

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 16, 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 June 16, 2020, Monopar Therapeutics Inc. (“Monopar”) issued a press release announcing a development collaboration with NorthStar Medical Radioisotopes, LLC to research and develop potential Radio-Immuno-Therapeutics (“RITs”) to treat severe COVID-19 (patients with SARS-CoV-2).

The press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference.

Item 8.01 Other Information

On June 15, 2020, Monopar executed a development collaboration agreement with NorthStar Medical Radioisotopes, LLC (“NorthStar”), a privately-held commercial producer and supplier of medical radioisotopes based in Beloit, Wisconsin to develop a potential treatment for severe COVID-19.

The agreement combines NorthStar’s medical radioisotope expertise with Monopar’s expertise in therapeutic drug development and its pre-IND stage humanized urokinase plasminogen activator receptor (“uPAR”) targeted monoclonal antibody known as MNPR-101, along with a proprietary portfolio of related monoclonal antibodies that target uPAR or its ligand uPA.

Each company will start out sharing development costs 50/50, and the initial financial commitment for each company is nominal. Additional financial contributions will be subject to mutual agreement of the parties. Each party will retain all existing intellectual property rights and will grant the other party a royalty-free, non-exclusive license to the intellectual property necessary to perform the development activities contemplated by the agreement. Intellectual property developed in the course of performance of the agreement that relates to the targeted product would be jointly owned.

The agreement provides an initial framework for design and development activities. It is expected that the first several months of the collaboration will focus on identifying the linker and radioisotope to conjugate to MNPR-101 or other Monopar antibodies. Additional capital would be required to complete preclinical and clinical development, and if successful, commercialization. If the research is successful, the agreement provides that the companies would negotiate a commercialization plan at that time, including the ongoing contributions of each company and respective revenue sharing.

The agreement has a ten-year term, but either party may terminate the agreement upon 30 days’ written notice.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release Dated June 16, 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 16, 2020

By: /s/ Kim R. Tsuchimoto

Name: Kim R. Tsuchimoto

Title: Chief Financial Officer, Secretary
and Treasurer



Monopar and NorthStar Join Forces to Develop Radio-Immuno-Therapeutics (RITs) Targeting Severe COVID-19

Chicago, IL and Beloit, WI, June 16, 2020 - Monopar Therapeutics Inc. (Nasdaq: MNPR) (Chicago, IL) and NorthStar Medical Radioisotopes, LLC (Beloit, WI) announced today a 50/50 collaboration to develop potential Radio-Immuno-Therapeutics (RITs) to treat severe COVID-19 (patients with SARS-CoV-2 infection). Monopar is a clinical-stage biopharmaceutical company and NorthStar is a commercial producer and supplier of medical radioisotopes. This collaboration combines NorthStar's expertise in the innovative production, supply, and distribution of important medical radioisotopes with Monopar's expertise in therapeutic drug development and its pre-IND stage humanized urokinase plasminogen activator receptor (uPAR) targeted monoclonal antibody known as MNPR-101, along with a proprietary portfolio of related monoclonal antibodies that target uPAR or its ligand uPA.

The uPA system (comprised of the serine protease enzyme uPA and its receptor uPAR) has been demonstrated to be selectively expressed on aberrantly activated immune cells. In response to coronavirus infection, these rogue immune cells produce pro-inflammatory cytokines that can cause runaway inflammation throughout the body, commonly referred to as a cytokine storm. It is this systemic hyper-inflammatory state that is thought to be largely responsible for the severe lung injury and further multiple organ damage that contributes to poor outcomes and death in patients with severe COVID-19.

In this collaboration, Monopar and NorthStar plan to couple MNPR-101 to a therapeutic radioisotope supplied by NorthStar in order to create a highly selective agent that has the potential to kill aberrantly activated cytokine-producing immune cells. By eradicating these cells with a targeted RIT, the goal is to spare healthy cells while quickly reducing the cytokine storm and its harmful systemic effects.

"This collaboration is a powerful combination of unique scientific and technical expertise to help combat severe COVID-19," said Chandler Robinson, MD, CEO of Monopar Therapeutics. "The companies will be conducting a development program to determine if Monopar's uPA/uPAR monoclonal antibodies can be transformed into RITs that are effective as treatments against severe COVID-19, as well as other corona viruses."

"We are pleased to work together with Monopar in the battle against COVID-19," said Stephen Merrick, CEO of NorthStar Medical Radioisotopes. "Our hope is that, by joining forces, we can develop a targeted radiopharmaceutical treatment that has the ability to prevent patients with severe COVID-19 from being placed on ventilators and from dying."

“To help mitigate the cytokine storm and reduce deaths associated with COVID-19, our goal is to develop an RIT that selectively eliminates the rogue aberrantly activated immune cells that produce these cytokines,” said Andrew Mazar, PhD, Chief Scientific Officer of Monopar. “uPAR is selectively expressed on these rogue immune cells but not on healthy cells. An antibody carrying a therapeutic radioisotope could gain entry into these cells through uPAR and deliver its cytotoxic payload to kill these cells while sparing normal tissue.”

“NorthStar will apply its expertise to identify and supply the optimal therapeutic radioisotope to couple with Monopar’s uPAR monoclonal antibodies,” said James T. Harvey, PhD, Senior Vice President and Chief Science Officer of NorthStar. “We will deploy the most appropriate development approaches and production technology to ensure that both development and, if successful, commercial-scale volumes of this radioisotope can be supplied in order to meet potential demand.”

This targeted therapeutic approach to treating severe COVID-19 is supported by a recently published study (Rovina et al. 2020) demonstrating that soluble urokinase plasminogen activator receptor (suPAR), which is shed by aberrantly activated immune cells that make uPAR, is an early predictor of severe respiratory failure in COVID-19 and its presence increases as patients develop severe COVID-19.

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 late-stage preclinical antibody MNPR-101. For more information, visit: <https://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: <https://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 the collaboration’s ability to develop a targeted radiopharmaceutical treatment that has the ability to prevent patients with severe COVID-19 from being placed on ventilators and from dying. 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 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 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 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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