# MBX Biosciences Reports First Quarter 2025 Financial Results and Recent Corporate Highlights

May 12, 2025

*Topline results for the Phase 2 Avail™ evaluating canvuparatide in patients with hypoparathyroidism expected in 3Q 2025*

*Investigational New Drug submission for MBX 4291 on track for 2Q 2025*

*$240.8 million in cash, cash equivalents and marketable securities as of March 31, 2025; expected to support operations into mid-2027*

CARMEL, Ind., May 12, 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 first quarter ended March 31, 2025, and highlighted recent corporate progress.

"We've followed up on our strong execution in 2024 with excellent progress on all our programs enabled by a strong balance sheet and cash position," said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. "Following full enrollment of the Phase 2 Avail trial investigating canvuparatide for the treatment of hypoparathyroidism, we look forward to reporting top line results in the third quarter of 2025. We're also on track to submit our investigational new drug (IND) application this quarter for MBX 4291, a novel glucagon-like peptide 1 (GLP-1)/glucose-dependent insulinotropic polypeptide (GIP) co-agonist prodrug for treating obesity. In addition to these milestones, we also expect to begin a Phase 2 trial for MBX 1416 in post-bariatric hypoglycemia patients in the second half of this year and share further details on our additional obesity candidates currently in pre-clinical development."

**First Quarter 2025 and Recent Corporate Highlights**

Hypoparathyroidism (HP): Canvuparatide (MBX 2109)

- **Phase 2 topline data from Avail trial expected in 3Q 2025.** MBX completed enrollment of 64 participants, exceeding its original enrollment target, in the Phase 2 Avail trial of canvuparatide, a potential long-acting parathyroid once-weekly hormone peptide prodrug candidate, in the first quarter of 2025. Topline results are expected in the third quarter of 2025.

Obesity: MBX 4291

- **IND application submission on track for Q2 2025:** MBX 4291, a GLP-1/GIP co-agonist prodrug, is being developed as a once-monthly treatment for obesity. The Company expects to submit an IND application for MBX 4291 this quarter.

Post-bariatric Hypoglycemia (PBH): MBX 1416

- **Phase 2 trial expected to be initiated in 2H 2025:** In January, MBX reported Phase 1 top line results for its MBX 1416 long-acting GLP-1 receptor antagonist developed for the treatment of PBH. A Phase 2 trial is expected to be initiated in the second half of 2025 following completion of an End of Phase 1 meeting with the U.S. Food & Drug Administration (FDA).

Corporate

- **New Independent Director**: Earlier in April, MBX announced the appointment of Steve Hoerter as an independent director to the Company's board of directors. As a veteran executive with a wealth of pharmaceutical leadership and commercialization, as well as extensive board experience, Mr. Hoerter will be instrumental in supporting MBX Biosciences during the next stage of the Company's growth.

**First Quarter 2025 Financial Results**

- *Cash and Cash Equivalents and Marketable Securities*: As of March 31, 2025, MBX Biosciences had cash, cash equivalents and marketable securities of $240.8 million. Based on its current operating plan, management 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 ended March 31, 2025, were $22.4 million compared to $11.0 million for the same period in 2024. The increase of $11.4 million was driven by costs associated with ongoing IND-enabling studies for MBX 4291 and the ongoing Phase 2 Avail trial of canvuparatide.

- *G&A Expenses*: General and administrative expenses for the three months ended March 31, 2025, were $4.1 million compared to $2.3 million for the same period in 2024. The increase of $1.8 million was 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 March 31, 2025, was $23.9 million compared to a net loss of $12.3 million for the same period in 2024.

**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 canvuparatide (MBX 2109) for the treatment of chronic hypoparathyroidism (HP) in Phase 2 development; MBX 1416 for the treatment of post-bariatric hypoglycemia (PBH) in Phase 1 development; and an obesity portfolio that includes MBX 4291, with an IND filing anticipated in Q2 2025, as well as multiple discovery and pre-clinical obesity candidates. 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 the timing of topline results; the expected timing of the IND application submission for MBX 4291; statements related to MBX 2491 being developed as a once-monthly treatment for obesity; expectations regarding development of MBX Biosciences' additional obesity candidates currently in pre-clinical development; the expected timing for the Phase 2 trial for MBX 1416 in PBH patients; statements related to the ability of MBX 1416 to be a treatment of PBH; statements related to the contribution of MBX Biosciences' leadership and board of directors; 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 three months ended March 31, 2025 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:** | **(Unaudited) Three months ended March 31,** | |
|---|---|---|
| *(in thousands, except per share and per share data)* | **2025** | **2024** |
| Operating expenses: | | |
| Research and development | $ 22,405 | $ 11,049 |
| General and administrative | 4,124 | 2,265 |
| Total operating expenses | 26,529 | 13,314 |
| Loss from operations | (26,529) | (13,314) |
| Interest and other income, net | 2,649 | 977 |
| Net loss | $ (23,880) | $ (12,337) |
| Net loss per common share, basic and diluted | $ (0.71) | $ (10.26) |
| Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted | 33,412,386 | 1,202,396 |

**(Unaudited)**

| **Balance Sheets Selected Financial Data:** | **March 31,** | **December 31,** |
|---|---|---|
| *(in thousands)* | **2025** | **2024** |
| Cash, cash equivalents and marketable securities | $ 240,786 | $ 262,149 |
| Working capital(1) | 233,795 | 256,235 |
| Total assets | 245,926 | 268,535 |
| Total liabilities | 10,504 | 11,093 |
| Accumulated deficit | (161,385) | (137,505) |
| Total stockholders' equity | 235,422 | 257,442 |

(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 Quarterly Report on Form 10-Q for the Three Months Ending March 31, 2025 and Year Ending December 31, 2024 for further details regarding our current assets and current liabilities.