

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): September 9, 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 September 9, 2020, Monopar Therapeutics Inc. (“Monopar”) issued a press release announcing, that Monopar and NorthStar Medical Radioisotopes, LLC, which are jointly developing urokinase plasminogen activator receptor targeted radio-immuno-therapeutics (“uPRITs”) for the potential treatment of patients with severe COVID-19, are collaborating with the University of Texas Health Science Center at Tyler (“UTHSCT”) and its Texas Lung Injury Institute (“TLII”). The UTHSCT is planning to perform *in vitro* and *in vivo* studies through the TLII and participate in the clinical development of uPRITs for the treatment of severe COVID-19 through its medical center.

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 September 9, 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: September 9, 2020

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



Monopar and NorthStar Collaborating with Texas Lung Injury Institute for Testing of Novel Potential Therapeutic for Severe COVID-19

WILMETTE, IL, BELOIT, WI, and TYLER, TX, SEPTEMBER 9, 2020 – Monopar Therapeutics Inc. (Nasdaq: MNPR) and NorthStar Medical Radioisotopes, LLC, which are jointly developing urokinase plasminogen activator receptor targeted radio-immuno-therapeutics (uPRITs) for the potential treatment of patients with severe COVID-19, today announced a collaboration with The University of Texas Health Science Center at Tyler (UTHSCT) and its Texas Lung Injury Institute (TLII). UTHSCT is planning to perform *in vitro* and *in vivo* studies through the TLII and participate in the clinical development of uPRITs for the treatment of severe COVID-19 through its medical center.

The University of Texas Health Science Center at Tyler has taken a leading role in the fight against COVID-19. UTHSCT was recently awarded a \$2 million National Institutes of Health (NIH) grant to investigate the potential use of convalescent plasma from recovered COVID-19 patients to prevent worsening lung symptoms, or death, in hospitalized COVID-19 patients. Enrollment for this study has already started. UTHSCT is also home to one of the leading laboratories in the world studying the role of urokinase plasminogen activator receptor (uPAR) in acute lung injury and respiratory distress, led by renowned pulmonologist Steven Idell, MD, PhD.

“Given their expertise in uPAR, acute lung injury, as well as the treatment of COVID-19 patients, UTHSCT and Dr. Steven Idell are the ideal partners for the preclinical and clinical development of uPRITs for severe COVID-19,” said Andrew Mazar, PhD, chief scientific officer of Monopar.

“Dr. Idell and UTHSCT have extensive experience with cell-based and animal models of respiratory distress, along with COVID-19 clinical trials. These resources and experiences should help accelerate the development of uPRITs,” said James T. Harvey, PhD, senior vice president and chief science officer of NorthStar.

“We are excited to be working with Monopar and NorthStar on developing a uPRIT, an innovative and clinically promising treatment for severe COVID-19 patients,” said Dr. Steven Idell, senior vice president for research and dean of the School of Medical Biological Sciences at UTHSCT.

The aim of this partnership is to evaluate uPRIT candidates in *in vitro* and *in vivo* models to facilitate the selection and IND-enabling development of a clinical candidate that could then move into first-in-human trials in patients with severe COVID-19 at UTHSCT.

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.monopar.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.northstarm.com.

About The University of Texas Health Science Center at Tyler

As part of the world-renowned University of Texas System, The University of Texas Health Science Center at Tyler (UTHSCT) is a graduate school providing programs for those seeking careers in the medical field. UTHSCT offers Master of Science in Biotechnology, Master of Public Health and Master of Health Administration degrees, as well as residency programs for medical school graduates in family medicine, general surgery, internal medicine, occupational medicine, rural family medicine, general psychiatry and rural psychiatry. Psychology internships and fellowships are also available. Graduate students, medical residents and other medical professionals-in-training develop marketable skills and qualifications to excel in the medical field as they learn alongside innovative scientists, physicians and other healthcare experts at UTHSCT and UT Health East Texas, a 10-hospital health system throughout East Texas. Led by Kirk A. Calhoun, MD, FACP, the university will soon become the home to the first medical school in East Texas, pending regulatory and accreditation approval. For more information, visit www.uthct.edu.

About the TLII

Housed within UTHSCT, the Texas Lung Injury Institute (TLII) was created in 2004 to provide state-of-the-art research that advances our understanding about the pathogenesis of lung disease and its treatment. For more information, visit: <https://www.uthct.edu/texas-lung-injury-institute>.

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 Monopar's and NorthStar's ability to develop uPRITs for the potential treatment of patients with severe COVID-19; UTHSCT's ability to perform *in vitro* and *in vivo* studies through the TLII and participate in the clinical development of uPRITs for the treatment of severe COVID-19 through its medical center; UTHSCT's ability to accelerate the development of uPRITs; uPRITs ability to be an innovative and clinically promising treatment for severe COVID-19 patients; and that uPRIT candidates in *in vitro* and *in vivo* models can facilitate the selection and IND-enabling development of a clinical candidate that could then move into first-in-human trials in patients with severe COVID-19 at UTHSCT. 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, the requirement for additional capital to complete preclinical and clinical development, potential for commercialization, 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 release this 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 TLII 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 TLII'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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