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 13, 2020 (January 12, 2020)

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 12, 2020, Alnylam Pharmaceuticals, Inc. (the "Company") announced its preliminary fourth quarter and full year 2019 global net product revenues for ONPATTRO® (patisiran) and GIVLAARI™ (givosiran) and provided additional updates on the products' commercial launches. The Company reported preliminary global net product revenues for ONPATTRO for the fourth quarter and full year 2019 of approximately $56 million and $166 million, respectively. For the period following approval of GIVLAARI in the U.S. on November 20 through year end, the Company reported preliminary global net product revenues of approximately $0.2 million for GIVLAARI. The Company also updated its cash guidance for the year ended December 31, 2019, stating that at December 31, 2019, it had preliminary cash, cash equivalents, marketable debt and equity securities, and restricted investments of approximately $1.5 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 2020.

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 12, 2020.
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 13, 2020

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

Exhibit 99.1

Contacts:

Alnylam Pharmaceuticals, Inc.
Christine Regan Lindenboom
(Investors and Media)
617-682-4340

Joshua Brodsky
(Investors)
617-551-8276

Alnylam Announces Preliminary* Fourth Quarter and Full Year 2019 Global Net Product Revenues and Provides Additional Commercial Updates

– Achieved Fourth Quarter and Full Year 2019 ONPATTRO® (patisiran) Preliminary Global Net Product Revenues of Approximately $56 Million and $166 Million, Respectively –

– As of Year-End 2019, Over 750 Patients Worldwide Receiving Commercial ONPATTRO and Over 1,000 Total Patients Worldwide Being Treated with Patisiran –

– Achieved Strong Initial Demand for GIVLAARI™ (givosiran) in the U.S., with 13 Start Forms Received in First Six Weeks after FDA Approval –

– Maintained Strong Balance Sheet with Year-End Cash and Investments Balance of Approximately $1.5 Billion –

CAMBRIDGE, Mass., January 12, 2020 – Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today announced its preliminary* fourth quarter and full year 2019 global net product revenues for ONPATTRO and GIVLAARI and provided additional updates on the products' commercial launches.

For **ONPATTRO**, the Company reported:

- Preliminary global net product revenues for the fourth quarter and full year 2019 were approximately $56 million and $166 million, respectively.
- As of year-end 2019, over 750 patients worldwide were receiving commercial ONPATTRO, and over 1,000 total patients worldwide were being treated with patisiran, when also including those patients in clinical studies and in the Company's global Expanded Access Program (EAP).
- In the U.S., 44% of Start Forms submitted in 2019 came from cardiologists, 38% from neurologists, and 18% from other physician specialties.
- Significant ONPATTRO new patient growth in the fourth quarter was seen in the U.S. and EU, along with a strong launch in Japan.

- In the U.S., Alnylam has now completed definitive value-based agreements (VBAs) with 14 commercial payers, including each of the top 5 commercial payers and 8 of the top 10, with signed VBAs now covering over 130 million U.S. lives in the aggregate.

For the period following approval of **GIVLAARI** in the U.S. on November 20 through year end, the Company reported:

- A total of 13 Start Forms were submitted.
- Preliminary global net product revenues were approximately $0.2 million representing initial channel stocking.
- The Company has made significant progress toward establishing VBAs, including a Prevalence-Based Adjustment feature, with multiple ongoing discussions with payers.

“In 2019 we achieved continued and steady growth of patients on ONPATTRO and we expect sustained growth in 2020 and beyond. We believe our preliminary results reflect strong patient and physician demand and excellent execution by our commercial teams around the world. With the early U.S. approval of GIVLAARI, we are now a multi-product commercial company, and are pleased with the strong initial interest from patients and physicians in the short period since the drug’s approval by the FDA. We’re also encouraged by the receptivity of U.S. payers to the value that GIVLAARI has the potential to deliver,” said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. “In 2020, we look forward to the continued launches of ONPATTRO and GIVLAARI, bringing the benefits of these innovative therapies to patients around the world. We also look forward to advancing lumasiran – as our third wholly owned RNAi therapeutic – as well as inclisiran – with our partners at Novartis – toward the market in 2020 and achieving additional milestones across our broad late-stage pipeline of investigational RNAi therapeutics, notably in our ATTR amyloidosis clinical programs.”

