MBX Biosciences Reports Third Quarter 2025 Financial Results and Recent Corporate Highlights

November 6, 2025

Reported positive topline results from the Phase 2 Avail™ trial of once-weekly canvuparatide in hypoparathyroidism (HP)

Completed upsized public offering, raising approximately $200 million in gross proceeds

$391.7 million in cash, cash equivalents and marketable securities as of September 30, 2025; expected to support operations into 2029

Updated 2026 corporate milestones include clinical data for three Precision Endocrine Peptide ™(PEP) programs and initiation of a Phase 3 trial in HP

CARMEL, Ind., Nov. 06, 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 third quarter ended September 30, 2025, and highlighted recent corporate progress.

"The third quarter of 2025 marked another quarter of significant execution as we reported positive topline results from our Phase 2 Avail™ trial of once-weekly canvuparatide," said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. "These strong results support our belief that canvuparatide has the potential to be best-in-class in hypoparathyroidism, an estimated multibillion dollar market. We are preparing for meetings with US and EU regulatory agencies, initiation of our Phase 3 trial and future commercialization. With a clinically validated PEP™ platform, and cash runway into 2029, MBX is well positioned to execute on our value-creating milestones in 2026 across our pipeline and become a leading, fully integrated endocrine and metabolic disease biopharma company."

In November 2025, the Company's board of directors appointed Steve Hoerter to serve as executive chairperson, to support the Company's executive team with his perspective and commercialization experience, as the Company prepares for the start of a Phase 3 trial and begins pre-commercial activities. Mr. Hoerter joined the Company's board of directors earlier this year, bringing more than 30 years of pharmaceutical commercialization and executive leadership experience, most recently as President and Chief Executive Officer of Deciphera Pharmaceuticals until its $2.4 billion acquisition by Ono Pharmaceutical in 2024. Jim Cornelius also retired from the board as of October 31, 2025, after more than five years of valuable service.

Third Quarter 2025 and Recent Corporate Highlights

Hypoparathyroidism (HP): Canvuparatide (MBX 2109)

- **Positive topline results from Phase 2 Avail™ trial of once-weekly canvuparatide support Phase 3 advancement:** The Company announced that once-weekly canvuparatide achieved the primary composite endpoint in the Phase 2 Avail™ trial in adults with hypoparathyroidism, with 63% of canvuparatide-treated patients achieving responder status at 12 weeks, and 79% achieving responder status at six months in the ongoing open-label extension study. Canvuparatide is the Company's potential once-weekly parathyroid hormone (PTH) peptide prodrug.
- The Company expects to conduct an End of Phase 2 meeting with the U.S. Food and Drug Administration and Scientific Advice with the European Medicines Agency in Q1 2026. The Company also intends to present Avail™ Phase 2 results at a medical meeting in Q2 2026; report one-year results from its ongoing canvuparatide open-label extension study in Q2 2026; and initiate a Phase 3 trial in Q3 2026.

Obesity: MBX 4291

- **Dosed first participant in Phase 1 trial of MBX 4291 for the treatment of obesity (NCT07142707)**: The Company initiated its first clinical trial in obesity with the dosing of the first participant in the Phase 1 study of MBX 4291, a Precision Endocrine Peptide™ (PEP™) glucagon-like peptide-1 (GLP-1)/glucose-dependent insulinotropic polypeptide (GIP) co-agonist prodrug. The three-part, randomized, double-blind, placebo-controlled trial is designed to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple ascending (SAD and MAD) doses in adults with obesity.
- **Planned 12-week MAD portion:** Following completion of Parts A and B, the Company plans to evaluate multiple ascending doses of MBX 4291, or matching placebo, administered over 12 weeks in up to two cohorts consisting of 30 participants each in a 2:1 randomization ratio. Participants are expected to receive up to a total of 12 study intervention administrations one week or one week and one month apart with increasing doses of MBX 4291 and will be followed for 120 days after the first dose. Results from the planned 12-week MAD portion are expected in Q4 2026.

