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 12, 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 2.02 Results of Operations and Financial Condition.

On November 12, 2020, Monopar Therapeutics Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2020. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the exhibit hereto are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release Dated November 12, 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 12, 2020

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

Monopar Therapeutics Reports Third Quarter 2020 Financial Results and Business Update

Validive® Phase 2b/3 Clinical Trial on Track to Start Before Year-end
Issuance of New Patents For Validive
Camsirubicin Phase 2 Clinical Trial to Start Late 2020/Early 2021

Wilmette, IL, November 12, 2020 – Monopar Therapeutics Inc. (Monopar or the Company) (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 third quarter 2020 financial results and business update.

Third Quarter Business Update

Lead Product Candidate Validive

- Monopar's Phase 2b/3 clinical trial of Validive (clonidine HCl mucobuccal tablet) for the prevention of severe oral mucositis (SOM) in patients undergoing chemoradiotherapy for oropharyngeal cancer (OPC) is on track to commence before year-end. There currently is no FDA-approved prevention or treatment for radiation-induced SOM.

- The U.S. Patent and Trademark Office allowed patent claims for Monopar's lead product candidate, Validive, covering "Clonidine and/or clonidine derivatives for use in the prevention and/or treatment of adverse side effects of chemotherapy." The recently issued patents would provide protection should Monopar determine in the future to conduct additional Validive development and commercialization activities related to adverse side effects of chemotherapy beyond OPC.

Camsirubicin

- The Phase 2 clinical trial of camsirubicin is anticipated to begin at the end of 2020 or in early 2021. Monopar has partnered with Grupo Español de Investigación en Sarcomas (GEIS), which will lead the multi-country, randomized, open-label Phase 2 clinical trial evaluating camsirubicin head-to-head against standard-of-care doxorubicin in patients with advanced soft tissue sarcoma (ASTS).

- The trial will begin with a dose escalation "run-in" prior to the randomization portion of the trial. The primary endpoint of the trial will be progression-free survival, with secondary endpoints including overall survival, response rate, and incidence of treatment-emergent adverse events.

MNPR-101

- Forward progress was made on the Monopar/NorthStar collaboration focused on developing a novel treatment for severe COVID-19 by partnering with 1) IsoTherapeutics Group, LLC to develop and manufacture radioimmunotherapeutics targeting uPAR (uPRITs), 2) Aragen Bioscience, Inc. to perform studies aimed at selecting a lead candidate uPRIT to advance into IND-enabling development, and 3) The University of Texas Health Science Center at Tyler and its Texas Lung Injury Institute (TLII) to perform *in vitro* and *in vivo* studies through the TLII and to participate in the clinical development of uPRITs.

Third Quarter Summary Financial Results

Results for the Third Quarter Ended September 30, 2020 Compared to the Third Quarter Ended September 30, 2019

Cash and Net Loss

Cash and cash equivalents as of September 30, 2020 were $18.0 million, which includes $6.7 million of net proceeds raised in the third quarter of 2020 under the Company's Capital on Demand® Sales Agreement with JonesTrading Institutional Services, at an average gross price per share of $9.66. Monopar anticipates that its current cash and cash equivalents will fund the Company's planned operations through 2021, including the initiation and completion of the Phase 2b portion of its Validive clinical trial and the initiation of the Phase 3 portion, the funding of the initiation of the GEIS Phase 2 camsirubicin clinical trial, and continuation of the development of the COVID-19 uPRIT program. The Company will need to raise funds or engage a partner to complete the Validive Phase 3 clinical trial. Net loss for the third quarter of 2020 was $1.6 million or $0.15 per share compared to net loss of $0.7 million or $0.08 per share for the third quarter of 2019.

Research and Development (R&D) Expenses

R&D expenses for the third quarter of 2020 were $1.2 million, compared to $0.2 million, for the third quarter of 2019. This increase of $1.0 million is primarily attributed to increases in expenses for the planning of the camsirubicin Phase 2 clinical trial and manufacturing expenses of $0.4 million, increases in the Validive clinical trial planning and manufacturing expenses of $0.3 million, and increases in R&D personnel salaries and benefits, including equity grants and salaries and benefits for three new R&D personnel of $0.3 million.

General and Administrative (G&A) Expenses

G&A expenses for the third quarter of 2020 were $0.4 million, compared to $0.5 million, for the third quarter of 2019.

About Monopar Therapeutics

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. The Company'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 preclinical stage uPAR targeted antibody, MNPR-101, for advanced cancers and severe COVID-19. For more information, and links to SEC filings that contain detailed financial information, visit:**https://ir.monopartx.com/quarterly-reports**.

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 commence its Phase 2b/3 clinical trial of Validive before the end of 2020, whether the recently issued patents would provide protection for development and commercialization in potential future indications, GEIS’s ability to begin the camsirubicin Phase 2 clinical trial at the end of 2020 or early 2021, whether the Monopar/NorthStar collaboration will be successful in developing a uPRIT to treat severe COVID-19 with its development partners and whether the Company’s current cash and cash equivalents will fund the Company’s planned operations through 2021. The forward-looking statements involve risks and uncertainties including, but not limited to, not commencing the Validive Phase 2b/3 clinical trial or the Phase 2 GEIS-sponsored camsirubicin clinical trial within expected timeframes, if at all, our ability to commence the Validive Phase 3 portion without additional fundraising or a development partnership, to raise sufficient funds or engage a partner to complete the Phase 3 clinical trial, and not successfully developing a COVID-19 uPRIT with the Company’s development collaborators. 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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