In addition, the Company today reported that at December 31, 2019, it had preliminary cash, cash equivalents, marketable debt and equity securities, and restricted investments of approximately $1.5 billion, as compared to $1.1 billion at December 31, 2018.

Alnylam management will discuss these preliminary selected financial results and commercial updates during a webcast presentation at the 38th Annual J.P. Morgan Healthcare Conference in San Francisco, California tomorrow, Monday, January 13, 2020, at 10:30 a.m. PT (1:30 p.m. ET).

* 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 2020.

About ONPATTRO® (patisiran)

ONPATTRO is an RNAi therapeutic that is approved in the United States and Canada for the treatment of the polyneuropathy of hATTR amyloidosis in adults. ONPATTRO is also approved in the European Union and Switzerland 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. Based on Nobel Prize-winning science, ONPATTRO is an intravenously

administered RNAi therapeutic targeting transthyretin (TTR). It is designed to target and silence TTR messenger RNA, thereby blocking the production of TTR protein before it is made. ONPATTRO blocks the production of TTR in the liver, reducing its accumulation in the body's tissues in order to halt or slow down the progression of the polyneuropathy associated with the disease. For more information about ONPATTRO, visit ONPATTRO.com.

ONPATTRO Important Safety Information

Infusion-Related Reactions

Infusion-related reactions (IRRs) have been observed in patients treated with ONPATTRO. In a controlled clinical study, 19 percent of ONPATTRO-treated patients experienced IRRs, compared to 9 percent of placebo-treated patients. The most common symptoms of IRRs with ONPATTRO were flushing, back pain, nausea, abdominal pain, dyspnea, and headache.

To reduce the risk of IRRs, patients should receive premedication with a corticosteroid, acetaminophen, and antihistamines (H1 and H2 blockers) at least 60 minutes prior to ONPATTRO infusion. Monitor patients during the infusion for signs and symptoms of IRRs. If an IRR occurs, consider slowing or interrupting the infusion and instituting medical management as clinically indicated. If the infusion is interrupted, consider resuming at a slower infusion rate only if symptoms have resolved. In the case of a serious or life-threatening IRR, the infusion should be discontinued and not resumed.

Reduced Serum Vitamin A Levels and Recommended Supplementation

ONPATTRO treatment leads to a decrease in serum vitamin A levels. Supplementation at the recommended daily allowance (RDA) of vitamin A is advised for patients taking ONPATTRO. Higher doses than the RDA should not be given to try to achieve normal serum vitamin A levels during treatment with ONPATTRO, as serum levels do not reflect the total vitamin A in the body.

Patients should be referred to an ophthalmologist if they develop ocular symptoms suggestive of vitamin A deficiency (e.g. night blindness).

Adverse Reactions

The most common adverse reactions that occurred in patients treated with ONPATTRO were upper respiratory-tract infections (29 percent) and infusion-related reactions (19 percent).

For additional information about ONPATTRO, please see the full Prescribing Information.

About GIVLAARI™ (givosiran)

GIVLAARI is an RNAi therapeutic targeting aminolevulinic acid synthase 1 (ALAS1) that is approved in the U.S. for the treatment of adults with acute hepatic porphyria (AHP). In the pivotal study, GIVLAARI was shown to significantly reduce the rate of porphyria attacks that required hospitalizations, urgent healthcare visits or IV 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, visit GIVLAARI.com.

GIVLAARI Important Safety Information

Contraindications

GIVLAARI is contraindicated in patients with known severe hypersensitivity to givosiran. Reactions have included anaphylaxis.

Anaphylactic Reaction

Anaphylaxis has occurred with GIVLAARI treatment (<1% of patients in clinical trials). Ensure that medical support is available to appropriately manage anaphylactic reactions when administering GIVLAARI. Monitor for signs and symptoms of anaphylaxis. If anaphylaxis occurs, immediately discontinue administration of GIVLAARI and institute appropriate medical treatment.

