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, 2024

Alnylam Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36407**	**77-0602661**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

675 West Kendall Street, **Henri A. Termeer Square** **Cambridge, Massachusetts**	**02142**
(Address of Principal Executive Offices)	(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 August 1, 2024, Alnylam Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter ended June 30, 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 August 1, 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: August 1, 2024

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ Jeffrey V. Poulton
Jeffrey V. Poulton
Executive Vice President, Chief Financial Officer

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

– Achieved Second Quarter 2024 Global Net Product Revenues of $410 Million, Representing 34% Year-Over-Year Growth Compared to Q2 2023, Driven by Continued Momentum from TTR Business, Which Delivered 37% Year-Over-Year Growth –

– Reported Positive Topline Results from HELIOS-B Phase 3 Study of Vutrisiran, Achieving Statistical Significance on Primary and All Secondary Endpoints in Both Overall and Monotherapy Populations –

– Updated 2024 Financial Guidance, Including Increased Combined Net Product Revenue Guidance from $1,400 Million - $1,500 Million to $1,575 Million - $1,650 Million –

CAMBRIDGE, Mass., August 1, 2024 – Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today reported its consolidated financial results for the second quarter ended June 30, 2024 and reviewed recent business highlights.

"Alnylam delivered strong results across the business in the second quarter. We achieved a robust 34% year-over-year growth, with global net product revenues of $410 million, primarily driven by our TTR business, leading to an upward revision of our combined net product revenue guidance for the year. On the clinical side, we announced positive topline results from the HELIOS-B Phase 3 study of vutrisiran, showing that it improved cardiovascular outcomes, including an impressive 35-36% mortality benefit, in patients with ATTR cardiomyopathy," said Yvonne Greenstreet, MBChB, Chief Executive Officer of Alnylam. "With these outstanding results in hand, and assuming successful regulatory review and approval, we believe we are positioned to deliver significant long-term topline growth, providing the capacity for strategic investment in our highly productive organic R&D platform, and further advancing us toward our *Alnylam P^{5}x25* goals and becoming a leading global biotech company."

Second 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 second quarter of $77 million and $230 million, respectively, representing 16% total TTR quarterly growth compared to Q1 2024, and 37% annual growth compared to Q2 2023, including 40% annual growth in the U.S.

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

- Achieved global net product revenues for GIVLAARI and OXLUMO for the second quarter of $62 million and $41 million, respectively, representing 2% total Rare quarterly growth compared to Q1 2024, and 25% annual growth compared to Q2 2023.

R&D Highlights

- Announced positive topline results from the HELIOS-B Phase 3 study of **vutrisiran** in patients with ATTR amyloidosis with cardiomyopathy (ATTR-CM).
  - The study met the primary endpoint, demonstrating statistically significant reductions of 28% and 33% in the composite of all-cause mortality and recurrent cardiovascular events in the overall and monotherapy populations, respectively.
  - Reduced all-cause mortality by 36% and 35% in the overall and monotherapy populations, respectively, in a pre-specified secondary endpoint.
  - Demonstrated clinically significant improvements vs. placebo on key measures of disease progression, including functional capacity, quality of life, and physician assessment of disease severity.
  - Observed consistent effects in all key subgroups, including baseline tafamidis use.
  - Demonstrated encouraging safety, consistent with vutrisiran's established profile.

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

- Initiated dosing in the cAPPricorn-1 Phase 2 study of investigational **mivelsiran** (ALN-APP) in patients with cerebral amyloid angiopathy (CAA).

- Initiated Part B of the Phase 1 study of **ALN-KHK**, in development for the treatment of Type 2 diabetes mellitus.

- Our collaboration partner, Sanofi, submitted regulatory filings for the investigational agent for hemophilia, **fitusiran**, in China, Brazil, and the U.S., with an FDA target action date of March 28, 2025.

- Our collaboration partner, Vir Biotechnology, reported new data for investigational **elebsiran** at the European Association for the Study of the Liver (EASL) Congress 2024. Vir also received Fast Track Designation for **tobevibart and elebsiran** for the treatment of hepatitis delta infection.

Additional Business Updates

- Updated collaboration agreements with Regeneron.
    - Amended license agreement under which Regeneron gains exclusive rights to **cemdisiran** as a monotherapy in exchange for a $10 million upfront payment, certain regulatory milestones, and low-double digit royalties on sales of cemdisiran as a monotherapy.
    - Alnylam now has full global development and commercialization rights to **mivelsiran** in all indications, as Regeneron opted out of further co-development and co-commercialization of mivelsiran, in development for CAA and Alzheimer's disease. Regeneron will be eligible to receive low-double digit royalties on sales of mivelsiran, if approved.

