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): February 6, 2020

Alnylam Pharmaceuticals, Inc.

Delaware	001-36407	77-0602661
(State or Other Juris-diction 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 February 6, 2020, Alnylam Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2019. 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 February 6, 2020.
104	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: February 6, 2020

ALNYLAM PHARMACEUTICALS, INC.

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

Exhibit 99.1

Alnylam Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results and Highlights Recent Period Activity

− Achieved Fourth Quarter and Full Year 2019 ONPATTRO® (patisiran) Global Net Product Revenues of $55.8 Million and $166.4 Million, Respectively –

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

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

− Reported Third Positive 2019 Phase 3 Result with Lumasiran and Initiated Rolling Submission of New Drug Application (NDA) with U.S. Food and Drug Administration (FDA) –

– Initiated HELIOS-B Phase 3 Study of Vutrisiran for the Treatment of Hereditary and Wild-Type ATTR Amyloidosis with Cardiomyopathy –

– Maintained Strong Balance Sheet with Year-End Cash and Investments Balance of $1.55 Billion –

− Provides 2020 ONPATTRO Revenue Guidance and Operating Expense Guidance –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--February 6, 2020--Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today reported its consolidated financial results for the fourth quarter and full year ended December 31, 2019 and reviewed recent business highlights.

“In 2019 we saw continued and steady growth of patients on ONPATTRO, and we expect growth to continue in 2020, driven by new patient finding, geographic expansion, and evidence-generating activities. We also believe that our ongoing APOLLO-B Phase 3 study, if positive, can potentially enable future label expansion for patisiran to treat the cardiomyopathy of hereditary and wild-type ATTR amyloidosis. With the early U.S. approval of GIVLAARI in the fourth quarter, Alnylam became a multi-product commercial company, and we are pleased with the strong initial interest from patients, physicians, and payers in the short period since the drug’s approval by the FDA,” said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. “Also in the fourth quarter, we reported positive topline Phase 3 results with lumasiran, Alnylam’s third program in 2019 to achieve positive Phase 3 results, and we’ve initiated the rolling submission of an NDA, setting us up for a potential approval later this year. In addition, in 2020 we look forward to advancing additional late-stage programs closer to the market, namely vutrisiran – with the HELIOS-A and -B studies in ATTR amyloidosis – and, inclisiran and fitusiran with our partners at Novartis and Sanofi, respectively. With continued execution across these and other programs we are confident that by year-end we’ll achieve our Alnylam 2020 goals of building a multi-product, global biopharma company with a deep clinical pipeline to fuel future growth and a robust product engine for sustainable and organic innovation, a profile rarely achieved in our industry.”

Fourth Quarter 2019 and Recent Significant Corporate Highlights

Commercial Performance

ONPATTRO®

- Achieved global net product revenues for the fourth quarter and full year 2019 of $55.8 million and $166.4 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).
- 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., 44% of Start Forms submitted in 2019 came from cardiologists, 38% from neurologists, and 18% from other physician specialties.
- In the U.S., Alnylam has now completed definitive value-based agreements (VBAs) with 15 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.
- Continued progress with market access efforts across the Canada, Europe, Middle East, and Africa (CEMEA) region, with a recent launch in the United Kingdom and reimbursement approvals in Belgium, Israel, and Italy.

GIVLAARI™

- A total of 13 Start Forms were submitted for the period following approval of GIVLAARI in the U.S. on November 20, 2019 through year-end 2019.
- Net product revenues for the fourth quarter of 2019 were $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.

R&D Highlights

- Continued to apply for marketing authorization of **patisiran** (the non-proprietary name for ONPATTRO) in additional countries for the treatment of hATTR amyloidosis patients with polyneuropathy and to advance the development of patisiran for the potential treatment of the cardiomyopathy of both hereditary and wild type ATTR amyloidosis.
    - Continued enrollment in the APOLLO-B Phase 3 study in ATTR amyloidosis patients with cardiomyopathy.
    - Filed a marketing authorization application with the Brazilian Health Regulatory Agency (ANVISA) for patisiran for the treatment of hATTR amyloidosis patients with polyneuropathy.