Hepatic Toxicity

Transaminase elevations (ALT) of at least 3 times the upper limit of normal (ULN) were observed in 15% of patients receiving GIVLAARI in the placebo-controlled trial. Transaminase elevations primarily occurred between 3 to 5 months following initiation of treatment.

Measure liver function tests prior to initiating treatment with GIVLAARI, repeat every month during the first 6 months of treatment, and as clinically indicated thereafter. Interrupt or discontinue treatment with GIVLAARI for severe or clinically significant transaminase elevations. In patients who have dose interruption and subsequent improvement, reduce the dose to 1.25 mg/kg once monthly. The dose may be increased to the recommended dose of 2.5 mg/kg once monthly if there is no recurrence of severe or clinically significant transaminase elevations at the 1.25 mg/kg dose.

Renal Toxicity

Increases in serum creatinine levels and decreases in estimated glomerular filtration rate (eGFR) have been reported during treatment with GIVLAARI. In the placebo-controlled study, 15% of patients receiving GIVLAARI experienced a renally-related adverse reaction. The median increase in creatinine at Month 3 was 0.07 mg/dL. Monitor renal function during treatment with GIVLAARI as clinically indicated.

Injection Site Reactions

Injection site reactions were reported in 25% of patients receiving GIVLAARI in the placebo-controlled trial. Symptoms included erythema, pain, pruritus, rash, discoloration, or swelling around the injection site. One (2%) patient experienced a single, transient, recall reaction of erythema at a prior injection site with a subsequent dose administration.

Drug Interactions

Concomitant use of GIVLAARI increases the concentration of CYP1A2 or CYP2D6 substrates, which may increase adverse reactions of these substrates. Avoid concomitant use of GIVLAARI with CYP1A2 or CYP2D6 substrates for which minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, decrease the CYP1A2 or CYP2D6 substrate dosage in accordance with approved product labeling.

Adverse Reactions

The most common adverse reactions that occurred in patients receiving GIVLAARI were nausea (27%) and injection site reactions (25%).

For additional information about GIVLAARI, please see full Prescribing Information.

About LNP Technology

Alnylam has licenses to Arbutus Biopharma 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 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

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), approved in the U.S., EU, Canada, Japan, and Switzerland, and GIVLAARI™ (givosiran), approved in the U.S. Alnylam has a deep pipeline of investigational medicines, including five product candidates that are in late-stage development. Alnylam is executing on its “Alnylam 2020” strategy of building a multi-product, commercial-stage biopharmaceutical company with a sustainable pipeline of RNAi-based medicines to address the needs of patients who have limited or inadequate treatment options. Alnylam employs over 1,300 people worldwide and 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 preliminary approximations or Alnylam's future expectations, plans and prospects, including, without limitation, unaudited, preliminary selected financial results, Alnylam's views and plans with respect to the potential for RNAi therapeutics, including ONPATTRO, GIVLAARI, lumasiran, and inclisiran, its plans for the continuing product launches of ONPATTRO and GIVLAARI, the advancement of lumasiran and inclisiran through regulatory review and toward the market, the achievement of additional pipeline milestones, and expectations regarding the potential to exceed its "Alnylam 2020" guidance for the advancement and commercialization of RNAi therapeutics, 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 finalization and audit of Alnylam's fourth quarter and 2019 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 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, including lumasiran, and maintaining regulatory approval and obtaining pricing and reimbursement for its products, including ONPATTRO and GIVLAARI; progress in continuing to establish a commercial and ex-United States infrastructure; successfully launching, marketing and selling its approved products globally, including ONPATTRO and GIVLAARI; Alnylam's ability to successfully expand the indication for ONPATTRO in the future; 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 achieve a self-sustainable financial profile in the future, obtain additional funding to support its business activities, and establish and maintain strategic business alliances and new business initiatives; Alnylam's dependence on third parties, including Regeneron, for development, manufacture and distribution of certain products, including eye and CNS products, and Ironwood, for assistance with the education about and promotion of GIVLAARI; 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.