

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 24, 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 24, 2021, Monopar Therapeutics Inc. issued a press release announcing the filing of a provisional patent with the U.S. Patent and Trademark Office (USPTO) titled “Bio-Targeted Radiopharmaceutical Compositions Containing Ac-225 and Methods of Preparation” 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 24, 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 24, 2021

By: /s/ Kim R. Tsuchimoto

Name: Kim R. Tsuchimoto

Title: Chief Financial Officer, Secretary
and Treasurer



Monopar Therapeutics



Monopar and NorthStar Announce Patent Filing on Promising Radiopharmaceutical Discovery

Potential to significantly improve the yield of Actinium-based radiopharmaceuticals

WILMETTE, Ill. and BELOIT, Wis., May 24, 2021 – Monopar Therapeutics Inc. (Nasdaq: MNPR) and NorthStar Medical Radioisotopes, LLC, today announced the filing of a provisional patent with the U.S. Patent and Trademark Office (USPTO) titled “Bio-Targeted Radiopharmaceutical Compositions Containing Ac-225 and Methods of Preparation.” Radiopharmaceutical therapy is a promising approach to treat cancer and other diseases using radioactive metals bound with proteins/antibodies to target and kill cells. Actinium-225 (Ac-225) is emerging as a radioactive isotope of choice for radiopharmaceuticals due to favorable properties such as its long half-life, high potency, and induction of localized cell death.

This provisional patent relates to the unexpected observation by Monopar and NorthStar that using the metal binding agent 3,6,9,15-tetraazabicyclo[9.3.1]pentadecan-1(15),11,13-triene-3,6,9-triacetic acid (PCTA) to attach Ac-225 to antibodies resulted in nearly 100% binding of Ac-225 to the PCTA-antibody conjugates. If validated through further evaluation, it could potentially improve efficacy and safety and enhance manufacturing efficiency of Actinium-based radiopharmaceuticals.

Based on Monopar and NorthStar’s work to date, PCTA-antibody conjugates appear to bind Ac-225 and its daughter ions such as Bi-213 with high affinity. This could be important in the situation of transportation delays resulting in Ac-225 decaying during transport. Furthermore, when compared to DOTA (the standard binding agent for attaching Ac-225 to an antibody), PCTA-antibody conjugates displayed a significantly higher affinity to Ac-225. This high affinity binding may decrease the amount of Ac-225 and its daughter ions that detach from the antibody, which could potentially increase efficacy and reduce off-target toxicity and enable higher dosing. Monopar and NorthStar plan to explore both internal development and out-licensing opportunities of this promising approach in Actinium-based radiopharmaceuticals.

“Actinium is quickly becoming a premier radioisotope in cancer-targeting therapies, but its potential is limited due to its price and scarcity,” said James Harvey, PhD, Chief Scientific Officer of NorthStar. “Enabling radiopharmaceutical manufacturers and drug developers to maximize the binding efficiency of Ac-225, and thereby reduce the quantity of Ac-225 required for purchase and use, would permit this promising class of drugs to reach its full potential.”

“Binding Actinium to antibodies using PCTA instead of DOTA has displayed unexpected and unique properties including substantially tighter binding of Ac-225 and a much higher incorporation into the PCTA-antibody conjugate,” said Andrew Mazar, PhD, Chief Scientific Officer of Monopar. “This technology could have broad applicability to the manufacturing of numerous radio-immuno-conjugates and may also extend to other proteins.”

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.monopartx.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. The Company'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.northstamm.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 radiopharmaceutical therapy is a promising approach to treat cancer and other diseases using radioactive metals bound with proteins/antibodies to target and kill cells; that binding Ac-225 to PCTA-antibody conjugates could potentially improve efficacy and safety and enhance manufacturing efficiency of Actinium-based radiopharmaceuticals; that this high affinity binding may decrease the amount of Ac-225 and its daughter ions that detach from the antibody, which could potentially increase efficacy and reduce off-target toxicity and enable higher dosing; that Monopar and NorthStar plan to explore both internal development and out-licensing opportunities of this promising approach in Actinium-based radiopharmaceuticals; that by reducing the quantity of Ac-225 required for purchase and use would permit this promising class of drugs to reach its full potential; and that this technology could have broad applicability to numerous radio-immuno-conjugates and may also extend to other proteins. The forward-looking statements involve risks and uncertainties including, but not limited to: whether the provisional patent will result in an issued patent; whether preliminary observations and findings to date will be validated by further evaluation; whether this technology will improve efficacy and safety and enhance manufacturing efficiency of Actinium-based radiopharmaceuticals, if at all; whether this technology could potentially reduce off-target toxicity and enable higher dosing of antibody conjugates; Monopar and NorthStar not successfully internally developing or out-licensing this technology; the lack of any clinical activities to date with respect to Ac-225 bound to antibodies using PCTA; the requirement for additional capital to complete preclinical and clinical development, and if successful, commercialization; the success and prevalence of the use of Ac-225 in radiopharmaceutical therapies; not being able to ensure volumes of this radioisotope can be manufactured and scaled up to meet potential demand; uncertainties about levels of demand if and when a treatment is available for 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. Monopar and NorthStar are not making any express or implied claims that these Ac-225 based radiopharmaceuticals have the ability to eliminate or mitigate cancers, severe COVID-19, or other diseases at this time. 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.

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