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): February 11, 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 February 11, 2021, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing the publication of a peer-reviewed study in the *European Journal of Cancer* which shows the potential utility of MNPR-101 as a uPAR imaging agent to improve surgical outcomes in bladder cancer.

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 February 11, 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: February 11, 2021

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

Monopar Announces Publication Demonstrating Potential Utility of MNPR-101 as an Imaging Agent to Improve Surgical Outcomes in Bladder Cancer

WILMETTE, IL, February 11, 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 in the *European Journal of Cancer* which shows the potential utility of MNPR-101 as a uPAR imaging agent to improve surgical outcomes in bladder cancer.

Using Monopar's proprietary humanized uPAR antibody, MNPR-101, a multimodal imaging probe was developed and tested *in vivo* in human bladder cancer models. The publication reports that high expression of uPAR in bladder cancer is localized at the tumor periphery, suggesting that using a fluorescent-conjugated MNPR-101 probe might allow surgeons to better visualize the borders of the tumor, potentially resulting in more complete tumor resection and thereby minimizing relapse. Similar approaches have been utilized successfully in the resection of other tumor types, such as breast cancer.

Bladder cancer is often treated with transurethral resection to remove cancerous tissue; however, recurrence can occur in up to 78% of patients within 5 years. Up to 40% of recurrent cases develop muscle invasive disease, which has a poor prognosis and requires complete removal of the bladder. Many patients with muscle-invasive bladder cancer unfortunately go on to develop and succumb to metastatic disease.

"This novel MNPR-101 based imaging agent has promising utility in allowing surgeons to easily identify tumor margins during surgery," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar and a co-author of the publication. "Given the specificity of uPAR expression in bladder cancer versus normal bladder tissue, and its high expression at the border of the tumor, we believe imaging uPAR using MNPR-101 targeting could improve surgical outcomes and potentially reduce recurrence of the disease."

"If confirmed in a clinical setting, an imaging probe based on MNPR-101 could result in a paradigm shift, altering how urologists survey and treat bladder cancer," said Cornelis Sier, PhD, member of the Image-Guided Surgery group at Leiden University Medical Center (LUMC), and the principal investigator on the study.

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 utility of MNPR-101 as a uPAR imaging agent, whether a MNPR-101 based imaging agent could improve surgical outcomes in bladder cancer and related matters. 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 preclinical development activities to date have been focused on the treatment of cancers and not medical devices; the requirement for additional capital to complete preclinical and clinical development of a medical device utilizing MNPR-101, and if successful, commercialization; if funding is available, not being able to develop MNPR-101 for use as a uPAR imaging agent in bladder cancer or any other indications; not being able to ensure volumes of MNPR-101 conjugates 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.

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