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Monopar Therapeutics Reports Third Quarter 2025 Financial Results and Recent Developments

WILMETTE, Ill., Nov. 13, 2025 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. ("Monopar" or the "Company") (Nasdaq: MNPR), a clinical-stage biopharmaceutical company developing innovative treatments for patients with unmet medical needs, today announced third quarter 2025 financial results and recent developments.

Recent Developments

ALXN1840 for Wilson Disease

On September 14-15, 2025, the Company presented new data on the long-term neurological efficacy and safety of ALXN1840 (tiomolybdate choline) at the 150th American Neurological Association (ANA) Annual Meeting. Matthew Lorincz, M.D., Ph.D., Professor of Neurology and Co-Director of the Wilson Disease Center of Excellence at the University of Michigan delivered the poster and oral presentations. The new findings presented at ANA highlight the long-term neurological benefit of ALXN1840, and follow the European Association for the Study of the Liver (EASL) International Liver Congress presentation in May on the long-term hepatic and systemic safety and efficacy data. Together, these findings underscore the potential of ALXN1840 to favorably impact both neurological and hepatic manifestations of Wilson disease.

On November 9, 2025, the Company presented new data and analyses from the Phase 2 ALXN1840-WD-204 copper balance study at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2025. In an oral presentation titled "*Rapidly Improved Cu Balance in Wilson Disease Patients on Tiomolybdate Choline,*" Professor Aftab Ala, MBBS, M.D., FRCP, Ph.D., Professor of Hepatology and Consultant Hepatologist at the Institute of Liver Studies at King's College Hospital in London, shared results showing that treatment with ALXN1840 led to a rapid and sustained improvement in daily copper balance in patients with Wilson disease, primarily through increased fecal copper excretion.

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

MNPR-101 for Radiopharmaceutical Use

On September 26, 2025, Monopar received FDA clearance on its IND application for MNPR-101-Lu, which covers the protocol titled "*Phase 1, Open-Label, Multicenter, Dosimetry and Dose-Escalation Trial to Characterize the Safety, Tolerability, and Anti-Tumor Activity of Fractionated MNPR-101-Lu Dosing in the Treatment of uPAR-Expressing Advanced or Metastatic Solid Tumors.*" This IND incorporates the Company's proprietary linker technology, which has been designed to enhance the stability and biodistribution of its therapeutic radiopharmaceuticals.

Recent Financing Capital Raise and Share Repurchase

On September 23, 2025, the Company priced an underwritten public offering (the "Offering") consisting of (i) 1,034,433 shares of its common stock and (ii) pre-funded warrants to purchase 960,542 shares of common stock, pursuant to an underwriting agreement (the "Underwriting Agreement") with Morgan Stanley & Co. LLC, Leerink Partners LLC, and Barclays Capital Inc. (the "Underwriters"). The public offering price was $67.67 per share and $67.669 per pre-funded warrant, which represents the per share offering price less a $0.001 per share exercise price. The aggregate net proceeds from the Offering were approximately $126.9 million, after deducting underwriting discounts and commissions but before offering expenses and the Share Repurchase (as defined below).

On September 24, 2025, the Company entered into a share purchase agreement (the "Share Purchase Agreement") with Tactic Pharma LLC ("Tactic Pharma"), an existing significant stockholder that held approximately 13.4% of the Company's common stock prior to the Offering and Share Repurchase. Pursuant to the Share Purchase Agreement, the Company used $35 million of the Offering proceeds to repurchase 550,229 shares of its common stock from Tactic Pharma at a purchase price of $63.6098 per share, which equals the public offering price per share less underwriting discounts and commissions (the "Share Repurchase"). After giving effect to the Share Repurchase, the Company's net proceeds from the Offering were approximately $91.9 million, before estimated offering expenses.

Financial Results for the Third Quarter Ended September 30, 2025, Compared to the Third Quarter Ended September 30, 2024

Cash and Net Loss

Cash, cash equivalents and investments as of September 30, 2025, were $143.7 million. Monopar expects that its current funds will be sufficient to continue operations at least through December 31, 2027, in order to: (1) assemble a regulatory package and file an NDA for the ALXN1840 investigational drug candidate for Wilson disease; (2) continue to conduct and conclude our first-in-human imaging and dosimetry clinical trial with MNPR-101-Zr, continue to conduct our first-in-human therapeutic clinical trial of MNPR-101-Lu, and advance our preclinical MNPR-101-Ac program into the clinic; and (3) invest in internal R&D projects to expand our radiopharmaceutical pipeline.

Net loss for the third quarter of 2025 was $3.4 million or $0.48 per share compared to net loss of $1.3 million or $0.37 per share for the third quarter of 2024.

Research and Development ("R&D") Expenses

R&D expenses for the third quarter of 2025 were $2,589,749, compared to $984,278 for the third quarter of 2024. This represents an increase of $1,605,471 attributed to (1) a $937,582 increase in manufacturing activities related to ALXN1840, (2) a $617,667 increase in R&D personnel expenses including stock-based compensation and (3) a net increase of $50,223 in other R&D expenses.

General and Administrative ("G&A") Expenses

G&A expenses for the third quarter of 2025 were $1,503,326, compared to $590,624 for the

third quarter of 2024. This represents an increase of $912,702 primarily attributed to (1) a $369,959 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 $287,749 increase in G&A personnel expenses including stock-based compensation, and (3) a net increase of $254,993 in other G&A expenses.

Interest Income

Interest income for the third quarter of 2025 increased by $556,129 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, as a result of the approximately $91.9 million raised in the Offering after giving effect to the Share Repurchase, deducting underwriting discounts and commissions but before offering expenses.

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 together, these findings underscore the potential of ALXN1840 to favorably impact both neurological and hepatic manifestations of Wilson disease; that Monopar is preparing to submit a New Drug Application (“NDA”) to the FDA in early 2026; that the MNPR-101-Lu IND incorporates the Company’s proprietary linker technology, which has been designed to enhance the stability and biodistribution of its therapeutic radiopharmaceuticals; and that Monopar expects that its current funds will be sufficient to continue operations at least through December 31, 2027. 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.

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