



MBX Biosciences Reports Fourth Quarter and Full-Year 2025 Financial Results and Recent Corporate Highlights

March 12, 2026

Phase 3 trial of once-weekly canvuparatide remains on track to initiate in Q3 2026 following recently completed, successful End-of-Phase 2 meeting with FDA

12-week MAD Phase 1 data from MBX 4291 for obesity anticipated in Q4 2026

Planned nomination of amycretin and GLP-1/GIP/glucagon receptor triple-agonist development candidates for obesity expected in Q2 and Q3 2026

\$459.1 million in pro forma cash and investments as of December 31, 2025, including \$85.4 million in net proceeds from top-tier institutional investors through ATM program; expected to support operations into 2029

CARMEL, Ind., March 12, 2026 (GLOBE NEWSWIRE) -- MBX Biosciences, Inc. (Nasdaq: MBX), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization 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, 2025, and highlighted recent corporate progress.

"2025 was a year of continued growth and execution for MBX, highlighted by the clinical validation of our Precision Endocrine Peptide (PEP™) platform," said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. "Following a successful End-of-Phase 2 meeting with the FDA, we now have a clear path to initiate our Phase 3 trial of once-weekly canvuparatide. We are also advancing a growing obesity pipeline, built on our clinically validated PEP™ platform and designed for once-monthly dosing and improved tolerability. We look forward to a data-rich year ahead and to continuing our pursuit of bringing differentiated and best-in-class medicines to patients."

Fourth Quarter 2025 and Recent Corporate Highlights

Once-Weekly Canvuparatide for Hypoparathyroidism (HP)

- **End-of-Phase 2 FDA meeting for once-weekly canvuparatide completed:** FDA feedback supported advancement into a Phase 3 trial and trial design elements have now been selected, including the number of patients, primary endpoint and key secondary endpoints, as well as dose selection, titration schedule and duration of the study. Initiation of the Phase 3 program remains on track for Q3 2026.
- **EU Orphan Drug Designation granted for canvuparatide:** The European Medicines Agency granted orphan drug designation to canvuparatide for the treatment of chronic hypoparathyroidism, supporting its continued clinical development in Europe.
- MBX expects to present the complete 12-week dataset and one-year follow-up data from the Phase 2 Avail™ trial for once-weekly canvuparatide at a medical conference in Q2 2026.

MBX4291 and Early Pipeline Programs for Obesity

- **MBX 4291 advancing through Phase 1:** MBX 4291, a GLP-1/GIP co-agonist prodrug designed for potential once-monthly dosing, continues to advance through Phase 1, with 12-week multiple ascending dose data on track to be reported in Q4 2026.
- **Obesity portfolio expansion planned in 2026:** MBX expects to nominate two additional obesity development candidates enabled by its PEP™ platform, each designed for potential once-monthly dosing with improved tolerability, including an amycretin prodrug targeted for nomination in Q2 2026 and a GLP-1/GIP/glucagon receptor (GCGR) triple-agonist prodrug candidate targeted for nomination in Q3 2026.

Long-Acting Imapexotide (MBX 1416) for Post-Bariatric Hypoglycemia (PBH)

- **Phase 2a trial of imapexotide (MBX 1416) ongoing:** Results from the ongoing Phase 2a STEADI™ trial of potential once-weekly imapexotide for post-bariatric hypoglycemia are expected in Q2 2026.

Corporate

- **Board Appointment:** In January 2026, the Company announced the appointment of Laurie Stelzer to its Board of Directors as an independent director and Audit Committee Chair, adding strategic, commercial, and financial leadership to support the Company's advancement toward late-stage development and long-term growth objectives.
- **Leadership Addition:** In March 2026, MBX announced the appointment of Karen Basbaum, MBA, as Chief Business Officer. Ms. Basbaum brings more than two decades of leadership in corporate strategy, business development, and strategic transactions across the biotechnology and pharmaceutical industries.
- **Strengthened Balance Sheet:** In February 2026, the Company raised \$85.4 million in net proceeds through its At-the-Market (ATM) facility, with participation from new and existing institutional investors.

Anticipated Milestones

- Canvuparatide
 - Q2 2026: Presentation of full Phase 2 Avail™ results at a medical conference, including data from the open-label extension
 - Q3 2026: Initiation of Phase 3 trial in chronic hypoparathyroidism
- MBX 4291 and Early Obesity Pipeline
 - Q2 2026: Nomination of amycretin prodrug candidate
 - Q3 2026: Nomination of GLP-1/GIP/GCGR triple-agonist prodrug candidate
 - Q4 2026: Results from 12-week multiple ascending dose portion of Phase 1 trial of MBX 4291
- Imapexide
 - Q2 2026: Phase 2a STEADI™ trial results of imapexide for the treatment of post-bariatric hypoglycemia

