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 12, 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 August 12, 2020, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing that it plans to advance the development of a test to potentially triage COVID-19 patients into those likely versus unlikely to progress to severe respiratory failure. The test would use Monopar's proprietary monoclonal antibody, ATN-658, to detect soluble urokinase plasminogen activator receptor (suPAR) in COVID-19 patient plasma. A suPAR test for COVID-19 patients, if successful, could identify those at high risk for severe respiratory failure, facilitating earlier therapeutic interventions or allowing for the staging of patients to an optimal treatment based on their disease characteristics.

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 12, 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 12, 2020

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

Monopar Announces Plan to Advance Development of Novel Triage Test for Severe COVID-19 Utilizing its Patented Technology

Potential Companion Diagnostic to Monopar's uPRIT Program

WILMETTE, IL, August 12, 2020 – Monopar Therapeutics Inc. (Nasdaq: MNPR) today announced its plan to develop a test to potentially triage COVID-19 patients into those likely versus unlikely to progress to severe respiratory failure. The test would use Monopar's proprietary monoclonal antibody, ATN-658, to detect soluble urokinase plasminogen activator receptor (suPAR) in COVID-19 patient plasma. A suPAR test for COVID-19 patients, if successful, could identify those at high risk for severe respiratory failure, facilitating earlier therapeutic interventions or allowing for the staging of patients to an optimal treatment based on their disease characteristics.

A prototype enzyme-linked immunosorbent assay (ELISA) for measuring blood suPAR levels using ATN-658 has been developed, and Monopar is currently in discussions with several parties to further develop and commercialize either an ELISA or other suPAR-based test using ATN-658. The aim is to clinically validate the suPAR-based test in COVID-19 patients.

The use of suPAR for triaging COVID-19 patients is supported by a growing body of recent studies. Rovina et al. 2020 showed that patients with elevated levels of suPAR at the time of hospital admission are 17 times more likely to develop severe respiratory failure (p=.0000000012). Arnold et al. 2020 showed suPAR to have the best performance in predicting outcome (such as intensive care unit admission and death) of all the biomarkers examined; and Eugen-Olsen et al. 2020 showed that low levels of suPAR are predictive of mild outcome in COVID-19 patients.

"suPAR is emerging as an important biomarker that predicts outcome in diseases characterized by rapid and severe systemic inflammatory responses including COVID-19, certain pneumonias, and sepsis," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar. "This suPAR test may enable the early identification of patients who will rapidly deteriorate, and thereby could greatly improve the treatment of COVID-19 patients."

suPAR is the cleaved, blood-circulating form of the cell-surface anchored protein called urokinase plasminogen activator receptor (uPAR). Monopar recently entered into a collaboration with NorthStar Medical Radioisotopes, LLC to develop a precision Radio-Immuno-Therapeutic (RIT) based on the same antibody scaffold that is used in the prototype ELISA to detect suPAR.

The aim of the NorthStar collaboration is to develop a uPAR-targeted RIT (uPRIT) to selectively target and eradicate the aberrantly activated ("rogue") immune cells that cause the cytokine storm and subsequent severe respiratory failure and death in COVID-19 patients. These rogue immune cells seem to be making uPAR and shedding it into the blood as suPAR. Fortunately, uPAR is a protein that is not found much, if at all, on normal healthy tissue, so there is an opportunity to potentially use a uPRIT to quickly shut down the cytokine storm by selectively killing the rogue immune cells while sparing healthy cells.

"If successful, the suPAR test could serve as a companion diagnostic to Monopar's uPRIT. Specifically, the test could identify those patients who are most appropriate for the potential uPRIT treatment," said Chandler Robinson, MD, Chief Executive Officer of Monopar.

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.

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 ability to develop a test to triage COVID-19 patients into those likely versus unlikely to progress to severe respiratory failure; ATN-658’s ability to detect soluble urokinase plasminogen activator receptor (suPAR) in COVID-19 patient plasma; the suPAR test’s ability to enable the early identification of COVID-19 patients who will rapidly deteriorate and thereby greatly improve the treatment of COVID-19 patients; that identification of such high risk for respiratory failure could facilitate therapeutic interventions earlier or allow for the staging of patients to an optimal treatment based on their disease characteristics; the success, if any, of Monopar’s discussions with several parties to further develop either an ELISA or other suPAR-based test for COVID-19 patients; Monopar’s or a future collaborator’s ability to clinically validate the suPAR-based test in COVID-19 patients; Monopar’s ability to replicate results of earlier third-party studies of suPAR; that suPAR as a novel biomarker could predict outcome in diseases; that Monopar’s collaboration with NorthStar will successfully result in a uPRIT for the treatment of COVID-19; that a uPRIT could quickly shut down the cytokine storm through selectively killing the rogue immune cells while sparing healthy cells; and that the suPAR test could serve as a companion diagnostic to Monopar’s uPRIT. The forward-looking statements involve risks and uncertainties including, but not limited to, the lack of any clinical activities to date with respect to ATN-658 or MNPR-101; the requirement for additional capital to complete preclinical and clinical development, and if successful, commercialization of the suPAR test and/or the uPRIT; the uPRIT not being able to kill aberrantly activated cytokine-producing immune cells; the uPRIT 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 chosen radioisotope can be manufactured and scaled up to meet potential demand; the suPAR test being unable to detect suPAR with sufficient precision, sensitivity and/or accuracy; uncertainties about levels of demand if and when a treatment and/or test is available for commercialization and the significant general risks and uncertainties surrounding the research, development, regulatory approval and commercialization of therapeutics and diagnostics. 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 undertakes 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 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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