Post-bariatric Hypoglycemia (PBH): Imapextide (MBX 1416)

- **Dosed first patient in Phase 2a STEADI™ trial of imapextide (MBX1416) for post-bariatric hypoglycemia (NCT07029412):** The Company initiated a Phase 2a, open-label exploratory study to evaluate preliminary efficacy of subcutaneous imapextide in patients with PBH. Approximately ten patients aged 18 to 65 years with a history of hypoglycemia following Roux-en-Y or sleeve gastrectomy will be included in the study. Participants will undergo three mixed-meal tolerance tests, one at baseline and again 48 hours after each imapextide administration, to evaluate the effect of imapextide on increasing post-prandial glucose nadir. Imapextide's effect in reducing post-prandial insulin and C-peptide peaks will also be evaluated. Results are expected in Q2 2026.

Corporate

- **Completed upsized public offering:** The Company completed an upsized public offering of its common stock, raising approximately $200 million in gross proceeds before deducting underwriting discounts, commissions, and other offering expenses.

Anticipated Milestones

- Canvuparatide
  - Q1 2026: End of Phase 2 meeting and EMA Scientific Advice
  - Q2 2026: Presentation of Phase 2 results at a medical meeting
  - Q2 2026: Phase 2 one-year open label extension study data
  - Q3 2026: Phase 3 canvuparatide HP trial initiation
- MBX 4291
  - Q4 2026: Results from 12-week multiple ascending dose portion of Phase 1 trial of MBX 4291 for the treatment of obesity
- Imapextide
  - Q2 2026: Phase 2a STEADI™ trial results of imapextide for the treatment of post-bariatric hypoglycemia (PBH)

Third Quarter 2025 Financial Results

- *Cash and Cash Equivalents and Marketable Securities*: As of September 30, 2025, the Company had cash, cash equivalents and marketable securities of $391.7 million, which includes proceeds from its upsized public offering. Based on its current operating plan, management expects the combined cash and marketable securities balance to fund operations into 2029.
- *R&D Expenses*: Research and development expenses for the three months ended September 30, 2025, were $19.3 million compared to $16.7 million for the same period in 2024. The increase of $2.6 million was driven by costs associated with the ongoing MBX 4291 Phase 1 clinical trial and the canvuparatide Phase 2 clinical trial.
- *G&A Expenses*: General and administrative expenses for the three months ended September 30, 2025, were $4.7 million compared to $2.9 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 as a public company.
- *Net Loss*: Net loss for the three months ended September 30, 2025, was $21.6 million compared to a net loss of $18.1 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) preparing for Phase 3 development; imapextide (MBX 1416) for the treatment of post-bariatric hypoglycemia (PBH) in Phase 2 development; and an obesity portfolio that includes MBX 4291 in Phase 1 development, 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 trial of canvuparatide, including timing of results from the open-label extension and timing of initiation of a Phase 3 trial; the potential for canvuparatide to be a best-in-class, once-weekly PTH replacement therapy; the expected timing of results from the Phase 2a trial for imapextide; statements related to the ability of imapextide to be a treatment of PBH; the expected timing of results from the Phase 1 trial for MBX 4291; 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 September 30, 2025, Annual Report on Form 10-K for the year ended December 31, 2024 filed with the Securities and Exchange Commission (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 September 30,		**Nine months ended September 30,**	
(in thousands, except per share and per share data)	**2025**	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 19,270	$ 16,747	$ 59,400	$ 42,192
General and administrative	4,656	2,865	12,860	7,392
Total operating expenses	23,926	19,612	72,260	49,584
Loss from operations	(23,926)	(19,612)	(72,260)	(49,584)
Interest and other income, net	2,308	1,470	7,351	3,248
Net loss	$ (21,618)	$ (18,142)	$ (64,909)	$ (46,336)
Net loss per common share, basic and diluted	$ (0.63)	$ (2.78)	$ (1.93)	$ (15.42)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	34,198,597	6,515,616	33,688,669	3,004,382

Balance Sheets Selected Financial Data:	**(Unaudited)**	
	September 30,	**December 31,**
(in thousands)	**2025**	**2024**
Cash, cash equivalents and marketable securities	$ 391,673	$ 262,149
Working capital(1)	385,440	256,235
Total assets	400,076	268,535
Total liabilities	12,538	11,093
Accumulated deficit	(202,414)	(137,505)
Total stockholders' equity	387,538	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 Quarter Ending September 30, 2025 and Year Ending December 31, 2024 for further details regarding our current assets and current liabilities.