Fourth Quarter and Full Year 2025 Financial Results

- *Cash and Cash Equivalents and Marketable Securities*: As of December 31, 2025, MBX Biosciences had cash, cash equivalents and marketable securities of \$373.7 million. Subsequently, on February 4, 2026, the Company raised an additional \$85.4 million in net proceeds through its ATM program, resulting in pro forma cash and investments of \$459.1 million as of December 31, 2025. Based on its current operating plan, the Company expects the combined cash, cash equivalents and marketable securities balance to fund operations into 2029.
- *R&D Expenses*: Research and development expenses for the three months and full year ended December 31, 2025, were \$19.8 million and \$79.2 million, respectively, compared to \$15.2 million and \$57.4 million for the same periods in 2024. The increases of \$4.6 million and \$21.8 million respectively were driven by costs associated with the ongoing MBX 4291 Phase 1 clinical trial, the canvuparatide Phase 2 Avail™ clinical trial and preparation activities for a Phase 3 clinical trial in canvuparatide.
- *G&A Expenses*: General and administrative expenses for the three months and full year ended December 31, 2025, were \$6.0 million and \$18.9 million, respectively, compared to \$3.4 million and \$10.8 million for the same periods in 2024. The increases of \$2.6 million and \$8.1 million, respectively, were driven by increased personnel-related costs as the Company expanded its infrastructure to support its growth in operations and higher professional fees to support operations as a public company.
- *Net Loss*: Net loss for the three months ended December 31, 2025, was \$22.1 million compared to a net loss of \$15.6 million for the same period in 2024. Net loss for the full year ended December 31, 2025 was \$87.0 million compared to a net loss of \$61.9 million for the same period in 2024.

About MBX Biosciences

MBX Biosciences is a biopharmaceutical company focused on the discovery, development and commercialization 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) preparing for Phase 3 development; an obesity portfolio that includes MBX 4291 in Phase 1 development, as well as multiple discovery and pre-clinical obesity candidates; and imapexide (MBX 1416) for the treatment of post-bariatric hypoglycemia (PBH) in Phase 2 development. 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 further advancement of its pipeline of programs in endocrine and metabolic disorders, including timing of initiation of a Phase 3 trial for canvuparatide in Q3 2026 and clinical data presentation in Q2 2026; statements regarding MBX Biosciences' delivery of differentiated endocrine and metabolic compounds allow patient freedom; MBX Biosciences' pro forma cash and investments as a result of sales under the ATM program; the contributions of its board of directors; the potential for canvuparatide to be a once-weekly PTH replacement therapy; the expected timing of the Phase 1 readout for MBX 4291 and candidate nominations; the potential for MBX Biosciences to develop therapies for obesity dosed once monthly; the expected timing for the Phase 2a STEADI™ trial results; the ability of MBX 1416 to be a treatment of PBH; 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; risks related to the competitive landscape for MBX Biosciences' product candidates; and final audit adjustments and other developments that may arise that would cause MBX Biosciences' expectations with respect to the estimate of cash, cash equivalents and marketable securities as of December 31, 2025 to differ,

perhaps materially, from the financial results that will be reflected in MBX Biosciences' audited consolidated financial statements for the fiscal year ended December 31, 2025; as well as other risks described in "Risk Factors," in MBX Biosciences' Quarterly Report on Form 10-Q for the three months ended September 30, 2025, Annual Report on Form 10-K for the year ended December 31, 2025, as well as subsequent filings filed with the Securities and Exchange Commission (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 Biosciences 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.

Media Contact:

George Shea
 We. Communications
gshea@wecommunications.com

Investor Contact:

Jim DeNike
 MBX Biosciences
jdenike@mbxbio.com

**MBX BIOSCIENCES, INC.
 SELECTED FINANCIAL INFORMATION**

Statements of Operations Data: <i>(in thousands, except per share and per share data)</i>	(Unaudited)			
	Three months ended December 31,		Year ended December 31,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 19,759	\$ 15,223	\$ 79,159	\$ 57,415
General and administrative	6,036	3,387	18,896	10,779
Total operating expenses	25,795	18,610	98,055	68,194
Loss from operations	(25,795)	(18,610)	(98,055)	(68,194)
Interest and other income, net	3,733	3,024	11,084	6,272
Net loss	\$ (22,062)	\$ (15,586)	\$ (86,971)	\$ (61,922)
Net loss per common share, basic and diluted	\$ (0.49)	\$ (0.47)	\$ (2.38)	\$ (5.82)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	44,866,468	33,392,615	36,506,092	10,642,954

Balance Sheets Selected Financial Data: <i>(in thousands)</i>	(Unaudited)	
	December 31,	December 31,
	2025	2024
Cash, cash equivalents and marketable securities	\$ 373,705	\$ 262,149
Working capital(1)	366,044	256,235
Total assets	385,144	268,535
Total liabilities	15,921	11,093
Accumulated deficit	(224,476)	(137,505)
Total stockholders' equity	369,223	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 Annual Report on Form 10-K for the Years Ending December 31, 2025 and December 31, 2024 for further details regarding our current assets and current liabilities.