

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 6, 2020

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 August 6, 2020, Monopar Therapeutics Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 6, 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: August 6, 2020

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



Monopar Therapeutics

Monopar Therapeutics Reports Second Quarter 2020 Financial Results and Business Updates

Collaboration Formed to Develop COVID-19 Therapeutic with Monopar's Proprietary MNPR-101 Technology

CHICAGO, IL, August 6, 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 second quarter 2020 financial results and business updates.

Second Quarter and Recent Highlights

Collaboration with NorthStar Medical Radioisotopes to Develop Potential Therapeutic for Severe COVID-19 and Other Respiratory Diseases

- o Monopar and NorthStar entered into a 50/50 collaboration to develop potential Radio-Immuno-Therapeutics (RITs) to treat severe COVID-19.
- o Monopar will provide its pre-IND stage humanized uPAR targeted monoclonal antibody, known as MNPR-101, and NorthStar will supply a cytotoxic radioisotope. The aim is to create a highly selective agent that has the potential to kill aberrantly activated cytokine-producing immune cells thought to be largely responsible for the severe lung injury that contributes to poor outcomes and death in patients with severe COVID-19.
- o Provisional patent has been filed that covers novel compositions and uses of cytotoxic radioisotopes attached to antibodies that bind to uPAR, thereby creating precision targeted radio-immuno-therapeutics (uPRITs) for the treatment of severe COVID-19 and other respiratory diseases.

Validive Phase 2b/3 Clinical Trial and Camsirubicin Phase 2 Clinical Trial Continue on Schedule

- o Monopar's two clinical-stage programs both continue to be on schedule for first patient dosing in the second half of 2020.

Second Quarter Summary Financial Results

Results for the Quarter Ended June 30, 2020 Compared to the Quarter Ended June 30, 2019

Cash and cash equivalents as of June 30, 2020 were \$12.5 million. Net loss for the three months ended June 30, 2020 was \$1.4 million or \$0.14 per share compared to net loss of \$0.9 million or \$0.10 per share for the three months ended June 30, 2019.

Research and Development (R&D) Expenses

R&D expenses for the three months ended June 30, 2020 were \$0.8 million, compared to \$0.3 million, for the three months ended June 30, 2019. This represents an increase of \$0.5 million primarily attributed to increases in camsirubicin and Validive clinical trial planning and materials manufacturing costs and increases in personnel expenses for three new R&D employees and higher salary and stock-based (non-cash) compensation for 2020.

General and Administrative (G&A) Expenses

G&A expenses for the three months ended June 30, 2020 were \$0.6 million, compared to \$0.6 million, for the three months ended June 30, 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 the potential for NorthStar Medical Radioisotopes' development collaboration to develop a COVID-19 uPRIT and the Company's ability to dose first patients in the Validive and camsirubicin clinical trials in the second half of 2020. The forward-looking statements involve risks and uncertainties including, but not limited to, not successfully developing a COVID-19 uPRIT with the Company's development collaborator, and not commencing the Validive Phase 2b/3 clinical trial and Phase 2 GEIS-sponsored camsirubicin clinical trial in the second half of 2020, if at all, and not commencing the Validive Phase 3 portion subject to fundraising and partnership efforts, if at all. 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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