Rhythm Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results

March 1, 2023

-- IMCIVREE® U.S. launch for Bardet-Biedl syndrome (BBS) reflects strong demand with more than 200 new prescriptions received since FDA approval --

-- IMCIVREE now available in eight ex-U.S. markets; first commercial sales for BBS expected in Germany in 2Q 2023 --

-- Pivotal Phase 3 trial evaluating setmelanotide in acquired hypothalamic obesity initiated --

-- Acquired Xinvento B.V., a rare disease company in preclinical development for congenital hyperinsulinism --

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

BOSTON, March 01, 2023 (GLOBE NEWSWIRE) -- 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 fourth quarter and full year ended December 31, 2022.

"Rhythm had a very strong 2022. Following U.S. Food and Drug Administration (FDA) approval in June, we successfully launched IMCIVREE® (setmelanotide) for Bardet-Biedl syndrome (BBS) in the United States, and we've continued to extend our reach globally, with IMCIVREE now available in eight international markets," said David Meeker, M.D., Chair, President and Chief Executive Officer of Rhythm. "With compelling Phase 2 data in hypothalamic obesity and FDA alignment on our pivotal trial design, we recently began screening patients for our Phase 3 study. We look forward to working toward the achievement of several additional clinical milestones in 2023 as we aim to expand the reach of setmelanotide as the first and only precision medicine to address the needs of patients and families living with hyperphagia and severe obesity caused by rare MC4R pathway diseases."

Dr. Meeker continued, "With the acquisition of Xinvento, we are excited to expand our pipeline into congenital hyperinsulinism (CHI), a rare disease that is well aligned with our corporate strategy and broadens our focus into an adjacent endocrine indication with a high unmet need."

Fourth Quarter and Recent Business Highlights

Bardet-Biedl Syndrome

- Today, Rhythm announced that it received more than 200 new prescriptions for IMCIVREE for BBS from more than 125 physicians in the United States with reimbursement approvals for more than 100 of those prescriptions from FDA approval on June 16, 2022 to December 31, 2022.
- In November 2022, Rhythm announced that Great Britain's Medicines & Healthcare products Regulatory Agency (MHRA) expanded the marketing authorization for IMCIVREE to include the treatment of obesity and control of hunger associated with genetically confirmed BBS in adult and pediatric patients 6 years of age and older. The Company is working closely with the National Health Service (NHS) to finalize guidance for coverage of IMCIVREE for BBS.
- Also in November 2022, Rhythm announced that Health Canada accepted for review its New Drug Submission (NDS) with Priority Review for setmelanotide, indicated in adults and pediatric patients 6 years of age and older with impairments in the MC4R pathway due to genetic diseases, for the treatment of obesity and control of hunger in BBS and POMC, PCSK1, or LEPR deficiencies.

POMC, PCSK1 and LEPR Deficiency Obesities

- In December 2022, Rhythm launched IMCIVREE in The Netherlands and Italy for patients with POMC, PCSK1 or LEPR deficiency obesity. In addition, Rhythm secured access for patients with POMC, PCSK1 or LEPR deficiency obesity through named patient sales programs in Austria and Turkey, and early access in Argentina.

Clinical Development Updates

- Today Rhythm announced that its pivotal Phase 3 trial evaluating setmelanotide in patients with acquired hypothalamic

obesity has been initiated, with patient screening underway.
- In January 2023, Rhythm announced that certain patients with BBS and obesity who participated in the Company's global Phase 3 clinical trial of setmelanotide reported clinically meaningful improvements across multiple health-related quality of life (HRQOL) measures, based on an analysis which was published in the peer-reviewed *Orphanet Journal of Rare Diseases*.
- In November 2022, Rhythm announced the publication of previously disclosed results from its Phase 3 clinical trial in patients with BBS in the peer-reviewed journal *The Lancet Diabetes and Endocrinology*.

Corporate Update

- In February 2023, Rhythm's Netherlands subsidiary, Rhythm Pharmaceuticals Netherlands B.V. ("Rhythm B.V."), acquired Xinvento B.V., a Netherlands-based biotech company focused on developing therapies for CHI. CHI is a rare genetic disease in which cells secrete excess insulin, causing hypoglycemia, which can result in serious health outcomes including seizures, coma, permanent brain damage and death. Xinvento is developing novel investigational therapeutic candidates designed to improve the care of patients with CHI. Following the closing of the transaction, Xinvento's founder Claudine van der Sande will join Rhythm B.V. as Vice President, Head of CHI Program.

