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): November 9, 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 November 9, 2020, Monopar Therapeutics Inc. ("Monopar") issued a press release announcing a series of recently issued patents for its Phase 2b/3 clinical-stage lead product candidate, Validive (clonidine HCl mucobuccal tablet), providing claims covering "Clonidine and/or clonidine derivatives for use in the prevention and/or treatment of adverse side effects of chemotherapy".

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 November 9, 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: November 9, 2020

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

Monopar Announces Issuance of New Patents Broadening Protections For Phase 2b/3 Clinical-Stage Lead Product Candidate Validive®

Strengthens Monopar's Validive IP Portfolio To 2035

WILMETTE, IL, November 9, 2020 – 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 a series of recently issued patents for its Phase 2b/3 clinical-stage lead product candidate, Validive (clonidine HCl mucobuccal tablet). These patents, including U.S. Patent No. 10,675,271, provide claims covering "Clonidine and/or clonidine derivatives for use in the prevention and/or treatment of adverse side effects of chemotherapy".

"These recently issued patents broaden the patent protection for the use of Validive in cancer patients," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar. "Specifically, they provide protection into 2035 for the potential ability of Validive to prevent or treat common chemotherapy-associated side effects such as gastrointestinal disorders, respiratory disorders, fatigue and headache."

"According to the U.S. Centers for Disease Control and Prevention, about 650,000 cancer patients receive chemotherapy each year in the U.S., and most of these experience side-effects as a result of their treatment," said Chandler Robinson, MD, Chief Executive Officer of Monopar. "These patents expand the potential use of Validive beyond the earlier allowed claims for the prevention of oral mucositis in patients receiving chemoradiotherapy. This in turn serves to advance Monopar's mission to develop treatments that improve quality of life in cancer patients undergoing treatment."

Monopar is currently developing Validive for the prevention of chemoradiation-induced severe oral mucositis in oropharyngeal cancer patients (OPC), an indication which currently has no FDA approved treatment. Monopar's Phase 2b/3 clinical trial in OPC patients is on track to start before year-end. The recently issued patents would provide protection should Monopar determine in the future to conduct additional Validive development activities related to adverse side effects of chemotherapy beyond OPC.

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 remain on track to start the Validive Phase 2b/3 clinical trial before year-end, the potential for Validive to prevent or treat common chemotherapy-associated side effects such as gastrointestinal disorders, respiratory disorders, fatigue and headache, the potential for Validive to prevent oral mucositis in patients receiving chemoradiotherapy, the advancement of Monopar's mission to develop treatments that improve quality of life in cancer patients undergoing treatment, and that Validive patents will strengthen and provide protection for Monopar's intellectual property portfolio. The forward-looking statements involve risks and uncertainties including, but not limited to the requirement for Monopar to raise additional capital or engage a partner in order to complete future clinical development of Validive as well as potential commercialization (including if Monopar determines to expand currently contemplated development activities to other adverse side effects of chemotherapy beyond OPC), 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 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.

CONTACTS:

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