- Achieved the second-ever regulatory approval of an RNAi therapeutic with the approval of **GIVLAARI (givosiran)** in the U.S.
    - Received FDA approval of GIVLAARI for the treatment of adults with AHP.
    - Received a positive opinion for givosiran for the treatment of AHP in adolescents and adults from the Committee for Medicinal Products for Human Use (CHMP) in the EU.
    - Filed a marketing authorization application for givosiran with the Brazilian Health Regulatory Agency (ANVISA).

- Advanced **lumasiran**, an investigational RNAi therapeutic in development for the treatment of primary hyperoxaluria type 1 (PH1).
    - Reported positive topline results from ILLUMINATE-A Phase 3 study of lumasiran for the treatment of PH1.
    - Initiated NDA rolling submission to the FDA, with remaining sections expected to be submitted in early 2020.
    - The Company announces today that it has completed enrollment in the ILLUMINATE-B Phase 3 study of lumasiran in PH1 patients less than six years of age with preserved renal function, and remains on track to report topline results in mid-2020.
    - Initiated the ILLUMINATE-C Phase 3 study of lumasiran for the treatment of advanced PH1 in patients of all ages with advanced renal disease.
    - Received a pediatric rare disease designation from the FDA for lumasiran for the treatment of PH1.
    - Announced positive efficacy results from the ongoing Phase 2 open-label extension (OLE) study of lumasiran at the American Society of Nephrology (ASN) 2019 Annual Meeting.

- Advanced **vutrisiran**, a subcutaneously administered investigational RNAi therapeutic in development for the treatment of ATTR amyloidosis.
    - Initiated the HELIOS-B Phase 3 study in patients with hereditary and wild-type ATTR amyloidosis with cardiomyopathy.
    - Continued enrollment in the HELIOS-A Phase 3 study in hereditary ATTR amyloidosis with polyneuropathy, with the study over 85% enrolled.

- Alnylam's partner, The Medicines Company, acquired by Novartis in January 2020, advanced **inclisiran**, an investigational RNAi therapeutic in development for the treatment of hypercholesterolemia.
    - Reported positive complete results from the ORION-9 and -10 Phase 3 studies of inclisiran in patients with heterozygous familial hypercholesterolemia (HeFH) and atherosclerotic cardiovascular disease (ASCVD).
    - Submitted an NDA and an MAA for inclisiran to the FDA and the EMA, respectively.
    - Novartis announced a groundbreaking agreement with the UK National Health Service (NHS) to study inclisiran in UK patients as part of a large-scale NHS clinical trial expected to start later this year. As part of the agreement, inclisiran is also expected to be available to UK patients through a population-level agreement, if approved and reimbursed.

- Alnylam's partner, Sanofi, continues enrollment in the ATLAS Phase 3 program for **fitusiran** in patients with hemophilia A or B with and without inhibitors.

- Advanced early-stage RNAi pipeline programs.
    - Announced initial positive clinical results with **ALN-AAT02** and **ALN-HBV02** (VIR-2218), providing initial human proof of concept for "Enhanced Stabilization Chemistry Plus" (ESC+) GalNAc conjugate delivery technology.
    - Presented initial positive clinical results, namely knockdown of serum angiotensinogen levels, from Phase 1 trial of **ALN-AGT**, an investigational RNAi therapeutic for hypertension, expanding potential opportunities for RNAi therapeutics in highly prevalent chronic diseases.
    - Reported strong progress in CNS and ocular delivery of RNAi therapeutics with seven initial programs selected as part of Regeneron collaboration, including **ALN-APP**, in development for the treatment of cerebral amyloid angiopathy and potentially other neurodegenerative diseases, and **ALN-HTT**, in development for the treatment of Huntington's disease.

Additional Business Updates

- Alnylam announces today that it ranked #3 in gender parity and #1 in fair representation for Women of Color at the leadership level among the top 25 employers in Massachusetts by the Eos Foundation's inaugural *Women's Power Gap in Corporate Massachusetts Survey and Rankings.*
- Received recognition as the world's #1 biopharma employer from *Science* magazine based on more than 7,500 responses to its annual survey of the biotech and pharmaceutical industry.

