
**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): May 2, 2024

Alnylam Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36407
(Commission
File Number)

77-0602661
(IRS Employer
Identification No.)

**675 West Kendall Street,
Henri A. Termeer Square
Cambridge, Massachusetts**
(Address of Principal Executive Offices)

02142
(Zip Code)

Registrant's telephone number, including area code: (617) 551-8200

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 (*see* General Instruction A.2. below):

☐ 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, \$0.01 par value per share	ALNY	The Nasdaq Stock Market LLC

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 May 2, 2024, Alnylam Pharmaceuticals, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2024. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits**(d) Exhibits**

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 [Press Release dated May 2, 2024.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

Date: May 2, 2024

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ Jeffrey V. Poulton

Jeffrey V. Poulton

Executive Vice President, Chief Financial Officer

Alnylam Pharmaceuticals Reports First Quarter 2024 Financial Results and Highlights Recent Period Activity

- *Achieved First Quarter 2024 Global Net Product Revenues of \$365 Million, Representing 32% Year-Over-Year Growth Compared to Q1 2023, Including Continued Momentum from Total TTR Delivering 29% Year-Over-Year Growth –*
- *Demonstrated Strong Progress with Zilebesiran Hypertension Program with Positive Results from KARDIA-2 Phase 2 Study and Initiation of KARDIA-3 Phase 2 Study –*
- *Remain on Track to Report Topline Results from HELIOS-B Phase 3 Study of Vutrisiran in Late June or Early July –*
- *Reiterated 2024 Financial Guidance, Including Combined Net Product Revenues of \$1,400 Million to \$1,500 Million –*

CAMBRIDGE, Mass., May 2, 2024 – Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today reported its consolidated financial results for the first quarter ended March 31, 2024 and reviewed recent business highlights.

“2024 is off to a strong start, with exceptional commercial performance where we delivered \$365 million in global net product revenues, representing 32% year-over-year growth for our four wholly owned products. We also made great progress with our pipeline, particularly with the zilebesiran program in hypertension, for which we reported positive results from the KARDIA-2 Phase 2 study, and initiated the KARDIA-3 Phase 2 study,” said Yvonne Greenstreet, MBChB, Chief Executive Officer of Alnylam. “Looking ahead, we are eagerly awaiting topline results from the HELIOS-B Phase 3 study of vutrisiran in late June or early July, potentially expanding our leadership in ATTR amyloidosis. Additionally, we look forward to early-stage developments with mivelsiran (formerly ALN-APP), where we expect to start a Phase 2 study in cerebral amyloid angiopathy in the coming months. These achievements position us well to deliver on our *Alnylam P⁵x25* goals of becoming a top-tier biotech company delivering sustained innovation and exceptional financial results.”

First Quarter 2024 and Recent Significant Corporate Highlights

Commercial Performance

Total TTR: ONPATTRO® (patisiran) & AMVUTTRA® (vutrisiran)

- Continued growth momentum in total TTR, achieving global net product revenues for ONPATTRO and AMVUTTRA for the first quarter of \$69 million and \$195 million, respectively, representing 4% total TTR quarterly growth compared to Q4 2023 and 29% annual growth compared to Q1 2023.

Total Rare: GIVLAARI® (givosiran) & OXLUMO® (lumasiran)

- Achieved global net product revenues for GIVLAARI and OXLUMO for the first quarter of \$58 million and \$43 million, respectively, representing 9% total Rare quarterly growth compared to Q4 2023 and 40% annual growth compared to Q1 2023.

R&D Highlights

Announced updates to the statistical analysis plan for the HELIOS-B Phase 3 study of **vutrisiran** in patients with ATTR amyloidosis with cardiomyopathy, including adjustments to the primary and secondary endpoints and analysis period. Topline results remain on track to be reported in late June or early July.

Reported positive results from the KARDIA-2 Phase 2 study of **zilebesiran** added to standard-of-care antihypertensives in patients with inadequately controlled hypertension.

Initiated the global KARDIA-3 Phase 2 study of **zilebesiran** in adult patients with high cardiovascular risk and uncontrolled hypertension despite treatment with two to four standard of care antihypertensive medications. Study initiation triggered a \$65 million milestone payment from Roche.

Published results from the Phase 2 KARDIA-1 study of **zilebesiran** in the *Journal of the American Medical Association* (JAMA).

