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): January 10, 2025

RHYTHM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38223**	**46-2159271**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

222 Berkeley Street
12th Floor
Boston, MA 02116
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(857) 264-4280**

N/A
(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, $0.001 par value per share	RYTM	The Nasdaq Stock Market LLC (Nasdaq Global 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 January 10, 2025, Rhythm Pharmaceuticals, Inc. (the "Company") issued a press release announcing, among other things, the Company's preliminary unaudited net product revenues for the fourth quarter of 2024 and the fiscal year ended December 31, 2024. The full text of the press release issued by the Company is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

On January 10, 2025, in connection with its participation in the J.P. Morgan Healthcare Conference, the Company posted a corporate slide presentation in the "Investors" portion of its website at www.rhythmtx.com. A copy of the presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information contained in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.2) shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 8.01. Other Events.

On January 10, 2025, the Company announced preliminary unaudited net revenues from global sales of IMCIVREE® (setmelanotide) of approximately $42 million for the fourth quarter of 2024, an increase of 26% on a sequential basis from the third quarter of 2024, and approximately $130 million for the full year of 2024. The sequential quarter-over-quarter increase was due to growth in reimbursed patients on therapy and inventory growth in the United States. U.S. sales of IMCIVREE contributed approximately 74% of the fourth quarter preliminary unaudited net product revenues and approximately 73% of the full year 2024 preliminary unaudited net product revenues.

The Company also provided the following clinical development updates:

- The Company is on track to report topline data from its Phase 3 trial evaluating setmelanotide in acquired hypothalamic obesity (the "Phase 3 acquired HO trial") in the first half of 2025.

- The Company completed enrollment in the supplemental, 12-patient Japanese cohort of the Phase 3 acquired HO trial. Data from this supplemental cohort will serve as the basis for a regulatory submission in Japan.

- The Company anticipates enrolling the first patients with congenital HO in a 34-week substudy of the Phase 3 acquired HO trial in the first quarter of 2025. This substudy is independent from the Phase 3 acquired HO trial.

- The Company completed enrollment in the Phase 3 EMANATE trial, which is comprised of four substudies: SH2B1 (n=121); POMC and/or PCSK1 (n=79); SRC1 (n=73); and LEPR (n=23). The four-substudy design of this trial allows for independent data readouts and potential registration for each genetic cohort. The primary endpoint for each substudy is the difference in mean percent change in BMI from baseline to 52 weeks in the setmelanotide arm compared to the placebo arm. The Company anticipates reporting topline data from the Phase 3 EMANATE trial in the first half of 2026.

- The Company plans to initiate a new, 26-week, open-label Phase 2 trial evaluating setmelanotide for treatment of Prader-Willi Syndrom ("PWS") in the first quarter of 2025. The Company plans to enroll up to 20 patients with PWS and obesity aged 6 to 65 years old. Patients will be dose escalated to 5 mg/day, as tolerated. The

primary endpoints are safety and tolerability. Key secondary endpoints will assess weight, hyperphagia, behavior and pharmacokinetics. This trial will be conducted at a single site in the United States.

- PWS is a rare genetic disorder that results in a number of physical, mental and behavioral problems. A key feature of PWS is a constant sense of hunger that usually begins at about 2 years of age. PWS is estimated to affect approximately 400,000 people worldwide and approximately 20,000 people in in the United States. Currently, there are no approved therapies for the treatment of PWS that effectively reduce extreme hyperphagia or address low energy expenditure.

- The Company is on track to complete enrollment in the Phase 2 trial evaluating bivamelagon, an oral MC4R agonist, in acquired HO in the first quarter of 2025.

- Following acceptance of a protocol amendment, the Company expects to begin dosing patients with acquired HO in Part C of the Phase 1 trial evaluating RM-718, a weekly MC4R agonist, in the first quarter of 2025. The Company plans to enroll up to 30 patients with acquired HO for 16 weeks in Part C of this Phase 1 trial.

Financial Disclosure Advisory

This Current Report on Form 8-K contains certain estimated preliminary financial results for the fourth quarter and fiscal year ended December 31, 2024. These estimates are based on the information available to the Company at this time. The Company's financial closing procedures for the fourth quarter and full year 2024 are not yet complete and, as a result, actual results may vary from the estimated preliminary results presented here due to the completion of the Company's financial closing and audit procedures. The estimated preliminary financial results have not been audited or reviewed by the Company's independent registered public accounting firm. These estimates should not be viewed as a substitute for the Company's full interim or annual financial statements. Accordingly, you should not place undue reliance on this preliminary data.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the Company's anticipated financial performance for any period of time, including preliminary unaudited revenues, for the fourth quarter and full year ending December 31, 2024; the potential, safety, efficacy, and regulatory and clinical progress, potential regulatory submissions, approvals and timing thereof of setmelanotide and other product candidates, including bivamelagon (LB54640) and RM-718; the announcement of data from our clinical trials, including our global Phase 3 trial evaluating setmelanotide in patients with acquired hypothalamic obesity; the ongoing enrollment of patients in our clinical trials; our participation in upcoming events and presentations; and the timing of any of the foregoing. Statements using words such as "expect", "anticipate", "believe", "may", "will", "aim" and similar terms are also forward-looking statements. Such statements are subject to numerous risks and uncertainties, including, but not limited to, our actual financial results for the fourth quarter and full year 2024 may differ from our preliminary estimates; our ability to enroll patients in clinical trials, the design and outcome of clinical trials, the ability to achieve necessary regulatory approvals, risks associated with data analysis and reporting, failure to identify and develop additional product candidates, unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, risks associated with the laws and regulations governing our international operations and the costs of any related compliance programs, the impact of competition, risks relating to product liability lawsuits, inability to maintain collaborations, or the failure of these collaborations, our reliance on third parties, risks relating to intellectual property, our ability to hire and retain necessary personnel, general economic conditions, risks related to internal control over financial reporting, and the other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and our other filings with the Securities and Exchange Commission. Except as required by law, we undertake no obligations to make any revisions to the forward-looking statements contained in this press release or to update them to reflect events or circumstances occurring after the date of this press release, whether as a result of new information, future developments or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following Exhibits 99.1 and 99.2 relate to Items 2.02 and 7.01, respectively, and shall each be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press release dated January 10, 2025
99.2	Corporate Presentation dated January 10, 2025
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

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

RHYTHM PHARMACEUTICALS, INC.

Date: January 10, 2025

By: /s/ Hunter Smith
Hunter Smith
Chief Financial Officer