**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 19, 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 19, 2020, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing a partnership with Aragen Bioscience, Inc., in collaboration with NorthStar Medical Radioisotopes, LLC on the development of urokinase plasminogen activator receptor targeted radio-immuno-therapeutics (uPRITs) for the potential treatment of patients with severe COVID-19. Aragen will perform studies aimed at selecting a lead candidate uPRIT to advance into IND-enabling development 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 19, 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 19, 2020

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

# Monopar and NorthStar Partner with Aragen for Testing of Novel Potential Therapeutic for Severe COVID-19

**WILMETTE, IL, BELOIT, WI, and MORGAN HILL, CA, AUGUST 19, 2020** – Monopar Therapeutics Inc. (Nasdaq: MNPR)(Wilmette, IL) and NorthStar Medical Radioisotopes, LLC (Beloit, WI), who are collaborating on the development of **u**rokinase **p**lasminogen activator receptor targeted **r**adio-**i**mmuno-**t**herapeutics (uPRITs) for the potential treatment of patients with severe COVID-19, today announced a partnership with Aragen Bioscience, Inc. (Morgan Hill, CA), a leading contract research organization focused on accelerating preclinical biologics product development. Aragen will perform studies aimed at selecting a lead candidate uPRIT to advance into IND-enabling development for severe COVID-19.

"Aragen's expertise in this specific area of preclinical research should accelerate selection of a lead uPRIT based on the MNPR-101 antibody scaffold to advance toward the clinic," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar.

"We are pleased to partner with Aragen on this important phase of the uPRIT program," said James T. Harvey, PhD, Senior Vice President and Chief Science Officer of NorthStar. "Using rigorous criteria to select the uPRIT candidate to advance into IND-enabling studies is a crucial part of our COVID-19 program."

"uPRIT has great therapeutic potential for severe COVID-19 patients" said Axel Schleyer, PhD, MBA, Chief Executive Officer of Aragen. "We are excited to partner with Monopar and NorthStar on this important endeavor."

The aim of this partnership is to identify the uPRIT with the optimal urokinase plasminogen activator receptor binding profile, enabling selective delivery of a cytotoxic radioisotope to just those aberrantly activated immune cells that produce the "cytokine storm" that causes severe lung injury, multiple organ damage, and death in severe COVID-19 patients.

**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.northstarnm.com.

**About Aragen Bioscience, Inc.**
Aragen Bioscience, Inc., a wholly owned subsidiary of GVK BIO, is a leading contract research organization based in the San Francisco Bay Area. Aragen Bioscience offers a diverse set of *in vitro* and *in vivo* services for the discovery, cell line development, production, characterization, activity and efficacy assessment and development of biologic and diagnostic products. For more information, visit: www.aragenbio.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 Aragen’s ability to select a lead candidate uPRIT, based on the MNPR-101 antibody scaffold, into IND-enabling development and toward the clinic for severe COVID-19, that uPRIT has great therapeutic potential for severe COVID-19 patients, and the partnership’s ability to identify the uPRIT with the optimal binding profile that enables selective delivery of a cytotoxic radioisotope to just those aberrantly activated immune cells that produce the “cytokine storm” that causes severe lung injury, multiple organ damage, and death in severe COVID-19 patients. 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 Aragen 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 Aragen’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

**For Aragen Bioscience, Inc.:**
David Lustig
dlustig@aragenbio.com