Received clearance from the U.S. Food and Drug Administration (FDA) to initiate the multiple-dose part (Part B) of the ongoing Phase 1 study of **mivelsiran (formerly ALN-APP)** in early onset Alzheimer's disease. The FDA has confirmed that multiple-dosing in the Phase 1 study may proceed at doses up to 180 mg given every six months, which covers all dose regimens planned to be explored in Part B. A partial clinical hold remains for higher or more frequent dosing regimens.

Presented new preclinical data for **ALN-HTT02**, an investigational RNAi therapeutic targeting huntingtin (HTT) in development for the treatment of Huntington's disease at the CHDI Foundation's 19th Annual Huntington's Disease Therapeutics Conference.

Upcoming Events

In early and mid-2024, Alnylam intends to:

- Report topline results from the HELIOS-B Phase 3 study of **vutrisiran** in late June or early July.
- Initiate a Phase 2 study of **mivelsiran** (formerly ALN-APP) in patients with cerebral amyloid angiopathy.
- Initiate Part B of the Phase 1 study of **ALN-KHK**, in development for the treatment of Type 2 diabetes mellitus.
- Initiate a Phase 1 study of **ALN-BCAT**, in development for the treatment of hepatocellular carcinoma.

Financial Results for the Quarter Ended March 31, 2024

	Three Months Ended March 31,	
	2024	2023
<i>(In thousands, except per share amounts)</i>		
Net product revenues	\$ 365,163	\$ 276,328
Net revenue from collaborations	\$ 118,548	\$ 36,462
Royalty revenue	\$ 10,622	\$ 6,500
GAAP Operating loss	\$ (43,435)	\$ (149,807)
Non-GAAP Operating gain (loss)	\$ 1,912	\$ (109,860)
GAAP Net loss	\$ (65,935)	\$ (174,101)
Non-GAAP Net loss	\$ (20,666)	\$ (131,887)
GAAP Net loss per common share - basic and diluted	\$ (0.52)	\$ (1.40)
Non-GAAP Net loss per common share - basic and diluted	\$ (0.16)	\$ (1.06)

For an explanation of our use of non-GAAP financial measures refer to the “Use of Non-GAAP Financial Measures” section later in this press release and for a reconciliation of each non-GAAP financial measure to the most comparable GAAP measures, see the table at the end of this press release.

Net Product Revenues

	Three Months Ended March 31,		Year over Year % Growth	
	2024	2023	As Reported	At CER*
<i>(In thousands, except percentages)</i>				
ONPATTRO net product revenues	\$ 69,217	\$ 102,493	(32)%	(33)%
AMVUTTRA net product revenues	195,241	101,768	92 %	93 %
Total TTR net product revenues	264,458	204,261	29 %	30 %
GIVLAARI net product revenues	58,056	47,906	21 %	21 %
OXLUMO net product revenues	42,649	24,161	77 %	75 %
Total Rare net product revenues	100,705	72,067	40 %	39 %
Total net product revenues	\$ 365,163	\$ 276,328	32 %	32 %

* CER = Constant Exchange Rate, representing growth calculated as if the exchange rates had remained unchanged from those used in the first quarter 2023. CER is a Non-GAAP measure.

- Total net product revenues increased 32% at both actual currency and CER during the three months ended March 31, 2024, as compared to the same period in 2023, due to strong growth from AMVUTTRA driven by increased patient demand, as well as increased patients on our GIVLAARI and OXLUMO therapies.

Net Revenues from Collaborations

- Net revenues from collaborations increased 225% during the three months ended March 31, 2024, as compared to the same period in 2023, primarily due to revenue recognized under our collaboration and license agreement with Roche, including \$65 million of milestone revenue associated with dosing the first patient in the zilebesiran KARDIA-3 clinical trial, and an increase in revenue recognized under our collaboration agreement with Regeneron as a result of an increase in activities under our research services arrangement and licensed programs.