Upcoming Events

- Alnylam announces today that it intends to present multiple new study results with patisiran at the XVII International Symposium on Amyloidosis on March 1-5, 2020 in Tarragona, Spain.
- The Company also intends to report full results from the ILLUMINATE-A Phase 3 study of lumasiran at the OxalEurope International Congress on March 31, 2020 in Amsterdam.

In addition, in early 2020, Alnylam intends to:

- Continue global commercialization of ONPATTRO.
- Continue global launch of GIVLAARI, including launch in Europe following expected approval from the European Medicines Agency (EMA).
- Complete enrollment in the HELIOS-A Phase 3 study of vutrisiran.
- Complete rolling submission of the lumasiran NDA and file MAA with the EMA.

Financial Results for the Quarter and Year Ended December 31, 2019

“We believe our fourth quarter and full year 2019 results reflect strong ONPATTRO patient demand and excellent execution by our commercial teams around the world. Notably, we saw significant ONPATTRO new patient growth in the U.S. and EU, and strong initial demand in Japan, together resulting in over 20 percent quarter-on-quarter growth in net product revenues. We expect growth to continue in 2020 and are guiding that we expect to achieve between $285 million and $315 million in ONPATTRO net product revenues for the year. We also look forward to now leveraging our global commercial capabilities for the launch of GIVLAARI,” said Jeff Poulton, Chief Financial Officer of Alnylam. “Our balance sheet remains strong with $1.55B in cash and investments at year-end, enabling continued investments in R&D and commercial execution. Looking forward, we are now focused on achieving a self-sustainable financial profile. The key elements of this transition include top line revenue growth from currently two marketed products – and in the not-too-distant future, potentially up to *six* marketed products – as well as disciplined investment in our operations.”

Financial Highlights
(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Product revenues, net	$ 55,949	$ 12,075	$ 166,537	$ 12,535
ONPATTRO net product revenues	$ 55,799	$ 12,075	$ 166,387	$ 12,535
GIVLAARI net product revenues	$ 150	$ —	$ 150	$ —
Net revenue from collaborators	$ 15,732	$ 8,958	$ 53,213	$ 62,373
GAAP research and development expenses	$ 201,301	$ 131,036	$ 655,114	$ 505,420
Non-GAAP research and development expenses	$ 166,515	$ 118,064	$ 566,184	$ 424,911
GAAP selling, general and administrative expenses	$ 156,277	$ 108,688	$ 479,005	$ 382,359
Non-GAAP selling, general and administrative expenses	$ 124,866	$ 93,687	$ 393,094	$ 305,116
GAAP net loss	$ (276,185)	$ (211,441)	$ (886,116)	$ (761,497)
Non-GAAP net loss	$ (221,255)	$ (183,468)	$ (731,964)	$ (624,309)
GAAP net loss per common share - basic and diluted	$ (2.47)	$ (2.09)	$ (8.11)	$ (7.57)
Non-GAAP net loss per common share - basic and diluted	$ (1.98)	$ (1.82)	$ (6.70)	$ (6.21)
Cash, cash equivalents, marketable debt and equity investments and restricted investments			$ 1,550,987	$ 1,128,980

Net Product Revenues

- Net product revenues were $55.9 million in the fourth quarter 2019 representing 21% growth from the third quarter 2019 primarily driven by the addition of new patients on therapy and expansion into new markets.
- Net product revenues grew from $12.5 million in 2018 to $166.5 million in 2019 primarily driven by the continued global launch of ONPATTRO during its first full-year on the market.

Net Revenues from Collaborators

- Net revenues from collaborators were $15.7 million in the fourth quarter 2019, an increase from $9.0 million in the fourth quarter 2018 primarily due to revenues from the Regeneron collaboration.
- Net revenues from collaborators were $53.2 million in 2019, a decrease from $62.4 million in 2018 primarily due to a decline in reimbursable activities from the Sanofi Genzyme collaboration, offset by revenues from the Regeneron collaboration.

