MBX Biosciences Reports Fourth Quarter and Full Year 2024 Financial Results and Recent Corporate Highlights

March 17, 2025

Enrollment complete in Phase 2 Avail™ trial of canvuparatide in hypoparathyroidism; topline results on track for Q3 2025

MBX 1416 Phase 2 trial in patients with post-bariatric hypoglycemia expected to begin in 2H 2025

Investigational New Drug submission anticipated in Q2 2025 for MBX 4291 in obesity

$262.1 million in cash, cash equivalents and marketable securities as of December 31, 2024; expected to support operations into mid-2027

CARMEL, Ind., March 17, 2025 (GLOBE NEWSWIRE) -- MBX Biosciences, Inc. (Nasdaq: MBX), a clinical-stage biopharmaceutical company focused on the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders, today reported financial results for the fourth quarter and full year ended December 31, 2024, and highlighted recent corporate progress.

"MBX is entering 2025 with strong momentum following significant and transformational progress in 2024," said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. "We are poised to deliver Phase 2 clinical data on our lead program in hypoparathyroidism, canvuparatide, with topline results from our Avail™ trial anticipated in the third quarter of 2025. Additionally, we are well-positioned to enter the clinic with our first obesity candidate later this year, pending clearance of our investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA). Finally, we look forward to initiating a Phase 2 trial evaluating MBX 1416 in post-bariatric hypoglycemia (PBH) patients in the second half of 2025."

Fourth Quarter 2024 and Recent Corporate Highlights

Hypoparathyroidism (HP): Canvuparatide (MBX 2109)

- **Completed Enrollment in Phase 2 Avail Trial in HP patients:** In March 2025, MBX announced the completion of enrollment of 64 patients with HP in the Phase 2 Avail trial of canvuparatide, the Company's potential long-acting parathyroid once-weekly hormone (PTH) peptide prodrug. Topline results from the randomized, double-blind, placebo-controlled 12-week trial are anticipated in the third quarter of 2025.
- **Published Phase 1 Trial Results:** In December 2024, MBX announced the publication of a peer-reviewed article highlighting results from the Phase 1 study of canvuparatide titled "MBX 2109, a Once-Weekly Parathyroid Hormone Replacement Therapy Prodrug: Phase 1, First-in-Human, Randomized Trial" in *The Journal of Clinical Endocrinology and Metabolism (JCEM)* and can be accessed here.

Post-bariatric Hypoglycemia (PBH): MBX 1416

- **Positive results from MBX 1416 Phase 1 trial support Phase 2 advancement:** In January 2025, the Company announced positive topline results from its Phase 1 single ascending dose and multiple ascending dose clinical trial of MBX 1416 in healthy adult volunteers. MBX 1416 is the Company's long-acting glucagon-like peptide 1 (GLP-1) receptor antagonist in development for the treatment of PBH. MBX anticipates initiating a Phase 2 study of MBX 1416 in patients with PBH in the second half of 2025 following completion of an End-of-Phase 1 meeting with the FDA.

Obesity: MBX 4291

- **IND filing on track for Q2 2025**: MBX expects to submit an IND application to the FDA in the second quarter of 2025 for MBX 4291, the Company's GLP-1/GIP co-agonist prodrug for the potential once-monthly treatment of obesity.

Corporate

- **Leadership Team Additions:** In March 2025, the Company announced the appointments of Chatan Charan, Ph.D. as Senior Vice President, Pharmaceutical Development and Chemistry, Manufacturing and Controls and Mark Hope as Senior Vice President, Regulatory and Quality, adding additional expertise in support of the company's ongoing advancement and expansion of its novel product candidates.

Fourth Quarter and Full Year 2024 Financial Results

- *Cash and Cash Equivalents and Marketable Securities*: As of December 31, 2024, MBX Biosciences had cash, cash equivalents and marketable securities of $262.1 million. Based on its current operating plan, the Company expects the combined cash, cash equivalents and marketable securities balance to fund operations into mid-2027.
- *R&D Expenses*: Research and development expenses for the three months and full year ended December 31, 2024, were $15.2 million and $57.4 million, respectively, compared to $7.7 million and $28.5 million for the same periods in 2023. The increases of $7.5 million and $28.9 million, respectively, were driven by costs associated with ongoing IND-enabling studies for MBX 4291 and the ongoing canvuparatide Phase 2 clinical trial.
- *G&A Expenses*: General and administrative expenses for the three months and full year ended December 31, 2024, were $3.4 million and $10.8 million, respectively, compared to $2.3 million and $6.8 million for the same periods in 2023. The

increases of $1.1 million and $4.0 million, respectively, were driven by increased personnel-related costs as the Company expanded its infrastructure to support its growth in operations.

- *Net Loss*: Net loss for the three months ended December 31, 2024, was $15.6 million compared to a net loss of $8.8 million for the same period in 2023. Net loss for the full year ended December 31, 2024 was $61.9 million compared to a net loss of $32.6 million for the same period in 2023.