Operating Expenses

<i>(In thousands, except percentages)</i>	Three Months Ended March 31,	
	2024	2023
Cost of goods sold	\$ 54,613	\$ 41,432
Cost of goods sold as a percentage of net product revenues	15.0 %	15.0 %
Cost of collaborations and royalties	\$ 11,363	\$ 13,437
GAAP research and development expenses	\$ 260,995	\$ 230,569
Non-GAAP research and development expenses	\$ 241,780	\$ 214,337
GAAP selling, general and administrative expenses	\$ 210,797	\$ 183,659
Non-GAAP selling, general and administrative expenses	\$ 184,665	\$ 159,944

Cost of Goods Sold

- Cost of goods sold as a percentage of net product revenues was consistent during the three months ended March 31, 2024, as compared to the same period in 2023, primarily due to increased royalties related to higher AMVUTTRA sales volume, partially offset by one-time favorability attributed to reduced ONPATTRO manufacturing cancellation fees.

Research & Development (R&D) Expenses

- GAAP and non-GAAP R&D expenses increased during the three months ended March 31, 2024, as compared to the same period in 2023, primarily due to increased development expenses associated with zilebesiran in the KARDIA-2 and KARDIA-3 clinical studies, increased expenses associated with our HELIOS-B study leading up to the topline data readout in late June or early July 2024, increased costs associated with our preclinical activities, specifically our CNS programs, and increased headcount and infrastructure expenses to support our R&D pipeline.

Selling, General & Administrative (SG&A) Expenses

- GAAP and non-GAAP SG&A expenses increased during the three months ended March 31, 2024, as compared to the same period in 2023, primarily due to increased

marketing investment associated with promotion of our TTR therapies and increased headcount and other investments supporting our strategic growth.

Other Financial Highlights

- Cash, cash equivalents and marketable securities were \$2.37 billion as of March 31, 2024 compared to \$2.44 billion as of December 31, 2023 with the decrease primarily due our operating loss in the first quarter 2024.

A reconciliation of our GAAP to non-GAAP results for the quarter is included in the tables at the end of this press release.

2024 Financial Guidance

Full year 2024 financial guidance is reiterated as follows:

Combined net product revenues for ONPATTRO, AMVUTTRA, GIVLAARI and OXLUMO ¹	\$1,400 million - \$1,500 million
Net Product Revenue Growth vs. 2023 at reported FX rates ¹	13% to 21%
Net Product Revenue Growth vs. 2023 at CER*	13% to 21%
Net revenues from collaborations and royalties	\$325 million - \$425 million
GAAP R&D and SG&A expenses	\$1,900 million - \$2,050 million
Non-GAAP R&D and SG&A expenses ²	\$1,675 million - \$1,775 million

¹ Uses January 31, 2024 FX rates including: 1 EUR = 1.08 USD and 1 USD = 147 JPY

² Primarily excludes \$225 - \$275 million of stock-based compensation expense from estimated GAAP R&D and SG&A expenses

*CER = Constant Exchange Rate, representing growth calculated as if the exchange rates had remained unchanged from those used in the twelve months ended December 31, 2023. CER is a Non-GAAP measure.

Use of Non-GAAP Financial Measures

This press release contains non-GAAP financial measures, including expenses adjusted to exclude certain non-cash expenses and non-recurring gains outside the ordinary course of the Company's business. These measures are not in accordance with, or an alternative to, GAAP, and may be different from non-GAAP financial measures used by other companies.

The items included in GAAP presentations but excluded for purposes of determining non-GAAP financial measures for the periods presented in this press release are stock-based compensation expenses and realized and unrealized losses on marketable equity securities. The Company has excluded the impact of stock-based compensation expense, which may fluctuate from period to period based on factors including the variability associated with performance-based grants for stock options and restricted stock units and changes in the Company's stock price, which impacts the fair value of these awards. The Company has excluded the impact of the realized and unrealized losses on marketable equity securities because the Company does not believe these adjustments accurately reflect the performance of the Company's ongoing operations for the

period in which such gains or losses are reported, as their sole purpose is to adjust amounts on the balance sheet.

Percentage changes in revenue growth at CER are presented excluding the impact of changes in foreign currency exchange rates for investors to understand the underlying business performance. The current period's foreign currency revenue values are converted into U.S. dollars using the average exchange rates from the prior period.

The Company believes the presentation of non-GAAP financial measures provides useful information to management and investors regarding the Company's financial condition and results of operations. When GAAP financial measures are viewed in conjunction with non-GAAP financial measures, investors are provided with a more meaningful understanding of the Company's ongoing operating performance and are better able to compare the Company's performance between periods. In addition, these non-GAAP financial measures are among those indicators the Company uses as a basis for evaluating performance, allocating resources and planning and forecasting future periods. Non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP financial measures. A reconciliation between GAAP and non-GAAP measures is provided later in this press release.