- Published 2023 **Corporate Responsibility Report**

Upcoming Events

Alnylam announced today that detailed results from the HELIOS-B Phase 3 study of **vutrisiran** will be presented as a Hot Line Oral Presentation at the European Society of Cardiology (ESC) Congress on Friday, August 30, 2024, at 11:00 am BST (6:00 am ET) in London, UK. The Company will host a webcast to discuss the results at 1:00 pm BST (8:00 am ET).

The Company also announced today that it will host a TTR Investor Day on October 9, 2024 in New York City. This event will feature presentations from Alnylam senior leaders and external experts related to the Company's TTR business. A live webcast of the event will also be available.

In mid- and late 2024, Alnylam intends to:

- Submit a supplemental New Drug Application (sNDA) for **vutrisiran** to the FDA using a Priority Review Voucher.
- Initiate a Phase 3 study of **ALN-TTRsc04** in patients with ATTR-CM at or around year-end.
- Report interim results from Part B of the Phase 1 study of **mivelsiran** (ALN-APP) in patients with Alzheimer's disease.
- Initiate a Phase 2 study of **mivelsiran** in patients with Alzheimer's disease at or around year-end.
- Initiate a Phase 1 study of **ALN-BCAT**, in development for the treatment of hepatocellular carcinoma.
- File 3 Investigational New Drug (IND) applications by year-end.

Financial Results for the Quarter Ended June 30, 2024

	Three Months Ended June 30,	
(In thousands, except per share amounts)	**2024**	**2023**
Net product revenues	$ 410,088	$ 305,705
Net revenue from collaborations	$ 227,338	$ 5,844
Royalty revenue	$ 22,399	$ 7,205
GAAP Operating income (loss)	$ 48,614	$ (229,831)
Non-GAAP Operating income (loss)	$ 137,902	$ (154,029)
GAAP Net loss	$ (16,889)	$ (276,024)
Non-GAAP Net income (loss)	$ 73,766	$ (201,622)
GAAP Net loss per common share - basic and diluted	$ (0.13)	$ (2.21)
Non-GAAP Net income (loss) per common share - basic	$ 0.58	$ (1.62)
Non-GAAP net income (loss) per common share - diluted	$ 0.56	$ (1.62)

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 measure, see the tables at the end of this press release.

Net Product Revenues

	Three Months Ended June 30,		Year over Year % Growth	
(In thousands, except percentages)	**2024**	**2023**	**As Reported**	**At CER***
ONPATTRO net product revenues	$ 77,244	$ 91,458	(16)%	(15)%
AMVUTTRA net product revenues	230,109	132,136	74 %	77 %
Total TTR net product revenues	307,353	223,594	37 %	39 %
GIVLAARI net product revenues	62,127	57,899	7 %	8 %
OXLUMO net product revenues	40,608	24,212	68 %	68 %
Total Rare net product revenues	102,735	82,111	25 %	26 %
Total net product revenues	$ 410,088	$ 305,705	34 %	35 %

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

- Total net product revenues increased 34% and 35% at actual currency and CER, respectively, during the three months ended June 30, 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 GIVLAARI and OXLUMO.

Net Revenues from Collaborations

- Net revenues from collaborations during the three months ended June 30, 2024, included approximately $185 million of revenue, which was previously deferred, upon modifying our collaboration agreement with Regeneron. As part of the modification to the collaboration agreement, we granted Regeneron exclusive license rights to cemdisiran monotherapy.

Operating Expenses

	Three Months Ended June 30,	
(In thousands, except percentages)	**2024**	**2023**
Cost of goods sold	$ 67,271	$ 75,336
Cost of goods sold as a percentage of net product revenues	*16.4 %*	*24.6 %*
Cost of collaborations and royalties	$ 1,401	$ 10,034
GAAP research and development expenses	$ 294,142	$ 248,526
Non-GAAP research and development expenses	$ 246,027	$ 215,725
GAAP selling, general and administrative expenses	$ 248,397	$ 214,689
Non-GAAP selling, general and administrative expenses	$ 207,224	$ 171,688

Cost of Goods Sold

- Cost of goods sold as a percentage of net product revenues decreased during the three months ended June 30, 2024, as compared to the same period in 2023, primarily due to higher costs in 2023 associated with cancelled manufacturing commitments for ONPATTRO and other adjustments to inventory, for which similar expenses did not occur in 2024.

Research & Development (R&D) Expenses

- GAAP and non-GAAP R&D expenses increased during the three months ended June 30, 2024, as compared to the same period in 2023, primarily due to increased costs associated with our preclinical activities, increased clinical research expenses associated with startup activities for the zilebesiran and mivelsiran clinical studies, and increased employee compensation expenses. GAAP R&D expenses further increased in the second quarter of 2024, compared with 2023, due to increased stock-based compensation expense.

