

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): May 13, 2021

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-39070
(Commission File Number)

32-0463781
(I.R.S. Employer Identification No.)

**1000 Skokie Blvd., Suite 350, Wilmette,
IL 60091**
(Address of principal executive offices)

60091
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 May 13, 2021, Monopar Therapeutics Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2021. 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 May 13, 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: May 13, 2021

By: /s/ Kim R. Tsuchimoto

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



Monopar Therapeutics

Monopar Therapeutics Reports First Quarter 2021 Financial Results and Recent Business Updates

First Patient Dosed in Validive® Phase 2b/3 VOICE Clinical Trial Camsirubicin Run-in Clinical Trial Now Planned to Start in 2H 2021 Potential Utility Reported for MNPR-101 as Imaging Agent in Cancer Surgery

Wilmette, IL, May 13, 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 first quarter 2021 financial results and recent business updates.

Recent Business Updates

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 a new patent with 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 uses of Validive in cancer patients beyond earlier allowed claims limited specifically to the prevention and/or treatment of oral mucositis in patients receiving CRT.

Camsirubicin and Novel Analogs

- Based on the Company's current inability to gain regulatory approval to initiate the camsirubicin Phase 2 clinical trial in Spain, Monopar is evaluating alternatives to move the dose escalation run-in clinical trial forward outside of Spain. Monopar believes that it will be able to initiate the run-in clinical trial in the second half of 2021 in the U.S. or another country.
- The USPTO allowed a new patent with claims covering compositions of matter for a novel family of camsirubicin analogs (2-pyrilino camsirubicins). 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-pyrilino camsirubicin analogs could be active against doxorubicin-resistant tumor cells and thereby may enable use in cancer types beyond those treatable with doxorubicin.

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 (1) IsoTherapeutics Group, LLC to develop, optimize and manufacture humanized urokinase plasminogen activator receptor radioimmunotherapeutics (uPRITs), (2) 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 (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 and to participate in the potential clinical development of uPRITs.
- A peer-reviewed preclinical study that reported the potential utility of MNPR-101 conjugates as uPAR imaging agents to improve surgical outcomes in bladder cancer and for surveillance post-resection was published in *The European Journal of Cancer*. This publication builds on previous studies using conjugates of MNPR-101 and its mouse analog, ATN-658, for the optical imaging of oral and colon cancer.
- A peer-reviewed study titled "*Engineered Antibody Fragment against the Urokinase Plasminogen Activator for Fast Delineation of Triple-Negative Breast Cancer by Positron Emission Tomography*" demonstrated the potential to identify breast cancers with urokinase plasminogen activator (uPA) overexpression, and monitor uPA expression during treatment using positron emission tomography (PET) imaging along with the Company's uPA antibody fragment radiotracer.

Results for the First Quarter Ended March 31, 2021 Compared to the First Quarter Ended March 31, 2020

Cash and Net Loss

Cash and cash equivalents as of March 31, 2021 were \$25.7 million. Monopar anticipates that its current cash and cash equivalents, which includes \$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 major programs at least through June 2022, including: funding and completing the Phase 2b portion of the VOICE clinical trial and commencing of the Phase 3 portion; funding the camsirubicin run-in clinical trial; continuing advancement of the COVID-19 uPRIT program; and developing other MNPR-101 related compounds and technologies. The Company plans to raise additional funds and/or engage a partner within the next 12 months to complete the VOICE clinical program and continue the camsirubicin clinical development beyond the run-in clinical trial.

Net loss for the first quarter of 2021 was \$1.9 million or \$0.16 per share compared to net loss of \$1.1 million or \$0.10 per share for the first quarter of 2020.

Research and Development (R&D) Expenses

R&D expenses for the first quarter of 2021 were \$1.2 million compared to \$0.3 million for the first quarter of 2020. This increase of \$0.9 million was primarily attributed to increases of (1) \$0.3 million for the planning of the GEIS-sponsored camsirubicin Phase 2 clinical trial including drug product manufacturing, (2) \$0.3 million for R&D personnel expenses, (3) \$0.2 million for the VOICE clinical trial and manufacturing-related expenses, and (4) \$0.1 million for other R&D operating expenses.

General and Administrative (G&A) Expenses

G&A expenses for the first quarter of 2021 were \$0.7 million, a nominal decrease from \$0.8 million of G&A expenses for the first quarter of 2020.

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, our ability to begin the camsirubicin run-in clinical trial in the second half 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 major programs through June 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 camsirubicin clinical program 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 camsirubicin clinical program; not successfully developing a COVID-19 uPRIT with the Company's development collaborators and not successfully developing MNPR-101 conjugates and related compounds for various potential indications and technologies. 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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