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): August 1, 2023

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 August 1, 2023, Rhythm Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2023. The full text of the press release issued by the Company in connection with the announcement 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 attached hereto) 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, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following Exhibit 99.1 relates to Item 2.02, and shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press release dated August 1, 2023
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: August 1, 2023

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

Exhibit 99.1

Rhythm Pharmaceuticals Reports Second Quarter 2023 Financial Results and Business Update

-- Second quarter 2023 net revenue of $19.2 million from global sales of IMCIVREE® (setmelanotide) --

-- Strong U.S. commercial progress continues with more than 125 new prescriptions for Bardet-Biedl syndrome (BBS) in 2Q 2023, more than 425 since FDA approval --

-- Achieved commercial sales milestone and now eligible to receive third investment tranche of $25 million from Healthcare Royalty Partners --

-- Announced plans to submit an investigational new drug application for RM-718, a new, weekly, MC4R-specific agonist, by end of 2023 --

-- Enrollment ongoing in pivotal Phase 3 trial evaluating setmelanotide in hypothalamic obesity; based on rapid progress, study now expected to be fully enrolled by the end of 2023 --

-- Management to host conference call today at 8:00 a.m. ET --

BOSTON, August 1, 2023 – Rhythm Pharmaceuticals, Inc. (Nasdaq: RYTM), a global commercial-stage biopharmaceutical company focused on transforming the lives of patients and their families living with hyperphagia and severe obesity caused by rare melanocortin-4 receptor (MC4R) pathway diseases, today reported financial results and provided a business update for the second quarter ended June 30, 2023.

"The first half of 2023 was marked by strong execution across global commercial and clinical development programs. Our strong revenue performance was supported by robust patient demand for IMCIVREE® (setmelanotide) in the U.S. with more than 125 Bardet-Biedl syndrome (BBS) prescriptions written in the second quarter of 2023. Globally, we have expanded our footprint with IMCIVREE to include Canada and in Gulf Cooperation Council (GCC) countries," said David Meeker, M.D., Chair, President and Chief Executive Officer of Rhythm. "And in July, we achieved the specified sales milestone under our Revenue Interest Financing Agreement (RIFA) with Healthcare Royalty Partners, making us eligible to receive an additional investment of $25 million in non-dilutive capital."

"Based on rapid progress and substantial patient and physician interest in our ongoing pivotal Phase 3 clinical trial of setmelanotide in hypothalamic obesity, we now expect to complete enrollment by the end of 2023. Finally, we look forward to providing additional details on our pre-clinical development programs later this year, including RM-718, a new weekly, MC4R-specific agonist designed not to cause hyperpigmentation. This program is on track for an IND submission by the end of this year."

Second Quarter and Recent Business Highlights

Commercial Updates

- Today, Rhythm announced that more than 125 new prescriptions for IMCIVREE for BBS have been written in the second quarter of 2023 and more than 425 in the United States since U.S. Food and Drug Administration (FDA) approval on June 16, 2022 through June 30, 2023. More than 250 physicians have written prescriptions since launch, and the Company has received payor approval for reimbursement for more than 250 of those prescriptions, as of June 30, 2023.

- Today, Rhythm announced that IMCIVREE is now commercially available in Canada following the May 5, 2023 approval by Health Canada of IMCIVREE for weight management in adult and pediatric patients 6 years of age and older with obesity due to BBS or genetically-confirmed biallelic pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency due to variants interpreted as pathogenic, likely pathogenic or of uncertain significance.
- In May 2023, Rhythm announced a collaboration with Genpharm Services FZ LLC (Genpharm) to commercialize IMCIVREE in GCC countries, including Saudi Arabia, United Arab Emirates, Kuwait, Qatar, Oman, and Bahrain. Under the terms of this exclusive agreement, Genpharm will distribute IMCIVREE to patients in GCC countries for the treatment of hyperphagia and obesity due to BBS or genetically-confirmed biallelic POMC, PCSK1 or LEPR deficiency. Providers in the region now have the ability to prescribe IMCIVREE to qualifying patients.