Selling, General & Administrative (SG&A) Expenses

- GAAP and non-GAAP SG&A expenses increased during the three months ended June 30, 2024, as compared to the same period in 2023, primarily due to increased marketing investment associated with promotion of our TTR therapies and increased employee compensation expenses.

Other Financial Highlights

- Cash, cash equivalents and marketable securities were $2.62 billion as of June 30, 2024, as compared to $2.44 billion as of December 31, 2023, with the increase primarily due to increased net product revenues and increased net proceeds from the issuance of common stock in connection with stock option exercises.

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 has been updated as follows:

	Provided 2/15/2024	**Updated 8/1/2024**
Combined net product revenues for ONPATTRO, AMVUTTRA, GIVLAARI and OXLUMO[1]	$1,400 million - $1,500 million	$1,575 million - $1,650 million
Net Product Revenue Growth vs. 2023 at reported FX rates[1]	13% to 21%	27% to 33%
*Net Product Revenue Growth vs. 2023 at CER**	13% to 21%	28% to 34%
Net revenues from collaborations and royalties	$325 million - $425 million	$575 million - $650 million
GAAP R&D and SG&A expenses	$1,900 million - $2,050 million	$2,000 million - $2,150 million
Non-GAAP R&D and SG&A expenses[2]	$1,675 million - $1,775 million	$1,775 million - $1,875 million

[1] Uses June 30, 2024 FX rates including: 1 EUR = 1.07 USD and 1 USD = 161 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 second quarter 2024 results as well as expectations for the future via conference call on Thursday, August 1, 2024 at 8:30 am ET. 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.

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, GIVLAARI 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.

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 P^{5}x25*" 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 leading global 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 potential submission of a sNDA for AMVUTTRA for patients with ATTR amyloidosis with cardiomyopathy by mid- to late 2024 for FDA review, the use of a Priority Review Voucher in connection with the submission of a sNDA for AMVUTTRA for patients with ATTR amyloidosis with cardiomyopathy, and the advancement towards its *"Alnylam P^{5}x25"* 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 P^{5}x25*" 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 mivelsiran; 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; 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. Vutrisiran has not been approved by any regulatory agency for the treatment of ATTR amyloidosis with cardiomyopathy. No conclusions can or should be drawn regarding its safety or effectiveness in treating cardiomyopathy in this population. 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)

	June 30, 2024	December 31, 2023
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 968,492	$ 812,688
Marketable debt securities	1,646,268	1,615,516
Marketable equity securities	9,889	11,178
Accounts receivable, net	309,481	327,787
Inventory	83,981	89,146
Prepaid expenses and other current assets	154,745	126,382
Total current assets	3,172,856	2,982,697
Property, plant and equipment, net	517,159	526,057
Operating lease right-of-use assets	198,303	199,732
Restricted investments	49,391	49,391
Other assets	71,925	72,003
Total assets	$ 4,009,634	$ 3,829,880
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 73,980	$ 55,519
Accrued expenses	808,643	713,013
Operating lease liability	41,656	41,510
Deferred revenue	69,009	102,753
Liability related to the sale of future royalties	61,963	54,991
Total current liabilities	1,055,251	967,786
Operating lease liability, net of current portion	239,352	243,101
Deferred revenue, net of current portion	2,402	188,175
Convertible debt	1,022,688	1,020,776
Liability related to the sale of future royalties, net of current portion	1,342,580	1,322,248
Other liabilities	350,428	308,438
Total liabilities	4,012,701	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 June 30, 2024 and December 31, 2023	—	—
Common stock, $0.01 par value per share, 250,000 shares authorized; 128,021 shares issued and outstanding as of June 30, 2024; 125,794 shares issued and outstanding as of December 31, 2023	1,281	1,259
Additional paid-in capital	7,122,704	6,811,063
Accumulated other comprehensive loss	(34,637)	(23,375)
Accumulated deficit	(7,092,415)	(7,009,591)
Total stockholders' deficit	(3,067)	(220,644)
Total liabilities and stockholders' deficit	$ 4,009,634	$ 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		Six Months Ended	
	June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Statements of Operations				
Revenues:				
Net product revenues	$ 410,088	$ 305,705	$ 775,251	$ 582,033
Net revenues from collaborations	227,338	5,844	345,886	42,306
Royalty revenue	22,399	7,205	33,021	13,705
Total revenues	659,825	318,754	1,154,158	638,044
Operating costs and expenses:				
Cost of goods sold	67,271	75,336	121,884	116,768
Cost of collaborations and royalties	1,401	10,034	12,764	23,471
Research and development	294,142	248,526	555,137	479,095
Selling, general and administrative	248,397	214,689	459,194	398,348
Total operating costs and expenses	611,211	548,585	1,148,979	1,017,682
Income (loss) from operations	48,614	(229,831)	5,179	(379,638)
Other (expense) income:				
Interest expense	(33,258)	(30,035)	(68,511)	(58,990)
Interest income	29,182	21,075	58,827	39,730
Other expense, net	(55,705)	(35,418)	(70,249)	(47,673)
Total other expense, net	(59,781)	(44,378)	(79,933)	(66,933)
Loss before income taxes	(11,167)	(274,209)	(74,754)	(446,571)
Provision for income taxes	(5,722)	(1,815)	(8,070)	(3,554)
Net loss	$ (16,889)	$ (276,024)	$ (82,824)	$ (450,125)
Net loss per common share - basic and diluted	$ (0.13)	$ (2.21)	$ (0.66)	$ (3.62)
Weighted-average common shares used to compute basic and diluted net loss per common share	126,733	124,659	126,435	124,387

