UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 9, 2023 (January 8, 2023)

Alnylam Pharmaceuticals, Inc.

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** **(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 January 8, 2023, Alnylam Pharmaceuticals, Inc. (the "Company") announced its preliminary fourth quarter and full year 2022 global net product revenues of approximately $262 million and $894 million, respectively, for ONPATTRO® (patisiran), AMVUTTRA® (vutrisiran), GIVLAARI® (givosiran) and OXLUMO® (lumasiran), and provided additional updates on the products' commercial launches. The Company also updated its cash guidance for the year ended December 31, 2022, stating that at December 31, 2022, it had preliminary cash, cash equivalents and marketable securities of approximately $2.2 billion.

The preliminary selected financial results reported by the Company are unaudited, subject to adjustment, and provided as an approximation in advance of the Company's announcement of complete financial results in February 2023.

The information in this Item 2.02 and Exhibit 99.1 attached hereto is intended to be furnished and 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 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 January 8, 2023.
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.

ALNYLAM PHARMACEUTICALS, INC.

Date: January 9, 2023

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

Exhibit 99.1

Contacts:
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(Investors)
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Alnylam Announces Preliminary* Fourth Quarter and Full Year 2022 Global Net Product Revenues and Provides Additional Updates

*– Achieved Full Year 2022 Preliminary Global Net Product Revenues of $894 Million for ONPATTRO®, AMVUTTRA®, GIVLAARI®, and OXLUMO®, Representing 35% Annual Growth (43% Using Constant Exchange Rate**) –*

– Strength of AMVUTTRA Launch Drove 37% Total TTR Annual Revenue Growth –

– Maintained Strong Balance Sheet with Year-End Cash and Investments Balance of Approximately $2.2 Billion –

CAMBRIDGE, Mass., January 8, 2023 – Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today announced its preliminary* fourth quarter and full year 2022 global net product revenues for ONPATTRO, AMVUTTRA, GIVLAARI, and OXLUMO and provided additional updates on the products' commercial launches.

Preliminary Fourth Quarter and Full Year 2022 Commercial and Financial Performance*

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

- Preliminary global net product revenues for ONPATTRO and AMVUTTRA for the fourth quarter were approximately $122 million and $69 million, respectively, representing 12% total TTR quarterly growth compared to Q3 2022, and for the full year 2022 were approximately $558 million and $94 million, respectively, representing 37% total TTR annual growth compared to full year 2021.
- As of year-end 2022, over 2,975 patients worldwide were receiving commercial ONPATTRO or AMVUTTRA.

* The preliminary selected financial results are unaudited, subject to adjustment, and provided as an approximation in advance of the Company's announcement of complete financial results in February 2023.

** CER = Constant Exchange Rate, representing growth calculated as if the exchange rates had remained unchanged from those used during 2021. CER is a Non-GAAP financial measure.

GIVLAARI® (givosiran)

- Preliminary global net product revenues for the fourth quarter and full year 2022 were approximately $47 million and $173 million, respectively, representing quarterly and annual growth of 3% and 35% compared to Q3 2022 and full year 2021, respectively.
- As of year-end 2022, over 520 patients worldwide were receiving commercial GIVLAARI.

OXLUMO® (lumasiran)

- Preliminary global net product revenues for the fourth quarter and full year 2022 were approximately $24 million and $70 million, respectively, representing quarterly and annual growth of 45% and 17% compared to Q3 2022 and full year 2021, respectively.
- As of year-end 2022, over 280 patients worldwide were receiving commercial OXLUMO.

Further, at December 31, 2022, Alnylam had preliminary cash, cash equivalents, and marketable securities of approximately $2.2 billion, as compared to $2.4 billion at December 31, 2021.

“We are pleased to have closed out 2022 on a very strong note with continued execution across our commercial portfolio, delivering top-line revenue in line with our guidance range. These preliminary results reflect healthy patient demand for our transformative products and strong commercial execution by our teams in delivering these important medicines to patients in need around the world. In 2022 we were particularly excited to celebrate the approval and global launch of AMVUTTRA, which has demonstrated an impressive commercial performance in its first two full quarters of launch,” said Yvonne Greenstreet, MBChB, Chief Executive Officer of Alnylam. “As we consider our commercial and financial performance, combined with robust execution on the R&D front, we believe we are well on our way to achieving our *Alnylam P^{5}x25* goals, positioning Alnylam as a top-tier, global, multi-product commercial company with a broad pipeline and organic platform poised to deliver sustainable innovation well into the future, a profile rarely seen in our industry.”

Alnylam management will discuss these preliminary selected financial results and commercial updates during a webcast presentation at the 41st Annual J.P. Morgan Healthcare Conference in San Francisco, California tomorrow, Monday, January 9, 2023 at 9:45 a.m. PT (12:45 p.m. ET).

About RNAi Therapeutics

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 20 years ago, 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 Twitter at @Alnylam, on LinkedIn, or on 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, expectations regarding Alnylam's aspiration to become a leading biotech company and the planned achievement of its *"Alnylam P5x25"* strategy, 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 products, and Alnylam's projected commercial and financial performance 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: 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 and the effectiveness or timeliness of Alnylam's efforts to mitigate the impact of the pandemic; the potential impact of the January 2022 leadership transition on Alnylam's ability to attract and retain talent and to successfully execute on its *"Alnylam P5x25"* strategy; the finalization and audit of Alnylam's fourth quarter and 2022 fiscal year financial results which could potentially result in changes or adjustments to the selected preliminary financial results presented herein; 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 its product candidates; actions or advice of regulatory agencies and Alnylam's ability to obtain and maintain regulatory approval for its product candidates, as well as favorable pricing and reimbursement; successfully launching, marketing and selling its approved products globally; delays, interruptions or failures in the manufacture and supply of its product candidates or its marketed products; obtaining, maintaining and protecting intellectual property; Alnylam's ability to successfully expand the indication for ONPATTRO or 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 Novartis, Sanofi, Regeneron and Vir; the outcome of litigation; the potential impact of a current government investigation and the risk of future government investigations; and unexpected expenditures; as well as those risks more fully discussed in the "Risk Factors" filed with Alnylam's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in its other SEC filings. 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.

Use of Non-GAAP Financial Measures

This press release contains a non-GAAP financial measure of Constant Exchange Rate (CER). This measure is not in accordance with, or an alternative to, GAAP, and may be different from non-GAAP financial measures used by other companies. 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 exchange rates from the prior period. The difference between the reported 35% annual GAAP growth rate and 43% annual CER growth rate is due to the inclusion of 8% additional net product revenue growth in the CER growth rate had exchange rates remained unchanged from 2021.