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): March 30, 2021

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 March 30, 2021, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing the publication of a peer-reviewed study titled "*Engineered Antibody Fragment against the Urokinase Plasminogen Activator for Fast Delineation of Triple-Negative Breast Cancer by Positron Emission Tomography.*"

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 March 30, 2021

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: March 30, 2021

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

Monopar's uPA Antibody Fragment Radiotracer Shows Potential for PET Imaging of Breast Cancer in Preclinical Study

WILMETTE, Ill., March 30, 2021 -- Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company primarily focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients, today announced the publication of a peer-reviewed study titled "*Engineered Antibody Fragment against the Urokinase Plasminogen Activator for Fast Delineation of Triple-Negative Breast Cancer by Positron Emission Tomography."* Urokinase plasminogen activator (uPA) is an established biomarker in current breast cancer clinical practice guidelines and its presence is used to select appropriate drug treatment. This study demonstrates the potential to identify breast cancers with uPA overexpression and monitor uPA activity during treatment using PET imaging and Monopar's uPA antibody fragment radiotracer. Monopar has a panel of proprietary antibodies and antibody fragments to uPA and its receptor uPAR (such as MNPR-101).

uPA and its receptor uPAR work together to drive aggressive tumor invasion, leading to metastasis, morbidity, and mortality in breast and other cancers. However, uPA is difficult to measure and currently requires a substantial amount of fresh frozen tissue. Monopar's antibody fragment (ATN-291 $F(ab')_2$) conjugated to a copper radiotracer enabled rapid PET visualization of tumors with uPA overexpression in a human breast cancer model in mice. PET imaging may expand the current application of uPA as a breast cancer biomarker and enable the monitoring of tumor uPA expression during treatment.

"The publication demonstrates the potential utility of Monopar's uPA antibody fragments as imaging agents in a model of aggressive triple negative breast cancer," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar and a co-author of the study. "Same-day PET imaging may guide treatment decisions for breast cancer, and potentially other solid cancers, given the established role of uPA in this disease."

"We are pleased with the results of this peer-reviewed study," said Chandler Robinson, MD, Chief Executive Officer of Monopar, "and we look forward to exploring the potential of our versatile panel of uPA/uPAR targeted monoclonal antibodies in cancer imaging, cancer treatment, and other possible applications."

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 the potential for same-day PET imaging of breast cancer, including aggressive triple negative breast cancer, using Monopar's uPA-targeted antibody fragment (ATN-291 $F(ab')_2$), whether PET imaging may expand the current application of uPA as a biomarker for breast cancer and enable the monitoring of tumor uPA expression during treatment, and the potential of Monopar's versatile panel of uPA/uPAR targeted monoclonal antibodies in cancer imaging, cancer treatment, and other possible applications. The forward-looking statements involve risks and uncertainties including, but not limited to: the lack of any clinical activities to date with respect to Monopar's uPA targeted antibody fragments; that Monopar's MNPR-101 and related compound preclinical development activities to date have been focused on the treatment of cancers and not imaging medical devices; the requirement for additional capital to complete preclinical and clinical development of a medical device utilizing Monopar's uPA antibody fragments, and if successful, commercialization; if funding is available, not being able to successfully develop Monopar's antibody fragments for use as uPA imaging agents in triple negative breast cancer detection, or any other uses or indications; not being able to ensure volumes of ATN-291 $F(ab')_2$) conjugates or its derivatives can be manufactured and scaled up to meet potential demand; uncertainties about levels of demand if and when a medical device is available for commercialization and the significant general risks and uncertainties surrounding the research, development, regulatory approval and commercialization of medical devices. 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.

CONTACT:

Monopar Therapeutics Inc.:

Investor Relations
Kim R. Tsuchimoto
Chief Financial Officer
kimtsu@monopartx.com

Follow Monopar on social media for updates:

Twitter: @MonoparTx
LinkedIn: Monopar Therapeutics