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 30, 2020

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39070**	**32-0463781**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 30, 2020, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing that, in collaboration with NorthStar Medical Radioisotopes, LLC, a provisional patent application entitled "Precision Radioimmunotherapeutic Targeting of the Urokinase Plasminogen Activator Receptor (uPAR) for Treatment of Severe COVID-19 Disease" has been filed with the U.S. Patent and Trademark Office. This application covers novel compositions and uses of cytotoxic radioisotopes attached to antibodies that bind to uPAR, thereby creating precision targeted radiotherapeutics for the treatment of severe COVID-19 and other respiratory diseases.

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 30, 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: June 30, 2020

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

Monopar and NorthStar Announce Filing of Provisional Patent Protecting Development and Use of Radio-Immuno-Therapeutics (RITs) Targeting Severe COVID-19 Through uPAR

Chicago, IL and Beloit, WI, June 30, 2020 - Monopar Therapeutics Inc. (Nasdaq: MNPR) (Chicago, IL) and NorthStar Medical Radioisotopes, LLC (Beloit, WI) announced today that a provisional patent application entitled "Precision Radioimmunotherapeutic Targeting of the Urokinase Plasminogen Activator Receptor (uPAR) for Treatment of Severe COVID-19 Disease" has been filed with the U.S. Patent and Trademark Office (USPTO).

This application covers novel compositions and uses of cytotoxic radioisotopes attached to antibodies that bind to uPAR, thereby creating precision targeted radiotherapeutics (uPRITs) for the treatment of severe COVID-19 and other respiratory diseases. Advanced COVID-19 patients frequently develop severe, life-threatening, pulmonary inflammation as a result of a viral induced cytokine storm. The development of this cytokine storm is associated with a high rate of mortality in severe COVID-19 patients, even with oxygen support and mechanical ventilation. uPRITs have been designed with the goal of selectively destroying the aberrantly activated white blood cells responsible for causing the cytokine storm. If successful, healthy tissue would be spared in the process as the uPAR target is primarily only present on this unique class of white blood cells and not in healthy tissue. The co-inventors of the provisional patent application are James Harvey, Chief Scientific Officer of NorthStar, and Andrew P. Mazar, Chief Scientific Officer of Monopar.

If granted, the patent would offer exclusivity to Monopar and NorthStar for the development and potential use of uPRITs in the treatment of severe COVID-19 and other respiratory diseases. This provisional patent application leverages the therapeutic radioisotope expertise of NorthStar and the translational expertise of Monopar to create a novel, targeted radioimmunotherapeutic. On June 16, 2020, Monopar and NorthStar announced a 50/50 collaboration to couple Monopar's MNPR-101 uPAR targeting monoclonal antibody to a therapeutic radioisotope provided by NorthStar.

About Monopar Therapeutics Inc. (Monopar)
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)
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.northstarnm.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 the collaboration’s ability to create precision targeted radiotherapeutics (uPRITs) for the treatment of severe COVID-19 and other respiratory diseases; and that the patent may be granted. The forward-looking statements involve risks and uncertainties including, but not limited to, whether or not the patent will be granted, the lack of any clinical activities to date with respect to MNPR-101 and that pre-clinical 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, not being able to couple MNPR-101 to a therapeutic radioisotope, the uPRITs may not selectively destroy the aberrantly activated white blood cells responsible for causing the cytokine storm while sparing healthy 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. Monopar and NorthStar are not making any express or implied claims that uPRITs have the ability to eliminate or mitigate severe COVID-19 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.

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@northstarnm.com

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

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