Clinical Development Updates

- Today, Rhythm provided an update on progress of its pivotal, Phase 3 clinical trial evaluating setmelanotide in patients with acquired hypothalamic obesity. Based on the initial pace of patient screening and site activations, Rhythm now expects to complete enrollment in the fourth quarter of 2023. This Phase 3 trial is designed to enroll 120 patients aged 4 years or older randomized 2:1 to setmelanotide therapy or placebo for a total of 60 weeks, including up to eight weeks for dose titration.
- Today, Rhythm announced that it anticipates submitting an investigational new drug application for RM-718, a new, weekly, MC4R-specific agonist, by the end of 2023. RM-718 is designed to be more targeted and potent than setmelanotide, and designed to be MC1R sparing, with the potential to not cause hyperpigmentation. This new product candidate is being developed as an injection administered through an autoinjector, for which Rhythm has patent protection into 2041, including patent term adjustment and patent term extension.
- On July 19, the Company announced two new publications detailing the burden of hyperphagia and obesity for adult caregivers, families and patients living with BBS based on results of The CAREgiver Burden in BBS (CARE-BBS) study were published in the peer-reviewed journal, *The Orphanet Journal of Rare Diseases.*
- In June 2023 at the Endocrine Society Annual Meeting & Expo (ENDO), Rhythm and its collaborators presented new data from the long-term extension portion of Rhythm's Phase 2 trial evaluating setmelanotide in patients with hypothalamic obesity. The data showed sustained and deepening reductions in weight and body mass index (BMI) in patients receiving at least six months of setmelanotide therapy. As of a data cutoff of November 30, 2022, 13 patients who had reached the 6-month point had achieved a 21.0 mean percent reduction in BMI from baseline, which progressed from a 16.8 mean percent reduction at week 16 across these 13 patients.

Corporate

- Today, Rhythm announced that in July 2023 it achieved a commercial sales milestone under the RIFA with HealthCare Royalty Partners entered into in June 2022. In connection with the achievement of the milestone, Rhythm became eligible for a final investment tranche of $25.0 million from HealthCare Royalty Partners. Rhythm previously received two tranches totaling $75.0 million under the RIFA.

Anticipated Upcoming Milestones

Rhythm expects to achieve the following near-term milestones:

- Present data analysis from the Phase 2 and long-term extension trials in hypothalamic obesity at a medical conference in the fall of 2023;
- Announce preliminary data from the open-label part of the Phase 2 DAYBREAK trial from one or more genetically-defined cohorts in the second half of 2023;
- Announce topline data from the ongoing Phase 3, open-label pediatrics trial evaluating one year of setmelanotide therapy in patients with MC4R pathway deficiencies between the ages of 2 and 6 years old in the second half of 2023;
- Provide pharmacokinetic and tolerability data from the ongoing Phase 3 switch trial evaluating a weekly formulation of setmelanotide in the second half of 2023;
- Complete patient enrollment in the pivotal Phase 3 clinical trial in hypothalamic obesity in the fourth quarter of 2023;
- Provide an update on pre-clinical development programs, including RM-718 and the Company's congenital hyperinsulinism (CHI) program, in the fourth quarter of 2023; and
- Initiate a Phase 3, randomized, double-blind trial in patients naïve to setmelanotide therapy ("de novo study") to evaluate the weekly formulation of setmelanotide in patients with BBS in 2024.

Second Quarter 2023 Financial Results:

- **Cash Position:** As of June 30, 2023, cash, cash equivalents and short-term investments were approximately $253.6 million, as compared to $333.3 million as of December 31, 2022. The June 30, 2023 cash position does not include the anticipated commercial sales milestone payment from HealthCare Royalty Partners of $24.4 million of proceeds, net of debt issuance costs.
- **Revenue:** Net product revenues relating to global sales of IMCIVREE were $19.2 million for the second quarter of 2023, as compared to $2.3 million for the second quarter of 2022. For the second quarter ended June 30, 2023, 86% of the Company's product revenue was generated in the United States.
- **License Revenue:** The Company did not record license revenue relating to out-license arrangements in the second quarter of 2023, following the termination of its agreement with RareStone Group Ltd. (RareStone) in October 2022. License revenue relating to the Company's out-license arrangement with RareStone was $6.8 million for the second quarter of 2022.
- **R&D Expenses:** R&D expenses were $33.5 million in the second quarter of 2023, as compared to $31.5 million in the second quarter of 2022. The year-over-year increase was primarily due to increased costs associated with certain clinical trials and pre-clinical studies and increased headcount. This was partially offset by decreased costs associated with certain trials and manufacturing of clinical material.
- **S,G&A Expenses:** S,G&A expenses were $30.0 million for the second quarter of 2023, as compared to $22.3 million for the second quarter of 2022. The year-over-year increase was primarily due to increased headcount in the United States and internationally, professional services and other expenses. This increase was partially offset by decreased marketing activities associated with the U.S. BBS launch.

- **Other income (expense), net.** Other income (expense), net decreased by $0.2 million from the second quarter of 2022 to the second quarter of 2023, primarily due to $3.3 million of interest expense related to the RIFA with HealthCare Royalty and a $0.1 million fair market value adjustment related to the RIFA embedded derivative, offset by interest income of $3.3 million earned on our short-term investments.
- **Net Loss:** Net loss was ($46.7) million for the second quarter of 2023, or a net loss per basic and diluted share of ($0.82), as compared to a net loss of ($45.0) million for the second quarter of 2022, or a net loss per basic and diluted share of ($0.89).

Year to Date 2023 Financial Results:

- **Revenue:** Net product revenues relating to sales of IMCIVREE were $30.7 million for the six months ended June 30, 2023, as compared to $3.8 million for the six months ended June 30, 2022.
- **License Revenue:** The Company did not report license revenue relating to out-license arrangements in the six months ended June 30, 2023, following the termination of its agreement with RareStone in October 2022. License revenue relating to the Company's out-license arrangement with RareStone was $6.8 million for the six months ended June 30, 2022.
- **R&D Expenses**: R&D expenses were $71.5 million for the six months ended June 30, 2023, as compared to $64.0 million for the six months ended June 30, 2022. This increase was primarily due to the acquisition of Xinvento B.V. and increased costs associated with headcount, certain clinical trials, pre-clinical studies and gene sequencing and was partially offset by decreased costs associated with manufacturing of clinical material, certain clinical trials and a development milestone payment associated with the weekly formulation paid to Camurus AB in 2022.
- **S,G&A Expenses**: S,G&A expenses were $54.7 million for the six months ended June 30, 2023, as compared to $43.8 million for the six months ended June 30, 2022. The increase was primarily due to increased headcount to support business and commercial operations in the United Sates and internationally, professional services and other expenses and was partially offset by decreased marketing activities associated with the BBS U.S. launch.
- **Other income (expense), net:** Other (income)/ expense, net increased by $0.2 million to $0.2 million for the six months ended June 30, 2023. Total other (income)/ expense, net for the six months ended June 30, 2023 consists of interest income of $6.7 million primarily due to higher interest rates, partially offset by $6.4 million of interest expense related to our RIFA with HealthCare Royalty. The fair market value adjustment related to our RIFA embedded derivative for the six months ended June 30, 2023 was de minimis.
- **Net Loss**: Net loss was ($98.9) million for the six months ended June 30, 2023, or a net loss per basic and diluted share of $(1.74), as compared to a net loss of ($97.8) million for the six months ended June 30, 2022, or a net loss per basic and diluted share of ($1.94).

Financial Guidance: For the year ending December 31, 2023, Rhythm continues to anticipate approximately $200 million to $220 million in Non-GAAP Operating Expenses (see below under "Non-GAAP Financial Measures" for more details), comprised of $120 million to $130 million from R&D expenses and $80 million to $90 million from S,G&A expenses. Based on its current operating plans, Rhythm expects that its existing cash, cash equivalents and short-term investments as of June 30, 2023, together with the anticipated $25 million milestone payment based on commercial sales from Healthcare Royalty Partners, will be sufficient to fund its operating expenses and capital expenditure requirements into 2025.

