

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): August 10, 2020

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 August 10, 2020, Monopar Therapeutics Inc. (“Monopar”) issued a press release announcing, in collaboration with NorthStar Medical Radioisotopes, LLC (“NorthStar”), a partnership with IsoTherapeutics Group, LLC (Angleton, TX) (“IsoTherapeutics”), to develop and manufacture Radio-Immuno-Therapeutics (“RITs”) for the potential treatment of severe COVID-19. IsoTherapeutics will modify Monopar’s proprietary urokinase plasminogen activator receptor (“uPAR”) targeted antibody, MNPR-101, by making conjugates that will allow the attachment of therapeutic radioisotopes supplied by NorthStar, creating a platform of uPAR-targeted RIT (“uPRIT”) candidates to be evaluated as treatments for severe COVID-19.

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 August 10, 2020

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: August 10, 2020

By: /s/ Kim R. Tsuchimoto

Name: Kim R. Tsuchimoto
Title: Chief Financial Officer, Secretary
and Treasurer



Monopar and NorthStar Partner with IsoTherapeutics for the Manufacturing of Potential Therapeutic for Severe COVID-19

WILMETTE, IL, BELOIT, WI, and ANGLETON, TX, August 10, 2020 - Monopar Therapeutics Inc. (Nasdaq: MNPR)(Wilmette, IL) and NorthStar Medical Radioisotopes, LLC (Beloit, WI), who are collaborating on the development of Radio-Immuno-Therapeutics (RITs) to treat patients with severe COVID-19, today announced a partnership with IsoTherapeutics Group, LLC (Angleton, TX), to develop and manufacture a RIT for the potential treatment of severe COVID-19.

IsoTherapeutics will modify Monopar's proprietary urokinase plasminogen activator receptor (uPAR) targeted antibody, MNPR-101, by making conjugates that will allow the attachment of therapeutic radioisotopes supplied by NorthStar, creating a platform of uPAR-targeted RIT (uPRIT) candidates to be evaluated as treatments for severe COVID-19. The plan is for IsoTherapeutics to then advance a clinical candidate identified from this platform through GMP manufacturing for Monopar and NorthStar to take into its first in human trials.

Recent publications have implicated uPAR-expressing immune cells in the development of severe lung injury, multiple organ failure, and death in severe COVID-19 patients. "A treatment that specifically targets and eradicates these over-activated immune cells could significantly improve patient outcomes in severe COVID-19," said Andrew Mazar, Ph.D., Chief Scientific Officer of Monopar.

"We are excited to partner with Monopar and NorthStar," said Jim Simón, Ph.D., Chief Scientific Officer of IsoTherapeutics. "A uPAR-targeted RIT has great therapeutic potential, and we are proud to contribute our expertise in radiopharmaceutical research and manufacturing to ensure its rapid and effective development."

James T. Harvey, Ph.D., Senior Vice President and Chief Science Officer of NorthStar, said "We have successfully worked with IsoTherapeutics on a previous project that led to an FDA approval, and we value their expertise. This is a crucial step in the development of a uPRIT for severe COVID-19."

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company primarily 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 late-stage preclinical 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.northstarmm.com.

About IsoTherapeutics Group, LLC

IsoTherapeutics Group is a radiopharmaceutical company that provides research and development services, including animal studies and early stage manufacturing for the purpose of aiding customers and collaborators in the development of radionuclide-based drug and device products. IsoTherapeutics scientists hold over 100 patents for novel chemistry and radiopharmaceutical formulations. For more information, visit: <http://isotherapeutics.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 IsoTherapeutics' ability to create a platform of uPAR-targeted RIT (uPRIT) candidates based upon MNPR-101 and a therapeutic radioisotope from NorthStar; IsoTherapeutics' ability to advance a clinical candidate identified from this platform through GMP manufacturing for Monopar and NorthStar to take into its first in human trials; that a treatment that specifically targets and eradicates these over-activated immune cells could significantly improve patient outcomes in severe COVID-19; that a uPAR-targeted RIT has great therapeutic potential; and that IsoTherapeutics' expertise in radiopharmaceutical research and manufacturing will ensure rapid and effective development of uPRIT candidates. The forward-looking statements involve risks and uncertainties including, but not limited to, the lack of any clinical activities to date with respect to MNPR-101 and that preclinical development activities to date have been focused on the treatment of cancers, the requirement for additional capital to complete preclinical and clinical development, and if successful, commercialization, IsoTherapeutics not being able to couple MNPR-101 to a therapeutic radioisotope, the conjugate not being able to kill aberrantly activated cytokine-producing immune cells, the conjugate not being able to use uPAR to gain entry into these cells and deliver cytotoxic payload to kill these cells while sparing normal tissue, 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. 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, NorthStar and IsoTherapeutics 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, NorthStar's and IsoTherapeutics' 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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