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): August 12, 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 August 12, 2021, Monopar Therapeutics Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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 August 12, 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: August 12, 2021

By: /s/ Kim R. Tsuchimoto

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

Exhibit 99.1

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

Camsirubicin Phase 1b Clinical Trial Anticipated to Start in the U.S. in Q4 2021
Validive® Phase 2b/3 VOICE Trial on Track for Reaching Interim Analysis in H1 2022

Wilmette, IL, August 12, 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 second 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 successfully reached its target of 20 activated clinical trial sites for the Phase 2b portion of the trial. Monopar plans to activate additional clinical trial sites, potentially including sites outside of the U.S. There is no FDA-approved prevention or treatment for CRT-induced SOM. The VOICE trial is on track for reaching interim analysis in the first half of 2022.

Camsirubicin and MNPR-202 and Related Analogs

- The U.S. Food and Drug Administration cleared Monopar to proceed under its Investigational New Drug (IND) application with an open-label Phase 1b dose-escalation clinical trial evaluating camsirubicin plus growth factor support (pegfilgrastim) in patients with advanced soft tissue sarcoma (ASTS). Monopar anticipates dosing the first patient in the fourth quarter of 2021.

- Monopar entered into a collaboration agreement with the Cancer Science Institute of Singapore, one of Asia's premier cancer research centers, at the National University of Singapore (consistently ranked as one of the world's top universities) to evaluate the activity of MNPR-202 and related analogs in preclinical models of multiple types of cancer. MNPR-202, a camsirubicin analog, was designed to retain the same potentially non-cardiotoxic backbone as camsirubicin but is modified at other positions which may enable it to be efficacious in certain cancers that are resistant to camsirubicin and doxorubicin. MNPR-202 and related analogs are covered under a newly issued U.S. composition of matter patent (US10,450,340).

MNPR-101 RIT and Related Compounds

- Monopar and NorthStar Medical Radioisotopes, LLC (NorthStar) filed a provisional patent application with the U.S. Patent and Trademark Office (USPTO) titled "Bio-Targeted Radiopharmaceutical Compositions Containing Ac-225 and Methods of Preparation." Radiopharmaceutical therapy is a promising approach to treat cancer and other diseases using radioactive metals bound to proteins/antibodies to target and kill cells. Actinium-225 (Ac-225) is emerging as a radioactive isotope of choice for radiopharmaceuticals due to favorable properties such as its long half-life and selective induction of localized tumor cell death.

- Monopar and NorthStar filed a provisional composition of matter patent application titled "Urokinase Plasminogen Activator Receptor-Targeted Radiopharmaceutical" covering a radiotherapeutic consisting of Monopar's proprietary antibody MNPR-101 bound to Ac-225 via the metal binding agent PCTA. This radioimmunotherapeutic (RIT) has demonstrated 98% radiochemical purity and high stability, and has the potential to be a highly selective, potent treatment for a variety of cancers, severe COVID-19, and other diseases characterized by aberrant urokinase plasminogen activator receptor expression.

Additions to Monopar's Executive Management Team

- Monopar appointed Andrew Cittadine, MBA, as its Chief Operating Officer. Mr. Cittadine is an experienced healthcare executive and serial entrepreneur who has founded or led multiple healthcare businesses from concept through acquisition by Fortune Global 1000 firms. These include founding two successful diagnostic imaging companies, Sensant Corp. and American Biooptics, where he also served as CEO, and led both through stock or asset acquisitions by Siemens and Olympus, respectively. He also served as CEO of a critical care company, SonarMed, which was acquired by Medtronic. Mr. Cittadine brings to Monopar considerable leadership experience, including managing manufacturing and quality systems implementation, executing multi-center clinical trials, and achieving regulatory clearances for new technologies in both the U.S. and Europe.

- Monopar appointed Octávio Costa, MD, as its Chief Medical Officer. Dr. Costa joined Monopar with over 30 years of experience overseeing clinical development, clinical operations, development strategy and global medical affairs. He has extensive Phase 1 through Phase 4 clinical development expertise and related regulatory experience. Dr. Costa's previous roles include positions of increasing responsibility in clinical development at Merck, Celgene, Novartis and most recently as Chief Medical Officer at Rafael Pharmaceuticals. He has played an important role in the development and life-cycle management of significant marketed oncology products, including the blockbuster product REVLIMID® (lenalidomide) in Latin America.

Results for the Second Quarter Ended June 30, 2021, Compared to the Second Quarter Ended June 30, 2020

Cash and Net Loss

Cash and cash equivalents as of June 30, 2021, were $24.3 million. Monopar anticipates that its current cash and cash equivalents will fund the Company's major programs at least through September 2022, including: completing the Phase 2b portion of the VOICE clinical trial and commencing of the Phase 3 portion; funding the camsirubicin Phase 1b clinical trial; continuing advancement of the MNPR-101 RIT program including related compounds; continuing the development of MNPR-101 and related technologies in cancer; and developing MNPR-202 and related analogs in various cancers. 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 Phase 1b clinical trial.

Net loss for the second quarter of 2021 was $2.1 million or $0.17 per share compared to net loss of $1.4 million or $0.14 per share for the second quarter of 2020.

Research and Development (R&D) Expenses

R&D expenses for the second quarter of 2021 were $1.4 million compared to $0.8 million for the second quarter of 2020. This increase of $0.6 million was primarily attributed to increases of (1) $0.3 million for VOICE clinical trial expenses, (2) $0.2 million for R&D personnel expenses, and (3) $0.1 million for planning of the Phase 1b camsirubicin clinical trial including regulatory and manufacturing-related expenses.

General and Administrative (G&A) Expenses

G&A expenses for the second quarter of 2021 were $0.6 million, essentially the same as the G&A expenses for the second 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; a late-stage preclinical antibody, MNPR-101, for advanced cancers and severe COVID-19; and an early-stage camsirubicin analog, MNPR-202, for various cancers. 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 plans to activate additional clinical trial sites potentially including sites outside of the U.S.; that the VOICE trial is on track for reaching interim analysis in the first half of 2022; that Monopar anticipates dosing the first patient in its Phase 1b camsirubicin clinical trial in the fourth quarter of 2021; and that Monopar’s cash and cash equivalents will fund major programs at least through September 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 Phase 1b 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 camsirubicin clinical program beyond the Phase 1b clinical trial; not successfully developing the MNPR-101 RIT or MNPR-202 with the Company’s development collaborators; not successfully developing MNPR-101 and potential technologies in cancer; 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.

Contact

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