Conference Call Information
Rhythm Pharmaceuticals will host a live conference call and webcast at 8:00 a.m. ET today to review its second quarter 2023 financial results and recent business activities. Participants may register for the conference call here. It is recommended that participants join the call ten minutes prior to the scheduled start.

A live webcast of the call will also be available under "Events and Presentations" in the Investor Relations section of the Rhythm Pharmaceuticals website at https://ir.rhythmtx.com/. The archived webcast will be available on Rhythm Pharmaceuticals' website approximately two hours after the conference call and will be available for 30 days following the call.

About Rhythm Pharmaceuticals
Rhythm is a commercial-stage biopharmaceutical company committed to transforming the lives of patients and their families living with hyperphagia and severe obesity caused by rare melanocortin-4 receptor (MC4R) diseases. Rhythm's lead asset, IMCIVREE (setmelanotide), an MC4R agonist designed to treat hyperphagia and severe obesity caused by rare MC4R pathway diseases, is approved by the U.S. Food and Drug Administration (FDA) for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1) or leptin receptor (LEPR) deficiency confirmed by genetic testing, or patients with a clinical diagnosis of Bardet-Biedl syndrome (BBS). Both the European Commission (EC) and the UK's Medicines & Healthcare Products Regulatory Agency (MHRA) have authorized setmelanotide for the treatment of obesity and the control of hunger associated with genetically confirmed BBS or genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic LEPR deficiency in adults and children 6 years of age and above. Additionally, Rhythm is advancing a broad clinical development program for setmelanotide in other rare MC4R pathway diseases, as well as a preclinical suite of small molecules for the treatment of congenital hyperinsulinism. Rhythm's headquarters is in Boston, MA.

Setmelanotide Indication
In the United States, setmelanotide is indicated for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to POMC, PCSK1 or LEPR deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1 or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) or BBS.

In the European Union, setmelanotide is indicated for the treatment of obesity and the control of hunger associated with genetically confirmed Bardet-Biedl syndrome (BBS) or genetically confirmed loss-of-function biallelic proopiomelanocortin (POMC), including PCSK1, deficiency or biallelic leptin receptor (LEPR) deficiency in adults and children 6 years of age and above.

Limitations of Use
In the United States and Europe, Setmelanotide should be prescribed and supervised by a physician with expertise in obesity with underlying genetic etiology.

Setmelanotide is not indicated for the treatment of patients with the following conditions as setmelanotide would not be expected to be effective:

- Obesity due to suspected POMC, PCSK1 or LEPR deficiency with *POMC*, *PCSK1* or *LEPR* variants classified as benign or likely benign

- Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, or BBS, including obesity associated with other genetic syndromes and general (polygenic) obesity.

WARNINGS AND PRECAUTIONS

Skin Monitoring: Setmelanotide may lead to generalized increased skin pigmentation and darkening of pre-existing naevi because of its pharmacologic effect. Full body skin examinations should be conducted annually to monitor pre-existing and new skin pigmentary lesions before and during treatment with setmelanotide.

Heart rate and blood pressure monitoring: Heart rate and blood pressure should be monitored as part of standard clinical practice at each medical visit (at least every 6 months) for patients treated with setmelanotide.

Prolonged penile erection: Spontaneous penile erections have been reported in clinical trials with setmelanotide. Patients who have a penile erection lasting longer than 4 hours should be instructed to seek emergency medical attention for potential treatment of priapism.

Depression: In clinical trials, depression has been reported in patients treated with setmelanotide. Patients with depression should be monitored at each medical visit during treatment with setmelanotide. Consideration should be given to discontinuing setmelanotide if patients experience suicidal thoughts or behaviors.

Pediatric Population: The prescribing physician should periodically assess response to setmelanotide therapy. In growing children, the impact of weight loss on growth and maturation should be evaluated. The prescribing physician should monitor growth (height and weight) using age- and sex-appropriate growth curves.

