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 18, 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**
(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 18, 2020, Monopar Therapeutics Inc. issued a press release annoucing thatit has been granted Orphan Drug Designation from the European Commission for its drug candidate camsirubicin in the treatment of soft tissue sarcoma, and the European Medicines Agency's Committee for Orphan Medicinal Products has issued its public summary of opinion for the designation. The press release is filed 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 18, 2020

SIGNATURES

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.

By: /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Chief Financial Officer

Date: February 18, 2020

Monopar Therapeutics Receives Orphan Drug Designation from the European Commission for Camsirubicin in the Treatment of Soft Tissue Sarcoma

CHICAGO, IL, February 18, 2020 – Monopar Therapeutics Inc. (NASDAQ: MNPR) today announced it has been granted Orphan Drug Designation from the European Commission for its drug candidate camsirubicin in the treatment of soft tissue sarcoma (STS), and the European Medicines Agency's Committee for Orphan Medicinal Products has issued its public summary of opinion for the designation, which can be found on the Company's website: https://www.monopartx.com/pipeline/Camsirubicin/development-strategy.

Orphan Drug Designation: is given to medicinal products that represent a significant benefit over existing treatments; are intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; and where prevalence of the condition in the European Union (EU) is less than 5 in 10,000 persons. Orphan Drug Designation benefits include protocol assistance, reduced EU regulatory filing fees and 10 years of market exclusivity. Designated orphan medicines are also eligible for conditional marketing authorization. Camsirubicin has already received orphan drug designation in the U.S. by the Food and Drug Administration (FDA), which provides for similar benefits such as fee reductions and 7 years of market exclusivity.

"We are pleased to receive Orphan Drug Designation from the European Commission as it is another important acknowledgement of the potential benefits of camsirubicin in the treatment of advanced soft tissue sarcoma (ASTS)," said Chandler Robinson, M.D., Chief Executive Officer of Monopar. "This designation complements our U.S. orphan drug designation already granted by the FDA. We look forward to initiating our previously announced Phase 2 clinical trial in ASTS in collaboration with our partner, Grupo Español de Investigación en Sarcomas (GEIS), in the first half of 2020."

Andrew Mazar, Ph.D., Chief Scientific Officer of Monopar added, "We are encouraged by camsirubicin's potential demonstrated in its early clinical data to date. As a novel analog of doxorubicin, camsirubicin has been designed to reduce the irreversible heart damage generated by doxorubicin while retaining anti-cancer activity." Dr. Mazar continued, "Doxorubicin's efficacy is highly dose dependent; however, higher cumulative doses have historically led to increased rates of irreversible heart damage. As a result, responding patients are pulled off treatment once a maximum lifetime cumulative dose has been reached. Disease progression and poor clinical outcomes in many patients is the unfortunate consequence of the maximum lifetime dose limitation. Camsirubicin offers the potential to administer drug without the risk of irreversible heart damage, thereby potentially improving efficacy by maintaining treatment in these patients as long as they demonstrate clinical benefit."

About Camsirubicin

Camsirubicin is a proprietary doxorubicin analog that is selective for topoisomerase-II alpha. It has been investigated in ASTS patients in a Phase 1 and a single arm Phase 2 clinical trial. In these studies, no camsirubicin-treated patients developed the irreversible cardiotoxicity common to doxorubicin. The most common adverse event observed in the Phase 1 study was neutropenia, which was mitigated in the Phase 2 study through the use of prophylactic G-CSF. Based on encouraging clinical results to date, Monopar has entered into a clinical trial partnership with Grupo Español de Investigación en Sarcomas (GEIS), an internationally renowned non-profit organization focused on the research and development of drugs for sarcoma cancers. GEIS will be conducting a multi-country, randomized, open-label Phase 2 clinical trial in the 1st line setting evaluating camsirubicin head-to-head against doxorubicin in patients with ASTS. Enrollment for the trial is expected to begin in the first half of 2020 and will include approximately 170 ASTS patients. The primary endpoint of the trial will be progression-free survival, with secondary endpoints that include overall survival.

About Monopar Therapeutics

Monopar Therapeutics is a clinical-stage biopharmaceutical company focused on developing proprietary therapeutics designed to improve clinical outcomes for cancer patients. The Company's pipeline consists of Validive® for the potential prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin for the potential treatment of advanced soft tissue sarcoma; and a late-stage preclinical antibody MNPR-101. 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 of camsirubicin and the timing of the GEIS clinical trial. The forward-looking statements involve risks and uncertainties including, but not limited to, the risk that camsirubicin will not replace doxorubicin as 1st line therapy for ASTS, and that enrollment of the trial will not begin in the first half of 2020, if at all. 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

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