Conference Call Information

Management will provide an update on the Company and discuss first quarter 2024 results as well as expectations for the future via conference call on Thursday, May 2, 2024 at 8:30 am ET. To access the call, please register online at <https://register.vevent.com/register/BI0abdd195e81a43d9ac0c44fe9d789f86>. Participants are requested to register at least 15 minutes before the start of the call. A replay of the call will be available two hours after the call and archived on the same web page for six months.

A live audio webcast of the call will be available on the Investors section of the Company's website at www.alnylam.com/events. An archived webcast will be available on the Alnylam website approximately two hours after the event.

About ONPATTRO® (patisiran)

ONPATTRO is an RNAi therapeutic that is approved in the United States and Canada for the treatment of adults with hATTR amyloidosis with polyneuropathy. ONPATTRO is also approved in the European Union, Switzerland and Brazil for the treatment of hATTR amyloidosis in adults with Stage 1 or Stage 2 polyneuropathy, and in Japan for the treatment of hATTR amyloidosis with polyneuropathy. ONPATTRO is an intravenously administered RNAi therapeutic targeting transthyretin (TTR). It is designed to target and silence TTR messenger RNA, thereby reducing the production of TTR protein before it is made. Reducing the pathogenic protein leads to a reduction in amyloid deposits in tissues. For more information about ONPATTRO, including full Prescribing Information, visit ONPATTRO.com.

About AMVUTTRA® (vutrisiran)

AMVUTTRA® (vutrisiran) is an RNAi therapeutic approved in the United States for the treatment of adults with hATTR amyloidosis with polyneuropathy. It is a double-stranded small

interfering RNA (siRNA) that targets mutant and wild-type transthyretin (TTR) messenger RNA (mRNA). Using Alnylam's Enhanced Stabilization Chemistry (ESC)-GalNAc-conjugate delivery platform, AMVUTTRA is designed for increased potency and high metabolic stability to allow for subcutaneous injection once every three months (quarterly). Results from the pivotal HELIOS-A Phase 3 study demonstrate AMVUTTRA rapidly reduces serum TTR levels, has the potential to reverse neuropathy impairment relative to baseline and improves other key measures of disease burden relative to external placebo in patients with the polyneuropathy of hATTR amyloidosis. For more information about AMVUTTRA, including the full U.S. Prescribing Information, visit [AMVUTTRA.com](https://www.alnylam.com/AMVUTTRA).

About GIVLAARI® (givosiran)

GIVLAARI (givosiran) is an RNAi therapeutic targeting aminolevulinic acid synthase 1 (ALAS1) approved in the United States and Brazil for the treatment of adults with acute hepatic porphyria (AHP). GIVLAARI is also approved in the European Union for the treatment of AHP in adults and adolescents aged 12 years and older. In the pivotal study, givosiran was shown to significantly reduce the rate of porphyria attacks that required hospitalizations, urgent healthcare visits or intravenous hemin administration at home compared to placebo. GIVLAARI is Alnylam's first commercially available therapeutic based on its Enhanced Stabilization Chemistry ESC-GalNAc conjugate technology to increase potency and durability. GIVLAARI is administered via subcutaneous injection once monthly at a dose based on actual body weight and should be administered by a healthcare professional. GIVLAARI works by specifically reducing elevated levels of ALAS1 messenger RNA (mRNA), leading to reduction of toxins associated with attacks and other disease manifestations of AHP. For more information about GIVLAARI, including the full U.S. Prescribing Information, visit [GIVLAARI.com](https://www.alnylam.com/GIVLAARI).

