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 25, 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 2.02 Results of Operations and Financial Condition.

On March 25, 2021, Monopar Therapeutics Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 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 March 25, 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 25, 2021

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

Monopar Therapeutics Reports Fourth Quarter and Full-Year 2020 Financial Results and Recent Business Updates

Validive® Phase 2b/3 VOICE Clinical Trial Commenced
Camsirubicin Phase 2 Clinical Trial Anticipated to Start in Q2 2021
MNPR-101-Conjugate Data Published in European Journal of Cancer

Wilmette, IL, March 25, 2021 – 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 fourth quarter and full-year 2020 financial results and recent business updates.

Recent Business Updates

Lead Product Candidate Validive

- Monopar's Phase 2b/3 VOICE clinical trial of Validive (clonidine HCl mucobuccal tablet) for the prevention of severe oral mucositis (SOM) in patients undergoing chemoradiotherapy (CRT) for oropharyngeal cancer (OPC) dosed its first patient in February 2021 and is actively recruiting patients and initiating additional clinical trial sites. There is no FDA-approved prevention or treatment for CRT-induced SOM.

- The U.S. Patent and Trademark Office (USPTO) allowed patent claims for Validive, covering "Clonidine and/or clonidine derivatives for use in the prevention and/or treatment of adverse side effects of chemotherapy." This patent expands coverage on the potential use of Validive in cancer patients beyond earlier allowed claims specifically for the prevention of oral mucositis in patients receiving CRT.

Camsirubicin

- The Phase 2 clinical trial of camsirubicin is anticipated to commence enrollment in the second quarter of 2021. Monopar's clinical development collaborator, Grupo Español de Investigación en Sarcomas (GEIS), 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 an open-label 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.

- The USPTO allowed patent claims covering compositions of matter (2-pyrrilino camsirubicin) for a novel family of camsirubicin analogs. This patent expires in 2038, not including any patent term extensions. The patent broadens Monopar's camsirubicin portfolio and covers a pipeline of compounds designed to retain the potentially favorable non-cardiotoxic chemical backbone of camsirubicin along with the potent broad-spectrum antitumor activity of doxorubicin. Preclinical evidence suggests that this new family of 2-pyrrilino camsirubicin analogs could be active against doxorubicin-resistant tumor cells which may enable use in cancer types beyond those treatable with camsirubicin.

MNPR-101 and Related Compounds

- Progress continues in the Monopar/NorthStar Medical Radioisotopes collaboration focused on developing a novel treatment for severe COVID-19 by partnering with (i) IsoTherapeutics Group, LLC to develop and manufacture humanized urokinase plasminogen activator receptor radioimmunotherapeutics (uPRITs), (ii) Aragen Bioscience, Inc. which performed studies to enable the selection of a lead candidate uPRIT along with back-up candidates to potentially advance into IND-enabling development, and (iii) The University of Texas Health Science Center at Tyler and its Texas Lung Injury Institute (TLII) to perform *in vitro* and *in vivo* studies and to participate in the clinical development of uPRITs.

- The *European Journal of Cancer* published a peer-reviewed preclinical study which shows the potential utility of MNPR-101 conjugates as uPAR imaging agents to improve surgical outcomes in bladder cancer and for surveillance post-resection.

Results for the Fourth Quarter and Year Ended December 31, 2020 Compared to the Fourth Quarter and Year Ended December 31, 2019

Cash and Net Loss

Cash and cash equivalents as of December 31, 2020 were $16.7 million. Monopar anticipates that its current cash and cash equivalents, which includes an additional $10.9 million of net proceeds raised in the first quarter of 2021 under the Company's Capital on Demand® Sales Agreement with JonesTrading Institutional Services, at an average gross price per share of $10.20, will fund the Company's planned operations at least through March 2022. Planned operations include funding and completing the Phase 2b portion of the Validive "VOICE" clinical trial and commencing of the Phase 3 portion; the funding of the run-in portion of the GEIS Phase 2 camsirubicin clinical trial; and continuation of the development of the COVID-19 uPRIT program along with other MNPR-101 related compounds. The Company plans to raise additional funds or engage a partner in the next 12 months to complete the VOICE clinical program and continue the GEIS camsirubicin clinical trial beyond the run-in phase.

Net loss for the fourth quarter of 2020 was $2.1 million or $0.19 per share compared to net loss of $1.2 million or $0.13 per share for the fourth quarter of 2019. Net loss for the year ended December 31, 2020 was $6.3 million or $0.58 per share compared to net loss of $4.2 million or $0.45 per share for the year ended December 31, 2019.

Research and Development (R&D) Expenses

R&D expenses for the fourth quarter of 2020 were $1.6 million compared to $0.6 million for the fourth quarter of 2019. This increase of $1.0 million is primarily attributed to increases in expenses of $0.5 million for the planning of the GEIS camsirubicin Phase 2 clinical trial including manufacturing, $0.2 million for the VOICE clinical trial planning and manufacturing costs, and $0.3 million for R&D personnel salary and benefits.

R&D expenses for the year ended December 31, 2020 were $4.1 million compared to $2.0 million for the year ended December 31, 2019. This represents an increase of approximately $2.1 million primarily attributed to increases in expenses of $1.1 million for the planning of the GEIS camsirubicin Phase 2 clinical trial including manufacturing, $0.1 million for the VOICE clinical trial planning and manufacturing costs, and $0.9 million for R&D personnel salary and benefits.

General and Administrative (G&A) Expenses

G&A expenses for the fourth quarter of 2020 were $0.6 million, equal to $0.6 million for the fourth quarter of 2019.

G&A expenses for the year ended December 31, 2020 were $2.4 million, equal to $2.4 million for the year ended December 31, 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 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 in the second quarter of 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 March 2022. The forward-looking statements involve risks and uncertainties including, but not limited to, not successfully recruiting patients and initiating additional clinical trial sites for the VOICE clinical trial or the Phase 2 GEIS-sponsored camsirubicin clinical trial within expected timeframes, if at all; the Company’s inability to raise sufficient funds or engage a partner to complete the Phase 3 portion of the VOICE clinical trial and continue the GEIS camsirubicin 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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