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 11, 2021 (January 10, 2021)

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 January 10, 2021, Alnylam Pharmaceuticals, Inc. (the "Company") announced its preliminary fourth quarter and full year 2020 global net product revenues for ONPATTRO® (patisiran), GIVLAARI® (givosiran) and OXLUMO™ (lumasiran), and provided additional updates on the Company's commercial launches, including initial OXLUMO demand. The Company reported preliminary global net product revenues for ONPATTRO and GIVLAARI for the fourth quarter and full year 2020 of approximately $112 million and $361 million, respectively. For the period following approval of OXLUMO in the U.S. and EU in late November 2020 through year end, the Company reported preliminary global net product revenues of approximately $0.3 million for OXLUMO. The Company also updated its cash guidance for the year ended December 31, 2020, stating that at December 31, 2020, it had preliminary cash, cash equivalents and marketable securities of approximately $1.9 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 2021.

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 10, 2021.
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 11, 2021

By: /s/ Jeff Poulton
Jeff Poulton
Executive Vice President, Chief Financial Officer

Exhibit 99.1

Contacts:
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Alnylam Launches "*Alnylam P5x25*" Strategy for Planned Transition to a Top Five Biotech in Market Capitalization Over Next Five Years

– New 5-Year Strategy Represents Alnylam's Commitment to Delivering Transformative Rare and Prevalent Disease Medicines for Patients Around the World Through Sustainable Innovation and Exceptional Financial Performance Driving Profitability –

– In Addition, Company Announces Full Year 2020 Preliminary Global Net Product Revenues for ONPATTRO® and GIVLAARI® of Approximately $306 Million and $55 Million, Respectively, and Strong Initial U.S. Demand for OXLUMO™ –*

CAMBRIDGE, Mass., – Jan. 10, 2021 – Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today announced its new 5-year strategy "*Alnylam P5x25*" focused on the Company's planned transition to a top-5 biotech (measured by market capitalization) in the next 5 years through: sustainable innovation yielding transformative medicines for rare and common diseases for patients around the world and delivery of exceptional financial performance. *Alnylam P5x25* extends the Company's decade-long heritage of providing longer term, 5-year business strategy guidance, the most recent of which was known as *Alnylam 2020*. In addition, Alnylam today reported preliminary fourth quarter and full year 2020 global net product revenues for ONPATTRO and GIVLAARI and provided additional updates on the Company's commercial launches, including initial OXLUMO demand.

New 5-Year Strategy: P5x25

Alnylam ended last year exceeding all metrics for its *Alnylam 2020* strategy, with 4 marketed products (versus 3), 12 clinical programs (versus 10), 6 of which are in late-stage development (versus 4), across 4 strategic therapeutic areas (versus 3).

The Company's *Alnylam P5x25* strategy is aimed at Alnylam's transition to a top 5 biotech company, as measured by market capitalization, over the next 5 years.

Specifically, the Company intends to end 2025 with the following profile**:

- **Patients**: Over 0.5 million on Alnylam RNAi therapeutics globally
- **Products**: 6 or more marketed products in rare and prevalent diseases
- **Pipeline**: Over 20 clinical programs, with 10 or more in late stages and 4 or more INDs per year

- **Performance**: ³40% revenue CAGR through YE 2025
- **Profitability**: Achieve sustainable non-GAAP profitability within the period

“We executed well on our *Alnylam 2020* strategy, exceeding all pre-set metrics and transitioning into a global, multi-product commercial company with a robust clinical pipeline and an organic product engine delivering sustainable innovation, a profile that has rarely been achieved in biotech history. It was especially gratifying to cap 2020 with positive Phase 3 HELIOS-A results for vutrisiran, which is set to become our 5th RNAi therapeutic to reach the market, if approved,” said John Maraganore, Ph.D., CEO of Alnylam Pharmaceuticals. “We are now thrilled to launch our new chapter with *Alnylam P5x25*, which is aimed at Alnylam’s planned transition to a top 5 biotech in market capitalization based on a proven and high-yielding technology for disruptive medical innovation and a foundational track record of commercial execution. Indeed, with *Alnylam P5x25*, we expect to sustainably and organically create and commercialize transformative rare and common disease medicines benefiting hundreds of thousands of patients around the world while delivering strong financial performance and profitability, resulting in a leading biotech profile.”

2020 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 2020 were approximately $90 million and $306 million, respectively.
    - Q4 results represent approximately 10 percent growth compared to Q3 and include 10 percent growth in the U.S. market segment driven by new patient demand.
    - Further, the full year ONPATTRO revenues reached the high end of the previously shared guidance range of $295 million - $310 million and represent over 80 percent growth from full year 2019.
- As of year-end 2020, about 1,350 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 2020 were approximately $22 million and $55 million, respectively.
    - These results represent greater than 30 percent quarter over quarter growth.
- As of year-end 2020, the product’s first full year of launch, over 200 patients are receiving commercial drug.

