope of choice for RITs; however, its full potential is presently constrained by its price and scarcity. On May 24, 2021, Monopar and NorthStar announced the filing of a provisional patent which may enable them to manufacture antibody-PCTA-Ac225 conjugates using less antibody and less Ac-225 starting material, and may also confer efficacy and safety advantages while also improving supply chain logistics.

“We are excited about working with Monopar to develop MNPR-101 as a radio-immuno-therapeutic, and advancing it further toward the clinic,” said James Harvey, PhD, Chief Scientific Officer of NorthStar.

“The binding of Actinium-225 to PCTA-MNPR-101 with 98% yield is highly encouraging,” said Andrew Mazar, PhD, Monopar’s Chief Scientific Officer. “If issued, this composition of matter patent could significantly expand the MNPR-101 patent estate.”

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® for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin for the treatment of advanced soft tissue sarcoma; and a preclinical stage uPAR targeted antibody MNPR-101 for advanced cancers and severe COVID-19. For more information, visit: www.monopartrx.com.

About NorthStar Medical Radioisotopes, LLC

NorthStar Medical Radioisotopes is a global innovator in the production and distribution of radioisotopes used for medical imaging and therapeutic purposes. NorthStar is a company committed to providing the United States with reliable and environmentally friendly radioisotope supply solutions to meet the needs of patients and to advance clinical research. NorthStar’s first product is the RadioGenix® System (technetium Tc 99m generator), an innovative and flexible platform technology initially approved by the U.S. Food and Drug Administration in February 2018. For more information, visit: www.northstarmm.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 MNPR101-PCTA-Ac225 has the potential to be a highly selective, potent RIT for the treatment of a variety of cancers, severe COVID-19, and other diseases characterized by aberrant urokinase plasminogen activator receptor (uPAR) expression; that the previously announced provisional patent filing may enable Monopar and NorthStar to manufacture MNPR101-PCTA-Ac225 using less antibody and less Ac-225 starting material and may also confer efficacy and safety advantages and improve supply chain logistics; that the RIT may move further toward the clinic; and that, if issued, this composition of matter patent could significantly expand the MNPR-101 patent estate. The forward-looking statements involve risks and uncertainties including, but not limited to: this and/or the previously announced provisional patent filing not resulting in issued patents; RITs not becoming an emerging class of drugs; Actinium not becoming a premier radioisotope of choice for RITs; whether RITs’ full potential continues to be constrained due to its price and scarcity; whether MNPR101-PCTA-Ac225 uses less antibody and less Ac-225 starting material and confer efficacy and safety advantages and improve supply chain logistics; whether the RIT will be successfully preclinically and clinically developed, if at all; the lack of any clinical activities to date with respect to MNPR-101 and related conjugates; the requirement for additional capital to complete preclinical and clinical development of RITs and if successful, commercialization; 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 and NorthStar undertake 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 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:

For Monopar Therapeutics Inc.

Investor Relations:
Kim R. Tsuchimoto
Chief Financial Officer
kimtsu@monopartx.com

For NorthStar Medical Radioisotopes, LLC

Investor Relations:
Paul Estrem
Senior Vice President and Chief Financial Officer
pestrem@northstarm.com

Corporate:
Lisa Holst
Vice President Sales and Marketing
678-471-9027
lholtst@northstarm.com

Media:
Priscilla Harlan
781-799-7917
pharlan@shiningrockllc.com