About OXLUMO® (lumasiran)

OXLUMO (lumasiran) is an RNAi therapeutic targeting hydroxyacid oxidase 1 (HAO1). HAO1 encodes glycolate oxidase (GO). Thus, by silencing HAO1 and depleting the GO enzyme, OXLUMO inhibits production of oxalate – the metabolite that directly contributes to the pathophysiology of PH1. OXLUMO utilizes Alnylam's Enhanced Stabilization Chemistry (ESC)-GalNAc-conjugate technology, which enables subcutaneous dosing with increased potency and durability and a wide therapeutic index. OXLUMO has received regulatory approvals from the U.S. Food and Drug Administration (FDA) for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients and from the European Medicines Agency (EMA) for the treatment of PH1 in all age groups. In the pivotal ILLUMINATE-A study, OXLUMO was shown to significantly reduce levels of urinary oxalate relative to placebo, with the majority of patients reaching normal or near-normal levels. In the ILLUMINATE-B pediatric Phase 3 study, OXLUMO demonstrated an efficacy and safety profile consistent to that observed in ILLUMINATE-A. In the ILLUMINATE-C study, OXLUMO resulted in substantial reductions in plasma oxalate in patients with advanced PH1. Across all three studies, injection site reactions (ISRs) were the most common drug-related adverse reaction. OXLUMO is administered via subcutaneous injection once monthly for three months, then once quarterly beginning one month after the last loading dose at a dose based on actual body weight. For patients who weigh less than 10 kg, ongoing dosing remains monthly. OXLUMO should be administered by a healthcare

professional. For more information about OXLUMO, including the full U.S. Prescribing Information, visit OXLUMO.com.

About LNP Technology

Alnylam has licenses to Arbutus Biopharma lipid nanoparticle (LNP) intellectual property for use in RNAi therapeutic products using LNP technology.

About RNAi

RNAi (RNA interference) is a natural cellular process of gene silencing that represents one of the most promising and rapidly advancing frontiers in biology and drug development today. Its discovery has been heralded as “a major scientific breakthrough that happens once every decade or so,” and was recognized with the award of the 2006 Nobel Prize for Physiology or Medicine. By harnessing the natural biological process of RNAi occurring in our cells, a new class of medicines known as RNAi therapeutics is now a reality. Small interfering RNA (siRNA), the molecules that mediate RNAi and comprise Alnylam’s RNAi therapeutic platform, function upstream of today’s medicines by potently silencing messenger RNA (mRNA) – the genetic precursors – that encode for disease-causing or disease pathway proteins, thus preventing them from being made. This is a revolutionary approach with the potential to transform the care of patients with genetic and other diseases.

About Alnylam Pharmaceuticals

Alnylam Pharmaceuticals (Nasdaq: ALNY) has led the translation of RNA interference (RNAi) into a whole new class of innovative medicines with the potential to transform the lives of people afflicted with rare and prevalent diseases with unmet need. Based on Nobel Prize-winning science, RNAi therapeutics represent a powerful, clinically validated approach yielding transformative medicines. Since its founding in 2002, Alnylam has led the RNAi Revolution and continues to deliver on a bold vision to turn scientific possibility into reality. Alnylam’s commercial RNAi therapeutic products are ONPATTRO® (patisiran), AMVUTTRA® (vutrisiran), GIVLAARI® (givosiran), OXLUMO® (lumasiran), and Leqvio® (inclisiran), which is being developed and commercialized by Alnylam’s partner, Novartis. Alnylam has a deep pipeline of investigational medicines, including multiple product candidates that are in late-stage development. Alnylam is executing on its “*Alnylam P⁵x25*” strategy to deliver transformative medicines in both rare and common diseases benefiting patients around the world through sustainable innovation and exceptional financial performance, resulting in a leading biotech profile. Alnylam is headquartered in Cambridge, MA. For more information about our people, science and pipeline, please visit www.alnylam.com and engage with us on X (formerly Twitter) at @Alnylam, or on LinkedIn, Facebook, or Instagram.

Alnylam 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. All statements other than historical statements of fact regarding Alnylam’s expectations, beliefs, goals, plans or prospects including, without limitation, statements regarding Alnylam’s aspiration to become a top-tier biotech company, the potential for Alnylam to identify new potential drug development candidates and advance its research and development programs, Alnylam’s ability to obtain