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.

- For the period following European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) approval of OXLUMO, in late November 2020, strong initial U.S. demand was observed with 8 Start Forms received through year-end.
- Preliminary global net product revenues for the fourth quarter were approximately $0.3 million representing initial patient demand in Europe

Finally, the Company today reported that it expects its full year 2020 non-GAAP operating loss to be substantially improved relative to the prior year, marking 2019 as Alnylam's peak non-GAAP operating loss year as the Company transitions towards a self-sustainable financial profile.

Further, at December 31, 2020, Alnylam had preliminary cash, cash equivalents, and marketable securities of approximately $1.9 billion, as compared to $1.5 billion at December 31, 2019. The Company balance sheet was strengthened by the 2020 strategic financing collaboration with Blackstone.

"We are extremely pleased with ONPATTRO and GIVLAARI performance in the fourth quarter and cumulatively for the year, reflecting strong commercial execution, a substantial increase in demand and new patient adds, despite the ongoing COVID-19 pandemic. Additionally, we're pleased to report that strong top-line revenue growth at the upper end of our guidance range and disciplined R&D and SG&A investments have delivered on a lower non-GAAP operating loss for 2020 compared with the prior year. We believe we're now firmly on our way toward a self-sustainable financial profile with significant growth from four revenue generating assets and moderated operating expenses, and a balance sheet that supports achievement of profitability without the need to access the equity markets," said Jeff Poulton, Chief Financial Officer of Alnylam. "As we now launch our *Alnylam P5x25* strategy, we're committed to delivering consistently strong financial performance driven by 40% or greater revenue CAGR over the next five years with non-GAAP profitability achieved within the period."

Alnylam management will discuss these preliminary selected financial results and commercial updates during a webcast presentation at the 39th Annual J.P. Morgan Healthcare Conference tomorrow, Monday, January 11, 2021, at 8:20 a.m. ET.

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 (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), and 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 or on LinkedIn.

Alnylam Forward Looking Statements

Various statements in this release concerning Alnylam's future expectations, plans and prospects, including, without limitation, Alnylam's views and plans with respect to its new 5-year "*Alnylam P5x25*" strategy, its intentions to achieve the metrics associated with this strategy including to become a profitable, top 5 biotech company, its unaudited, preliminary selected financial results for 2020, the potential for RNAi therapeutics, including ONPATTRO, GIVLAARI, OXLUMO, Leqvio (inclisiran) and vutrisiran, its plans for the continuing launch of its commercial products and the advancement of vutrisiran through regulatory review and toward the market, the achievement of additional pipeline milestones, and the continued development and commercialization of Leqvio (inclisiran) by its partner, Novartis, 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, such as the scope and duration of the outbreak, government actions and restrictive measures implemented in response, the broad availability of safe and effective vaccine(s), material delays in diagnoses of rare diseases, initiation or continuation of treatment for diseases addressed by Alnylam products, or in patient enrollment in clinical trials, potential supply chain disruptions, and other potential impacts to Alnylam's business, the effectiveness or timeliness of steps taken by Alnylam to mitigate the impact of the pandemic, and Alnylam's ability to execute business continuity plans to address disruptions caused by the COVID-19 or any future pandemic; the finalization and audit of Alnylam's fourth quarter and 2020 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, which may not be replicated or continue to occur in other subjects or in additional studies or otherwise support further development of product candidates for a specified indication or at all; actions or advice of regulatory agencies, which may affect the design, initiation, timing, continuation and/or progress of clinical trials or result in the need for additional pre-clinical and/or clinical testing; delays, interruptions or failures in the manufacture and supply of its product candidates or its or its partner Novartis' marketed products; obtaining, maintaining and protecting intellectual property; intellectual property matters including potential patent litigation relating to its platform, products or product candidates; obtaining regulatory approval for its product candidates, and maintaining regulatory approval and obtaining pricing and reimbursement for its

products; successfully launching, marketing and selling its approved products globally; Alnylam's ability to successfully expand the indication for ONPATTRO in the future; the ability of Novartis to successfully obtain and maintain additional regulatory approvals and pricing and reimbursement for Leqvio (inclisiran); competition from others using technology similar to Alnylam's and others developing products for similar uses; Alnylam's ability to manage its growth and operating expenses and its ability to achieve a self-sustainable financial profile in the future without the need for future equity financing; Alnylam's ability to establish and maintain strategic business alliances and new business initiatives; Alnylam's dependence on third parties, including Novartis, Regeneron and Vir, for the continued development and commercialization of certain products; the outcome of litigation; the risk of 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 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.

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* 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 2021.

** The "*Alnylam P^{5}x25*" metrics on Patients, Products, and Pipeline include proprietary and partnered products and programs.