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

	Three Months Ended	
	June 30, 2024	June 30, 2023
Reconciliation of GAAP to Non-GAAP Research and development:		
GAAP Research and development	$ 294,142	$ 248,526
Less: Stock-based compensation expenses	(48,115)	(32,801)
Non-GAAP Research and development	$ 246,027	$ 215,725
Reconciliation of GAAP to Non-GAAP Selling, general and administrative:		
GAAP Selling, general and administrative	$ 248,397	$ 214,689
Less: Stock-based compensation expenses	(41,173)	(43,001)
Non-GAAP Selling, general and administrative	$ 207,224	$ 171,688
Reconciliation of GAAP to Non-GAAP Operating income (loss):		
GAAP Operating income (loss)	$ 48,614	$ (229,831)
Add: Stock-based compensation expenses	89,288	75,802
Non-GAAP Operating income (loss)	$ 137,902	$ (154,029)
Reconciliation of GAAP Net loss to Non-GAAP Net income:		
GAAP Net loss	$ (16,889)	$ (276,024)
Add: Stock-based compensation expenses	89,288	75,802
Add (Less): Realized and unrealized loss (gain) on marketable equity securities	1,367	(1,400)
Non-GAAP Net income (loss)	$ 73,766	$ (201,622)
Reconciliation of GAAP Net loss to Non-GAAP Net income (loss) per common share- basic:		
GAAP Net loss per common share - basic	$ (0.13)	$ (2.21)
Add: Stock-based compensation expenses	0.70	0.61
Add (Less): Realized and unrealized loss (gain) on marketable equity securities	0.01	(0.01)
Non-GAAP Net income (loss) per common share - basic	$ 0.58	$ (1.62)
Reconciliation of GAAP Net loss to Non-GAAP Net income (loss) per common share- diluted:		
GAAP net loss per common share - diluted	$ (0.13)	$ (2.21)
Add: Stock-based compensation expenses	0.70	0.61
Add (Less): Realized and unrealized loss (gain) on marketable equity securities	0.01	(0.01)
Less: Impact to earnings per common share as a result of diluted weighted-average common shares outstanding during the period*	(0.02)	—
Non-GAAP net income (loss) per common share - diluted*	$ 0.56	$ (1.62)

*Diluted non-GAAP net income per share is calculated by dividing the non-GAAP net income by the weighted-average number of common shares and dilutive potential common share equivalents then outstanding during the period. The diluted weighted-average common shares outstanding for the three-months ended June 30, 2024 would be 132,061,000.

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)

	June 30, 2024
	Three Months Ended
ONPATTRO net product revenue growth, as reported	(16)%
Add: Impact of foreign currency translation	1
ONPATTRO net product revenue growth at constant currency	(15)%
AMVUTTRA net product revenue growth, as reported	74 %
Add: Impact of foreign currency translation	3
AMVUTTRA net product revenue growth at constant currency	77 %
Total TTR net product revenue growth, as reported	37 %
Add: Impact of foreign currency translation	2
Total TTR net product revenue growth at constant currency	39 %
GIVLAARI net product revenue growth, as reported	7 %
Add: Impact of foreign currency translation	1
GIVLAARI net product revenue growth at constant currency	8 %
OXLUMO net product revenue growth, as reported	68 %
Add: Impact of foreign currency translation	—
OXLUMO net product revenue growth at constant currency	68 %
Total net product revenue growth, as reported	34 %
Add: Impact of foreign currency translation	1
Total net product revenue growth at constant currency	35 %