About MBX Biosciences
MBX Biosciences is a biopharmaceutical company focused on the discovery and development of novel precision peptide therapies based on its proprietary PEP™ platform, for the treatment of endocrine and metabolic disorders. The Company is advancing a pipeline of novel candidates for endocrine and metabolic disorders with clinically validated targets, established endpoints for regulatory approval, significant unmet medical needs and large potential market opportunities. The Company's pipeline includes its lead product candidate canvuparatide (MBX 2109), in Phase 2 development for the treatment of chronic hypoparathyroidism (HP); MBX 1416, in Phase 1 development for the treatment of post-bariatric hypoglycemia (PBH); and an obesity portfolio that includes MBX 4291, with an IND filing anticipated in Q2 2025, as well as multiple discovery and pre-clinical candidates in development for the treatment of obesity. The Company is based in Carmel, Indiana. To learn more, please visit the Company website at www.mbxbio.com and follow it on LinkedIn.

About MBX's Proprietary Precision Endocrine Peptide (PEP™) Platform
MBX was founded by global leaders with a transformative approach to peptide drug design and development. Leveraging this expertise, the Company designed its proprietary Precision Endocrine Peptide™ (PEP™) platform to overcome the key limitations of unmodified and modified peptide therapies and to improve clinical outcomes and simplify disease management for patients. PEPs are selectively engineered to have optimized pharmaceutical properties, including extended time-action profiles and consistent drug concentrations with low peak-to-trough concentration ratios, consistent exposure to target tissues, and less frequent dosing.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding: MBX Biosciences' expectations regarding the Phase 2 Avail™ trial of canvuparatide, including enrollment and the timing of topline results; statements related to the potential for canvuparatide to be a once-weekly PTH replacement therapy; the expected timing for the Phase 2 trial for MBX 1416 and statements related to an end-of-phase 1 meeting with the FDA; statements related to the ability of MBX 1416 to be a treatment of PBH; the expected timing of the IND filing for MBX 4291 and initiation of a Phase 1 trial thereafter; statements related to the contribution of leadership; and expectations regarding MBX Biosciences' uses of capital, expenses and financial results, including the anticipated cash runway timing.

Forward looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect MBX Biosciences' business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to the Company's research and development activities; MBX Biosciences' ability to execute on its strategy including obtaining the requisite regulatory approvals on the expected timeline, if at all; uncertainties relating to preclinical and clinical development activities; the Company's dependence on third parties to conduct clinical trials, manufacture its product candidates and develop and commercialize its product candidates, if approved; MBX Biosciences' ability to attract, integrate and retain key personnel; risks related to the Company's financial condition and need for substantial additional funds in order to complete development activities and commercialize a product candidate, if approved; risks related to regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; risks related to establishing and maintaining MBX Biosciences' intellectual property protections; and risks related to the competitive landscape for MBX Biosciences' product candidates; as well as other risks described in "Risk Factors," in MBX Biosciences' Quarterly Report on Form 10-Q for the nine months ended September 30, 2024 filed with the Securities and Exchange Commission (SEC), its Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC, as well as subsequent filings with the SEC. MBX Biosciences expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law, and claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

MBX uses and intends to continue to use its Investor Relations website as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor the Company's Investor Relations website, in addition to following the Company's press releases, SEC filings, public conference calls, presentations, and webcasts.

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MBX BIOSCIENCES, INC.
SELECTED FINANCIAL INFORMATION

Statements of Operations Data:
(in thousands, except share and per share data)
(Unaudited)

	Three months ended December 31,		Year ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 15,223	$ 7,727	$ 57,415	$ 28,534

General and administrative	3,387	2,264	10,779	6,777
Total operating expenses	18,610	9,991	68,194	35,311
Loss from operations	(18,610)	(9,991)	(68,194)	(35,311)
Interest and other income, net	3,024	1,148	6,272	2,748
Net loss	$ (15,586)	$ (8,843)	$ (61,922)	$ (32,563)
Net loss per common share, basic and diluted	$ (0.47)	$ (7.74)	$ (5.82)	$ (31.96)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	33,392,615	1,143,186	10,642,954	1,018,787

Balance Sheets Data
(In thousands)
(Unaudited)

	December 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 262,149	$ 80,676
Working capital(1)	256,235	79,539
Total assets	268,535	84,180
Total liabilities	11,093	4,291
Convertible preferred stock	-	152,357
Accumulated deficit	(137,505)	(75,583)
Total stockholders equity (deficit)	257,442	(72,468)

(1) Working capital is defined as total current assets less total current liabilities. See our financial statements and the related notes thereto included in our Annual Report on Form 10-K for the Year Ending December 31, 2024 for further details regarding our current assets and current liabilities.