August 12, 2025

Monopar Therapeutics Reports Second Quarter 2025 Financial Results and Recent Developments

WILMETTE, Ill., Aug. 12, 2025 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. ("Monopar" or the "Company") (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for patients with unmet medical needs, today announced second quarter 2025 financial results and recent developments.

Recent Developments

ALXN1840 for Wilson Disease

On June 6, 2025, Alexion Pharmaceuticals officially transferred sponsorship of the investigational new drug ("IND") application for ALXN1840 to Monopar. The U.S. Food and Drug Administration ("FDA") acknowledged this change on July 29, 2025, confirming that the transfer was effective as of June 6, 2025. Monopar is now fully responsible for the program, including its commercial advancement and compliance with all applicable federal regulations.

Monopar is preparing to submit a New Drug Application ("NDA") to the FDA in early 2026.

MNPR-101 for Radiopharmaceutical Use

The Company's MNPR-101-Zr Phase 1 (imaging and dosimetry) and MNPR-101-Lu (therapeutic) Phase 1a clinical trials in advanced cancers are active and enrolling in Australia, and the Company's Expanded Access Program (also referred to as compassionate use) for MNPR-101-Zr and MNPR-101-Lu is active and enrolling in the U. S. Monopar continues its preclinical work with MNPR-101-Ac (therapeutic) with plans to enter the clinic in the future.

Financial Results for the Second Quarter Ended June 30, 2025, Compared to the Second Quarter Ended June 30, 2024

Cash and Net Loss

Cash, cash equivalents and investments as of June 30, 2025, were $53.3 million. Monopar expects that its current funds will be sufficient to continue operations at least through December 31, 2026, in order to: (1) assemble a regulatory package and file an NDA for ALXN1840; (2) continue to conduct and conclude its first-in-human imaging and dosimetry clinical trial with MNPR-101-Zr; (3) continue to conduct its first-in-human therapeutic clinical trial of MNPR-101-Lu; (4) advance its preclinical MNPR-101-Ac program into the clinic; and (5) invest in internal research and development projects to expand its radiopharmaceutical and rare disease pipeline.

Net loss for the second quarter of 2025 was $2.5 million or $0.35 per share compared to net

loss of $1.7 million or $0.49 per share for the second quarter of 2024.

Research and Development ("R&D") Expenses

R&D expenses for the second quarter of 2025 were $1,730,000, compared to $1,130,978 for the second quarter of 2024. This represents an increase of $599,023 attributed to (1) a $636,300 increase in R&D personnel expenses including stock-based compensation, partially offset by (2) a net decrease of $37,277 in other R&D expenses.

General and Administrative ("G&A") Expenses

G&A expenses for the second quarter of 2025 were $1,504,295, compared to $657,806 for the second quarter of 2024. This represents an increase of $846,489 primarily attributed to (1) a $370,103 increase in Board compensation resulting from the grant of stock options in March 2025 (no stock options were granted to the Board in 2024), (2) a $255,650 increase in G&A personnel expenses including stock-based compensation, (3) a $114,322 increase in legal fees, (4) a $63,200 increase in state franchise taxes, (5) a $41,416 increase in insurance expenses and (6) a net increase of $1,798 in other G&A expenses.

Interest Income

Interest income for the three months ended June 30, 2025, increased by $707,294 compared to the same period in 2024. The increase is attributed to interest earned on U.S. Treasury securities and higher bank balances in 2025, resulting from over $55 million of funds raised in the fourth quarter of 2024.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company with late-stage ALXN1840 for Wilson disease, and radiopharmaceutical programs including Phase 1-stage MNPR-101-Zr for imaging advanced cancers, and Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac for the treatment of advanced 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: that Monopar is responsible for advancing the program commercially; that Monopar is preparing to submit an NDA to the FDA in early 2026; that Monopar continues its preclinical work with MNPR-101-Ac with the plan to enter the clinic in the future; and that Monopar expects that its current funds will be sufficient to continue operations at least through December 31, 2026. The forward-looking statements involve risks and uncertainties including, but not limited to: uncertainties related to the regulatory process that Monopar intends to initiate related to ALXN1840 and the outcome

thereof; the rate of market acceptance and competitiveness in terms of pricing, efficacy and safety, of any products for which Monopar receives marketing approval, and Monopar's ability to competitively market any such products as compared to larger pharmaceutical firms; Monopar's ability to raise sufficient funds in order for the Company to support continued preclinical, clinical, regulatory, precommercial and commercial development of its programs and to make contractual milestone payments, as well as its ability to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of imaging agents and 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:

Monopar Therapeutics Inc.
Investor Relations
Quan Vu
Chief Financial Officer
vu@monopartx.com

Follow Monopar on social media for updates:

X: @MonoparTx LinkedIn: Monopar Therapeutics

Monopar Therapeutics

Source: Monopar Therapeutics Inc.