Excipients: This medicinal product contains 10 mg benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions. Patients who are pregnant or breastfeeding should be advised of the potential risk from the excipient benzyl alcohol, which might accumulate over time and cause metabolic acidosis. This medicinal product should be used with caution in patients with hepatic or renal impairment, because of the potential risk from the excipient benzyl alcohol which might accumulate over time and cause metabolic acidosis.

Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free.”

ADVERSE REACTIONS
The most frequent adverse reactions are hyperpigmentation (51%), injection site reaction (39%), nausea (33%), and headache (26%).

USE IN SPECIFIC POPULATIONS

Pregnancy
There are no data from the use of setmelanotide in pregnant women. Animal studies do not indicate direct harmful effects with respect to reproductive toxicity. However, administration of setmelanotide to pregnant rabbits resulted in decreased maternal food consumption leading to embryo-fetal effects. As a precautionary measure, setmelanotide should not be started during pregnancy or while attempting to get pregnant as weight loss during pregnancy may result in fetal harm. If a patient who is taking setmelanotide has reached a stable weight and becomes pregnant, consideration should be given to maintaining setmelanotide treatment as there was no proof of teratogenicity in the nonclinical data. If a patient who is taking setmelanotide and still losing weight gets pregnant, setmelanotide should either be discontinued, or the dose reduced while monitoring for the recommended weight gain during pregnancy. The treating physician should carefully monitor weight during pregnancy in a patient taking setmelanotide.

Breast-feeding
It is unknown whether setmelanotide is excreted in human milk. A nonclinical study showed that setmelanotide is excreted in the milk of nursing rats. No quantifiable setmelanotide concentrations were detected in plasma from nursing pups. A risk to the newborn/infant cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from setmelanotide therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the mother.

Fertility
No human data on the effect of setmelanotide on fertility are available. Animal studies did not indicate harmful effects with respect to fertility.

To report SUSPECTED ADVERSE REACTIONS, contact Rhythm Pharmaceuticals at +1 (833) 789-6337. See Summary of Product Characteristics' APPENDIX V for a list of European national reporting systems to communicate adverse reactions.

Please see the full Prescribing Information for additional Important Safety Information.

Forward-Looking Statements
This press release 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 potential, safety, efficacy, and regulatory and clinical progress of setmelanotide, including the anticipated timing for initiation of clinical trials and release of clinical trial data, our expectations surrounding potential regulatory submissions, approvals and timing thereof, our business strategy and plans, including regarding commercialization of setmelanotide in certain international regions, expectations surrounding sales and reimbursement of IMCIVREE, the potential financial impact, growth prospects and benefits of our acquisition of Xinvento B.V., expectations surrounding lead development candidate selection for the treatment of CHI and related timing, our anticipated financial performance and financial position, including estimated Non-GAAP Operating Expenses for the year ending December 31, 2023, the sufficiency of our cash, cash equivalents and short-term investments to fund our operations and the anticipated commercial sales milestone payment from Healthcare Royalty Partners, and our participation in upcoming events and presentations. Statements using word 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, risks relating to our liquidity and expenses, 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 our 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, the impact of the COVID-19 pandemic and general economic conditions on our business and operations, including our preclinical studies, clinical trials and commercialization prospects, failure to realize the anticipated benefits of our acquisition of Xinvento B.V. or significant integration difficulties related to the acquisition, and the other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 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 release or to update them to reflect events or circumstances occurring after the date of this release, whether as a result of new information, future developments or otherwise.

Non-GAAP Financial Measures
This press release includes Non-GAAP Operating Expenses, a supplemental measure of our performance that is not required by, or presented in accordance with, U.S. GAAP and should not be considered as an alternative to operating expenses or any other performance measure derived in accordance with GAAP.

We define Non-GAAP Operating Expenses as GAAP operating expenses excluding stock-based compensation.

