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 10, 2022 (January 9, 2022)

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**	**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 January 9, 2022, Alnylam Pharmaceuticals, Inc. (the "Company") announced its preliminary fourth quarter and full year 2021 global net product revenues for ONPATTRO® (patisiran), GIVLAARI® (givosiran) and OXLUMO® (lumasiran), and provided additional updates on the products' commercial launches. The Company reported preliminary global net product revenues for ONPATTRO, GIVLAARI and OXLUMO for the fourth quarter and full year 2021 of approximately $199 million and $662 million, respectively. The Company also updated its cash guidance for the year ended December 31, 2021, stating that at December 31, 2021, it had preliminary cash, cash equivalents and marketable securities of approximately $2.4 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 2022.

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 9, 2022.
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 10, 2022

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

Exhibit 99.1

Contacts:
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(Investors)
617-551-8276

Alnylam Announces Preliminary* Fourth Quarter and Full Year 2021 Global Net Product Revenues and Provides Additional Updates

– Achieved Full Year 2021 Preliminary Global Net Product Revenues of $662 Million, Representing 83% Annual Growth Compared to 2020 –

– Maintained Strong Balance Sheet with Year-End Cash and Investments Balance of Approximately $2.4 Billion –

CAMBRIDGE, Mass., January 9, 2022 – Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today announced its preliminary* fourth quarter and full year 2021 global net product revenues for ONPATTRO, GIVLAARI and OXLUMO and provided additional updates on the products' commercial launches.

2021 Preliminary Commercial and Financial Performance*

ONPATTRO® (patisiran), a commercial-stage RNAi therapeutic targeting transthyretin (TTR) for the treatment of polyneuropathy in adult patients with hATTR amyloidosis.

- Preliminary global net product revenues for the fourth quarter and full year 2021 were approximately $139 million and $475 million, respectively, representing quarterly and annual growth of 15% and 55% compared to Q3 2021 and full year 2020, respectively.
- As of year-end 2021, over 2,050 patients worldwide were receiving commercial ONPATTRO.

GIVLAARI® (givosiran), a commercial-stage RNAi therapeutic for the treatment of adults with acute hepatic porphyria (AHP).

- Preliminary global net product revenues for the fourth quarter and full year 2021 were approximately $41 million and $128 million, respectively, representing quarterly and annual growth of 28% and 132% compared to Q3 2021 and full year 2020, respectively.
- As of year-end 2021, over 350 patients worldwide were receiving commercial GIVLAARI.

OXLUMO® (lumasiran), a commercial-stage RNAi therapeutic for the treatment of primary hyperoxaluria type 1 to lower urinary oxalate levels in pediatric and adult patients.

- Preliminary global net product revenues for the fourth quarter and full year 2021 were approximately $19 million and $60 million, respectively, representing quarterly growth of 29% compared to Q3 2021.
- As of year-end 2021, over 140 patients worldwide were receiving commercial OXLUMO.

Finally, the Company today reported that it expects its full year 2021 non-GAAP operating loss to be substantially improved relative to the prior year, as the Company continues to transition toward a self-sustainable financial profile.

Further, at December 31, 2021, Alnylam had preliminary cash, cash equivalents, and marketable securities of approximately $2.4 billion, as compared to $1.9 billion at December 31, 2020.

“We are pleased to have closed out 2021 on a very strong note with continued execution across our commercial portfolio, delivering top-line revenue at the upper end of our guidance range. These preliminary results reflect the dedication of our teams to deliver these important medicines to patients in need around the world, despite the variable dynamics posed by the ongoing pandemic. We’re also excited to have ended the year with Leqvio, partnered with Novartis, becoming the fourth RNAi therapeutic approved in the U.S., and the first indicated to treat a major risk factor for a highly prevalent disease,” said Yvonne Greenstreet, MBChB, Chief Executive Officer of Alnylam. “Furthermore, as we reflect upon the one year anniversary of the announcement of our *Alnylam P5x25* strategy, we believe we are well on our way to achieving or potentially exceeding these ambitious 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 40th Annual J.P. Morgan Healthcare Conference, being held virtually, tomorrow, Monday, January 10, 2022 at 9:45 am 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 (Nasdaq: ALNY) is leading 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 genetic, cardio-metabolic, hepatic infectious, and central nervous system (CNS)/ocular diseases. Based on Nobel Prize-winning science, RNAi therapeutics represent a powerful, clinically validated approach for the treatment of a wide range of severe and debilitating diseases. Founded in 2002, Alnylam is delivering on a bold vision to turn scientific possibility into reality, with a robust RNAi therapeutics platform. Alnylam’s commercial RNAi therapeutic products are

ONPATTRO® (patisiran), GIVLAARI® (givosiran), OXLUMO® (lumasiran), and Leqvio® (inclisiran) being developed and commercialized by Alnylam's partner Novartis. Alnylam has a deep pipeline of investigational medicines, including six 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

Various statements in this release concerning Alnylam's expectations, plans, aspirations, and goals, including, without limitation, those related to its unaudited, preliminary selected financial results for 2021, and its aspiration to become a leading biotech company, and the planned achievement or potential exceeding of its "Alnylam *P5x25*" strategy, constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. 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 recent 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 its fourth quarter and 2021 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 (and potentially vutrisiran, if approved) 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, 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.

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