approval for new commercial products or additional indications for its existing commercial products, and Alnylam's projected commercial and financial performance, including the expected range of net product revenues and net revenues from collaborations and royalties for 2024, the expected range of aggregate annual GAAP and non-GAAP R&D and SG&A expenses for 2024, the expected timing of topline data from the HELIOS-B Phase 3 clinical study, and the planned achievement of its "*Alnylam P⁵x25*" strategy, should be considered forward-looking statements. Actual results and future plans may differ materially from those indicated by these forward-looking statements as a result of various important risks, uncertainties and other factors, including, without limitation, risks and uncertainties relating to: Alnylam's ability to successfully execute on its "*Alnylam P⁵x25*" strategy; Alnylam's ability to discover and develop novel drug candidates and delivery approaches and successfully demonstrate the efficacy and safety of its product candidates; the pre-clinical and clinical results for Alnylam's product candidates, including vutrisiran, zilebesiran, and ALN-APP; actions or advice of regulatory agencies and Alnylam's ability to obtain and maintain regulatory approval for its product candidates, including vutrisiran, as well as favorable pricing and reimbursement; successfully launching, marketing and selling Alnylam's approved products globally; delays, interruptions or failures in the manufacture and supply of Alnylam's product candidates or its marketed products; obtaining, maintaining and protecting intellectual property; Alnylam's ability to successfully expand the approved indications for AMVUTTRA in the future; Alnylam's ability to manage its growth and operating expenses through disciplined investment in operations and its ability to achieve a self-sustainable financial profile in the future without the need for future equity financing; the direct or indirect impact of the COVID-19 global pandemic or any future pandemic on Alnylam's business, results of operations and financial condition; Alnylam's ability to maintain strategic business collaborations; Alnylam's dependence on third parties for the development and commercialization of certain products, including Roche, Novartis, Sanofi, Regeneron and Vir; the outcome of litigation; the risk of future government investigations; and unexpected expenditures; as well as those risks and uncertainties more fully discussed in the "Risk Factors" filed with Alnylam's 2023 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), as may be updated from time to time in Alnylam's subsequent Quarterly Reports on Form 10-Q, and in other filings that Alnylam makes with the SEC. In addition, any forward-looking statements represent Alnylam's views only as of today and should not be relied upon as representing its views as of any subsequent date. Alnylam explicitly disclaims any obligation, except to the extent required by law, to update any forward-looking statements.

This release discusses investigational RNAi therapeutics and uses of previously approved RNAi therapeutics in development and is not intended to convey conclusions about efficacy or safety as to those investigational therapeutics or uses. There is no guarantee that any investigational therapeutics or expanded uses of commercial products will successfully complete clinical development or gain health authority approval.

ALNYLAM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	March 31, 2024	December 31, 2023
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 681,879	\$ 812,688
Marketable debt securities	1,678,147	1,615,516
Marketable equity securities	11,256	11,178
Accounts receivable, net	321,377	327,787
Inventory	93,988	89,146
Prepaid expenses and other current assets	201,960	126,382
Total current assets	2,988,607	2,982,697
Property, plant and equipment, net	523,460	526,057
Operating lease right-of-use assets	195,468	199,732
Restricted investments	49,390	49,391
Other assets	67,461	72,003
Total assets	\$ 3,824,386	\$ 3,829,880
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 78,148	\$ 55,519
Accrued expenses	698,865	713,013
Operating lease liability	41,672	41,510
Deferred revenue	76,850	102,753
Liability related to the sale of future royalties	46,174	54,991
Total current liabilities	941,709	967,786
Operating lease liability, net of current portion	237,829	243,101
Deferred revenue, net of current portion	185,506	188,175
Convertible debt	1,021,732	1,020,776
Liability related to the sale of future royalties, net of current portion	1,336,892	1,322,248
Other liabilities	319,990	308,438
Total liabilities	4,043,658	4,050,524
Commitments and contingencies (Note 13)		
Stockholders' deficit:		
Preferred stock, \$0.01 par value per share, 5,000 shares authorized and no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, \$0.01 par value per share, 250,000 shares authorized; 126,463 shares issued and outstanding as of March 31, 2024; 125,794 shares issued and outstanding as of December 31, 2023	1,265	1,259
Additional paid-in capital	6,881,977	6,811,063
Accumulated other comprehensive loss	(26,988)	(23,375)
Accumulated deficit	(7,075,526)	(7,009,591)
Total stockholders' deficit	(219,272)	(220,644)
Total liabilities and stockholders' deficit	\$ 3,824,386	\$ 3,829,880

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alnylam's Annual Report on Form 10-K which includes the audited financial statements for the year ended December 31, 2023.