We caution investors that amounts presented in accordance with our definition of Non-GAAP Operating Expenses may not be comparable to similar measures disclosed by our competitors because not all companies and analysts calculate this non-GAAP financial measure in the same manner. We present this non-GAAP financial measure because we consider it to be an important supplemental measure of our performance and believe it is frequently used by securities analysts, investors, and other interested parties in the evaluation of companies in our industry. Management believes that investors' understanding of our performance is enhanced by including this non-GAAP financial measure as a reasonable basis for comparing our ongoing results of operations.

Management uses this non-GAAP financial measure for planning purposes, including the preparation of our internal annual operating budget and financial projections; to evaluate the performance and effectiveness of our operational strategies; and to evaluate our capacity to expand our business. This non-GAAP financial measure has limitations as an analytical tool, and should not be considered in isolation, or as an alternative to, or a substitute for operating expenses or other financial statement data presented in accordance with GAAP in our consolidated financial statements.

Rhythm has not provided a quantitative reconciliation of forecasted Non-GAAP Operating Expenses to forecasted GAAP operating expenses because the Company is unable, without making unreasonable efforts, to calculate the reconciling item, stock-based compensation expenses, with confidence. This item, which could materially affect the computation of forward-looking GAAP operating expenses, is inherently uncertain and depends on various factors, some of which are outside of Rhythm's control.

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Rhythm Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	$ 19,221	$ 2,312	$ 30,691	$ 3,810
License revenue	—	6,754	—	6,754
Total revenues	19,221	9,066	30,691	10,564
Costs and expenses:				
Cost of sales	2,236	378	3,657	608
Research and development	33,543	31,456	71,487	63,966
Selling, general, and administrative	30,046	22,328	54,674	43,777
Total costs and expenses	65,825	54,162	129,818	108,351
Loss from operations	(46,604)	(45,096)	(99,127)	(97,787)
Other income (expense):				
Other income, net	(17)	(133)	34	(366)
Interest expense	(3,303)	(46)	(6,449)	(46)
Interest income	3,221	274	6,660	434
Total other (expense) income, net	(99)	95	245	22
Net loss	$ (46,703)	$ (45,001)	$ (98,882)	$ (97,765)
Net loss per share, basic and diluted	$ (0.82)	$ (0.89)	$ (1.74)	$ (1.94)
Weighted-average common shares outstanding, basic and diluted	56,867,662	50,398,003	56,788,757	50,362,512
Other comprehensive loss:				
Net loss	$ (46,703)	$ (45,001)	$ (98,882)	$ (97,765)
Foreign currency translation adjustment	(48)	—	(27)	—
Unrealized gain (loss), net on short-term investments	40	(277)	105	(905)
Comprehensive loss	$ (46,711)	$ (45,278)	$ (98,804)	$ (98,670)

Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 115,684	$ 127,677
Short-term investments	137,918	205,611
Accounts receivable, net	13,831	6,224
Inventory	6,178	2,917
Prepaid expenses and other current assets	10,267	11,807
Total current assets	283,878	354,236
Property and equipment, net	1,773	2,197
Right-of-use asset	990	1,182
Intangible assets, net	7,456	7,883
Restricted cash	328	328
Other long-term assets	15,518	16,655
Total assets	$ 309,943	$ 382,481
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 8,383	$ 4,797
Accrued expenses and other current liabilities	35,708	32,894
Deferred revenue	1,286	1,434
Lease liability	726	684
Total current liabilities	46,103	39,809
Long-term liabilities:		
Deferred royalty obligation	79,347	75,810
Lease liability	888	1,260
Derivative liability	1,320	1,340
Total liabilities	127,658	118,219
Stockholders' equity:		
Preferred stock, $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value: 120,000,000 shares authorized; 56,896,068 and 56,612,429 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	57	56
Additional paid-in capital	991,182	974,356
Accumulated other comprehensive loss	(14)	(92)
Accumulated deficit	(808,940)	(710,058)
Total stockholders' equity	182,285	264,262
Total liabilities and stockholders' equity	$ 309,943	$ 382,481