UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 07, 2024

MBX Biosciences, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-42272**	**84-1882872**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11711 N. Meridian Street **Suite 300** **Carmel, Indiana** **(Address of Principal Executive Offices)**	**46032** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (317) 659-0200

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	MBX	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 7, 2024, MBX Biosciences, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2024. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information included under Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto), is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release Issued by MBX Biosciences, Inc. on November 7, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MBX BIOSCIENCES, INC.

Date: November 7, 2024

By: /s/ P. Kent Hawryluk

President and Chief Executive Officer (Principal Executive Officer)

Exhibit 99.1

MBX Biosciences Reports Third Quarter 2024 Financial Results and Provides Business Update

Total gross proceeds from upsized initial public offering and Series C financing were approximately $251.2 million

Last subject last visit in Phase 1 trial of MBX 1416 anticipated by late November; topline results to be reported in early January 2025

Enrollment of Phase 2 Avail™ trial of MBX 2109 in hypoparathyroidism on track to complete in Q1 2025; topline results anticipated in Q3 2025

Strong cash position, with $277.1 million expected to support operations into mid-2027

CARMEL, Ind., November 7, 2024 (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, 2024, and highlighted recent progress.

“The third quarter of 2024 has been transformational for MBX, as we transitioned to a publicly traded company and advanced our clinical-stage precision peptide programs,” said Kent Hawryluk, President and Chief Executive Officer of MBX Biosciences. “Our team is committed to delivering on our upcoming clinical milestones, including completion of the last subject visit in the Phase 1 trial of MBX 1416 anticipated by late November, and we expect to report top line results for this trial in early January 2025. In addition, enrollment in the Phase 2 trial of MBX 2109 in patients with hypoparathyroidism is on track to be complete in the first quarter of 2025, and we continue to expect topline results in the third quarter of 2025. The capital raised in our initial public offering in September and our Series C financing in August enables us to execute on these clinical milestones and advance the development of our early-stage pipeline programs, including our obesity portfolio, as we aim to overcome limitations of current therapies and improve the standard of care.”

Third Quarter 2024 and Recent Business Highlights

MBX 2109

- **Presented the rationale and design of the Phase 2 Avail™ trial of MBX 2109:** In September 2024, the Phase 2 Avail trial of MBX 2109, the Company’s potential long-acting parathyroid hormone (PTH) peptide prodrug, in adults with hypoparathyroidism

(HP) was featured in a poster presentation at the American Society for Bone and Mineral Research 2024 Annual Meeting held in Toronto, ON, Canada.

- **Initiated Phase 2 Avail trial of MBX 2109**: In August 2024, the Company announced that the first patient was dosed in the Phase 2 Avail trial of MBX 2109. Enrollment is expected to complete in the first quarter of 2025 with topline results expected in the third quarter of 2025.

MBX 1416

- **Last Subject Last Visit in MBX 1416 Phase 1 trial anticipated by late November 2024:** MBX expects the last subject visit to be completed by the end of November in the Phase 1 single and multiple ascending dose trial of MBX 1416, the Company's long-acting glucagon-like peptide 1 (GLP-1) receptor antagonist in development for the treatment of post-bariatric hypoglycemia. The Company plans to announce topline results in early January 2025.

MBX 4291

- **Progressing MBX 4291 IND-enabling studies**: MBX is in the process of completing investigational new drug (IND) enabling studies for its GLP-1/GIP co-agonist prodrug MBX 4291 for the potential treatment of obesity and expects to submit an IND application to the U.S. Food and Drug Administration in the second quarter of 2025. The Company also has additional programs in the lead optimization stage of development for the treatment of obesity and associated comorbidities.

Corporate

- **Completed upsized initial public offering (IPO) and Series C financing:** In September 2024, MBX completed its IPO following its Series C financing in August. Total gross proceeds from the Initial Public Offering and Series C financing were approximately $251.2 million.

Third Quarter 2024 Financial Results

- *Cash and Cash Equivalents and Marketable Securities:* As of September 30, 2024, MBX had cash, cash equivalents and marketable securities of $277.1 million compared to $80.7 million as of December 31, 2023. 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 September 30, 2024, were $16.7 million compared to $9.1 million for the same period in 2023. The increase of $7.7 million was driven by costs associated with ongoing IND-enabling studies for MBX 4291 and the ongoing MBX 2109 Phase 2 clinical trial.

- *G&A Expenses:* General and administrative expenses for the three months ended September 30, 2024, were $2.9 million compared to $1.9 million for the same period in 2023. The increase of $1.0 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 September 30, 2024, was $18.1 million compared to a net loss of $10.2 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 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, 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 MBX 2109, including the timing of patient enrollment and topline results, the Phase 1 trial of MBX 1416, including the timing of the last subject visit and topline results, IND-enabling studies in MBX 4291, including MBX Biosciences' intention to submit an IND and the timing related thereto, and other product candidates in the lead optimization stage; and expectations regarding MBX Biosciences' uses of capital, expenses and financial results, including the expected cash runway.

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' Registration Statement on Form S-1 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.

CONDENSED FINANCIAL INFORMATION
(Unaudited)

Condensed Statements of Operations Data:	Three months ended September 30,		Nine months ended September 30,	
(in thousands, except per share and per share data)	2024	2023	2024	2023
Operating expenses				
Research and development	$ 16,747	$ 9,073	$ 42,192	$ 20,807
General and administrative	2,865	1,872	7,392	4,513
Total operating expenses	19,612	10,945	49,584	25,320
Loss from operations	(19,612)	(10,945)	(49,584)	(25,320)
Interest and other income, net	1,470	783	3,248	1,600
Net loss	$ (18,142)	$ (10,162)	$ (46,336)	$ (23,720)
Net loss per common share, basic and diluted	$ (2.78)	$ (9.40)	$ (15.42)	$ (24.28)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	6,515,616	1,081,349	3,004,382	976,824

Condensed Balance Sheet Data:	September 30, 2024	December 31, 2023
	(in thousands)	
Cash, cash equivalents and marketable securities	$ 277,063	$ 80,676
Working capital[(1)]	270,250	79,539
Total assets	282,400	84,180
Total liabilities	11,032	4,291
Convertible preferred stock	—	152,357
Accumulated deficit	(121,919)	(75,583)
Total stockholders' equity (deficit)	271,368	(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 Quarterly Report on Form 10-Q for the Quarter Ending September 30, 2024 for further details regarding our current assets and current liabilities.