Key Upcoming 2023 Milestones

Rhythm expects to achieve the following near-term milestones:

- Secure market access and launch IMCIVREE in Germany for BBS in the second quarter of 2023, pending reimbursement negotiations with German authorities; Rhythm also anticipates launching IMCIVREE for BBS in The Netherlands in the second half of 2023, pending local negotiations;
- Complete regulatory review by Health Canada and, pending approval, make IMCIVREE commercially available in Canada for the treatment of BBS, or POMC, PCSK1 or LEPR deficiencies in the second half of 2023;
- 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 the second half 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; and
- Announce topline data from the ongoing Phase 3 switch trial evaluating a weekly formulation of setmelanotide in the second half of 2023.

Fourth Quarter and Full Year 2022 Financial Results:

- **Cash Position:** As of December 31, 2022, cash, cash equivalents and short-term investments were approximately $333.3 million, as compared to $294.9 million as of December 31, 2021.
- **Revenue:** Product revenue, net relating to global sales of IMCIVREE was $8.8 million for the fourth quarter of 2022 and $16.9 million for the year ended December 31, 2022, as compared to $1.8 million for the fourth quarter of 2021 and $3.2 million for the year ended December 31, 2021. For the years ended December 31, 2022, and 2021, 85% and 100%, respectively, of the Company's product revenue was generated in the United States.
- **License Revenue:** License revenue was $6.8 million in 2022 and was entirely related to the RareStone license agreement. Rhythm, entered into a license agreement with RareStone in December 2021 and completed activities required to transfer the license to RareStone during the second quarter of 2022, which resulted in the recognition of the license revenue.
- **R&D Expenses:** R&D expenses were $23.5 million in the fourth quarter of 2022 and $108.6 million for the year ended December 31, 2022, as compared to $31.6 million in the fourth quarter of 2021 and $104.1 million for the year ended December 31, 2021. The year-over-year increase was due to:
    - an increase of $2.9 million for purchases of clinical supply material; an increase of $2.8 million in gene sequencing costs to support expanded clinical programs; an increase of $2.4 million in clinical trial costs associated with new and planned clinical trials, including Phase 2 DAYBREAK and Phase 3 EMANATE trials, Phase 3 pediatrics trial, Phase 2 hypothalamic obesity trial, Phase 3 hypothalamic obesity trial and increased enrollment in the long-term extension and weekly switch trials. These increases were partially offset by reduced activity due to the completion and winding down of the Phase 3 POMC and LEPR trials, QTc trial, BBS trial, Phase 2 Basket trial and renal study. These increases were further offset by a $2.3 million refund due upon the close out and reconciliation of the GO-ID study, all of which resulted in an insignificant change in clinical trial expense; an increase of $2.1 million in salaries, benefits and stock-based compensation related to the hiring of additional full-time employees in order to support the growth of research and development programs; an increase of $1.0 million in development milestones earned by Camurus AB, related to development milestone achieved related to our weekly formulation; and an increase of $0.9 million related to IP and patent related filing activities.
    - The above increases were partially offset by a decrease of $4.0 million in costs associated with medical affairs; and a decrease of $0.9 million in costs associated with next generation research and development activities.

- **S,G&A Expenses:** S,G&A expenses were $26.3 million in the fourth quarter of 2022 and $92.0 million for the year ended December 31, 2022, as compared to $21.0 million for the fourth quarter of 2021 and $68.5 million for the year ended December 31, 2021. The year-over-year increase was due to:

    - an increase of $9.6 million due to increased compensation and benefits related costs associated with additional headcount to support expanding business operations as well as to establish commercial operations in the United States and internationally;
    - an increase of $8.6 million related to increased costs associated with commercial operations, sales and marketing activities for IMCIVREE in connection with preparing for the U.S. approval for BBS obtained in June 2022 and EC approval in September 2022;
    - an increase of $5.0 million due to increased costs associated with information technology, international office space, sponsorships and general corporate travel related expenses for an expanding workforce.
- **Other (expense) income, net:** Other (expense) income, net decreased by $102.4 million to ($2.0) million in 2022, a decrease of 102%. The decrease was primarily due to the sale of Rhythm's Priority Review Voucher (PRV) in February 2021. The sale of the PRV in the prior year was a non-recurring transaction. Other (expense) income, net consists of $5.2 million of interest expense related to Royalty Interest Financing Agreement (RIFA) with HealthCare Royalty Partners (including amortization of debt discount and deferred financing fees) and a $1.0 million other than temporary impairment of RareStone equity, partially offset by $4.0 million of interest income and $0.3 million of other income resulting from the remeasurement of the embedded derivative related to the RIFA.
- **Provision/(Benefit) for income taxes:** There was no provision (benefit) for income taxes during for the three months and year ended December 31, 2022, respectively. During the three months ended December 31, 2021, we recorded a benefit for income taxes of $8.0 million related to the unwinding of the tax provision recorded earlier in the year as a result of the sale of the PRV upon generating sufficient losses from operations to offset the tax provision.
- **Net Loss:** Net loss was $42.5 million for the fourth quarter of 2022 and $181.1 million for the year ended December 31, 2022, or a net loss per basic and diluted share of ($0.75) and ($3.47), respectively, as compared to a net loss of $42.9 million for the fourth quarter of 2021 and $69.6 million for the year ended December 31, 2021, or a net loss per basic and diluted share of $0.85 and $1.40, respectively.

Financial Guidance: Rhythm today announced that, for the year ending December 31, 2023, it currently anticipates 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 December 31, 2022 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 fourth quarter and full year 2022 financial results and recent business activities. Participants may register for the conference call here. While not required, 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 pro-opiomelanocortin (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., management changes, our anticipated financial performance and financial position, including estimated Non-GAAP Operating Expenses for the year ending December 31, 2023, and the sufficiency of our cash, cash equivalents and short-term investments to fund our operations, 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 Annual Report on Form 10-K for the year ended December 31, 2022 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
(in thousands, except share and per share data)
(Unaudited)

	Three months ended December 31,		Twelve months ended December 31,	
	2022	2021	2022	2021
Product revenue, net	$8,790	$1,817	$16,884	$3,154
Collaboration revenue	-	-	$6,754	-
Operating expenses:				
Cost of sales	$1,028	$236	$2,133	$599
Research and development	$23,548	$31,574	$108,630	$104,128
Selling, general, and administrative	$26,318	$20,997	$92,032	$68,486
Total operating expenses	$50,894	$52,807	$202,795	$173,213
Loss from operations	($42,104)	($50,990)	($179,157)	($170,059)
Other income (expense):				
Other income	($420)		($790)	$100,000
Interest expense	($3,010)		($5,201)	
Interest income	$3,040	$134	$4,029	$447
Total other income (expense):	($390)	$134	($1,962)	$100,447
Net income (loss) before taxes	($42,494)	($50,856)	($181,119)	($69,612)
Provision for taxes		($7,989)		
Net loss and comprehensive loss	($42,494)	($42,867)	($181,119)	($69,612)
net income	($42,494)	($42,867)	($181,119)	($69,612)
Net loss per share, basic and diluted	$(0.75)	$(0.85)	$(3.47)	$(1.40)
Weighted-average common shares outstanding, basic and diluted	56,299,525	50,270,801	52,120,701	49,600,294

Rhythm Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 127,677	$ 59,248
Short-term investments	205,611	235,607
Accounts receivable, net	6,224	1,025
Inventory	2,917	111
Prepaid expenses and other current assets	11,807	12,396
Total current assets	354,236	308,387
Property and equipment, net	2,197	2,813
Right-of-use asset	1,182	1,522
Intangible assets, net	7,883	4,658
Restricted cash	328	328
Other long-term assets	16,655	11,815
Total assets	$ 382,481	$ 329,523

Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,797	$ 5,737
Accrued expenses and other current liabilities	32,894	30,084
Deferred revenue	1,434	7,000
Lease liability	684	606
Total current liabilities	39,809	43,427
Long-term liabilities:		
Deferred royalty obligation	75,810	—
Lease liability	1,260	1,945
Derivative liability	1,340	—
Total liabilities	118,219	45,372
Stockholders' equity:		
Preferred Stock, $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value: 120,000,000 shares authorized; 56,612,429 and 50,283,574 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	56	50
Additional paid-in capital	974,356	813,041
Accumulated other comprehensive loss	(92)	(1)
Accumulated deficit	(710,058)	(528,939)
Total stockholders' equity	264,262	284,151
Total liabilities and stockholders' equity	$ 382,481	$ 329,523

Source: Rhythm Pharmaceuticals, Inc.