ALNYLAM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended	
	March 31, 2024	March 31, 2023
Statements of Operations		
Revenues:		
Net product revenues	\$ 365,163	\$ 276,328
Net revenues from collaborations	118,548	36,462
Royalty revenue	10,622	6,500
Total revenues	494,333	319,290
Operating costs and expenses:		
Cost of goods sold	54,613	41,432
Cost of collaborations and royalties	11,363	13,437
Research and development	260,995	230,569
Selling, general and administrative	210,797	183,659
Total operating costs and expenses	537,768	469,097
Loss from operations	(43,435)	(149,807)
Other (expense) income:		
Interest expense	(35,253)	(28,955)
Interest income	29,645	18,655
Other expense, net	(14,544)	(12,255)
Total other expense, net	(20,152)	(22,555)
Loss before income taxes	(63,587)	(172,362)
Provision for income taxes	(2,348)	(1,739)
Net loss	\$ (65,935)	\$ (174,101)
Net loss per common share - basic and diluted	\$ (0.52)	\$ (1.40)
Weighted-average common shares used to compute basic and diluted net loss per common share	126,138	124,111

ALNYLAM PHARMACEUTICALS, INC.
RECONCILIATION OF SELECTED GAAP MEASURES TO NON-GAAP MEASURES
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended	
	March 31, 2024	March 31, 2023
Reconciliation of GAAP to Non-GAAP Research and development:		
GAAP Research and development	\$ 260,995	\$ 230,569
Less: Stock-based compensation expenses	(19,215)	(16,232)
Non-GAAP Research and development	<u>\$ 241,780</u>	<u>\$ 214,337</u>
Reconciliation of GAAP to Non-GAAP Selling, general and administrative:		
GAAP Selling, general and administrative	\$ 210,797	\$ 183,659
Less: Stock-based compensation expenses	(26,132)	(23,715)
Non-GAAP Selling, general and administrative	<u>\$ 184,665</u>	<u>\$ 159,944</u>
Reconciliation of GAAP to Non-GAAP Operating gain (loss):		
GAAP Operating loss	\$ (43,435)	\$ (149,807)
Add: Stock-based compensation expenses	45,347	39,947
Non-GAAP Operating gain (loss)	<u>\$ 1,912</u>	<u>\$ (109,860)</u>
Reconciliation of GAAP to Non-GAAP Other expense, net:		
GAAP Other expense, net	\$ (20,152)	\$ (22,555)
(Less) Add: Realized and unrealized (gain) loss on marketable equity securities	(78)	2,267
Non-GAAP Other expense, net	<u>\$ (20,230)</u>	<u>\$ (20,288)</u>
Reconciliation of GAAP to Non-GAAP Net loss:		
GAAP Net loss	\$ (65,935)	\$ (174,101)
Add: Stock-based compensation expenses	45,347	39,947
(Less) Add: Realized and unrealized (gain) loss on marketable equity securities	(78)	2,267
Non-GAAP Net loss	<u>\$ (20,666)</u>	<u>\$ (131,887)</u>
Reconciliation of GAAP to Non-GAAP Net loss per common share- basic and diluted:		
GAAP Net loss per common share - basic and diluted	\$ (0.52)	\$ (1.40)
Add: Stock-based compensation expenses	0.36	0.32
(Less) Add: Realized and unrealized (gain) loss on marketable equity securities	—	0.02
Non-GAAP Net loss per common share - basic and diluted	<u>\$ (0.16)</u>	<u>\$ (1.06)</u>

Please note that the figures presented above may not sum exactly due to rounding

ALNYLAM PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO NON-GAAP
PRODUCT REVENUE GROWTH AT CONSTANT CURRENCY
(Unaudited)

	Three Months Ended March 31, 2024
Total TTR net product revenue growth, as reported	29 %
Add: Impact of foreign currency translation	1
Total TTR net product revenue growth at constant currency	30 %
GIVLAARI net product revenue growth, as reported	21 %
Add: Impact of foreign currency translation	—
GIVLAARI net product revenue growth at constant currency	21 %
OXLUMO net product revenue growth, as reported	77 %
Add: Impact of foreign currency translation	(2)
OXLUMO net product revenue growth at constant currency	75 %
Total net product revenue growth, as reported	32 %
Add: Impact of foreign currency translation	—
Total net product revenue growth at constant currency	32 %
Total revenue growth, as reported	55 %
Add: Impact of foreign currency translation	—
Total revenue growth at constant currency	55 %

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