Research & Development (R&D) and Selling, General & Administrative (SG&A) Expenses

- R&D expenses increased in the fourth quarter and full year 2019 compared to the same periods in 2018 on a GAAP and non-GAAP basis primarily due to increased activity related to the advancement of the Company's late stage programs.
- SG&A expenses increased in the fourth quarter and full year 2019 compared to the same periods in 2018 on a GAAP and non-GAAP basis primarily due to increases in commercial and medical affairs activities supporting continued investment in the ongoing ONPATTRO launch and the launch of GIVLAARI in late 2019.
- R&D and SG&A expenses on a GAAP basis also increased in the fourth quarter 2019 compared to the same period in 2018 due to an increase in stock-based compensation primarily due to the probability of or achievement of certain performance-based vesting events under outstanding equity awards.

Cash and Investments

- Cash and investments were $1.55 billion at the end of 2019 compared to $1.13 billion at the end of 2018. The increase was due to proceeds received under the Company's equity offering in the first quarter of 2019 and proceeds received under the collaboration and equity agreements with Regeneron offset by cash used in the Company's operations.

A reconciliation of GAAP to non-GAAP results is included in the tables of this press release.

2020 Financial Guidance

Full year 2020 financial guidance consists of the following:

- ONPATTRO net product revenues of $285 million - $315 million
- Net revenues from collaborators of $100 million - $150 million
- GAAP R&D and SG&A expenses of $1,180 million - $1,300 million
- Non-GAAP R&D and SG&A expenses of $1,025 million - $1,125 million*
- The Company expects that its current cash, cash equivalents, and marketable debt and equity securities will support company operations for multiple years based on its current operating plans.

*Excludes $155 million - $175 million of stock-based compensation from GAAP R&D and SG&A expenses.

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 the press release are stock-based compensation expense, a gain on equity securities, a gain on the change in fair value of a liability obligation, and a gain on litigation settlement. 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 gain on equity securities, the change in fair value of liability obligation and the gain on litigation settlement because the Company believes these items are one-time events occurring outside the ordinary course of the Company's business.

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 fourth quarter and year-end 2019 results as well as expectations for the future via conference call on Thursday, February 6, 2020 at 8:30 am ET. To access the call, please dial 800-239-9838 (domestic) or +1-323-794-2551 (international) five minutes prior to the start time and refer to conference ID 6976021. A replay of the call will be available beginning at 11:30 am ET on the day of the call. To access the replay, please dial 888-203-1112 (domestic) or +1-719-457-0820 (international) and refer to conference ID 6976021.

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 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 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), 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, Alnylam's views and plans with respect to the potential for RNAi therapeutics, including ONPATTRO, GIVLAARI, lumasiran, patisiran, vutrisiran, inclisiran, fitusiran, ALN-AAT02, ALN-HBV02, ALN-AGT, ALN-APP and ALN-HTT, expectations regarding the continued regulatory review and approval of GIVLAARI by the EMA, its plans for additional global regulatory filings and the continuing product launches of ONPATTRO and GIVLAARI, expectations regarding reimbursement for ONPATTRO and GIVLAARI in various territories and the status of VBA negotiations and executed agreements, the advancement of lumasiran and inclisiran through regulatory review and toward the market, the achievement of additional pipeline milestones, including relating to ongoing clinical studies of lumasiran and vutrisiran, its expectations relating to continued ONPATTRO growth and the expected range of ONPATTRO net product revenues for 2020, as well as the range for net revenues from collaborations for 2020, the expected range of 2020 aggregate annual non-GAAP and GAAP R&D and SG&A expenses, its expectations regarding the length of time its current cash, cash equivalents and marketable debt and equity securities will support company operations based on its current operating plan, plans to advance toward financial self-sustainability and expectations regarding the achievement or 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.

ALNYLAM PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product revenues, net	$ 55,949	$ 12,075	$ 166,537	$ 12,535
Net revenue from collaborators	15,732	8,958	53,213	62,373
Total revenues	71,681	21,033	219,750	74,908
Costs and expenses:				
Cost of goods sold	$ 12,176	$ 1,665	$ 25,062	$ 1,802
Research and development	201,301	131,036	655,114	505,420
Selling, general and administrative	156,277	108,688	479,005	382,359
Total costs and expenses	369,754	241,389	1,159,181	889,581
Loss from operations	(298,073)	(220,356)	(939,431)	(814,673)
Other income (expense):				
Interest income	7,253	10,571	33,448	29,262
Other income (expense)	14,237	(1,295)	11,308	4,173
Change in fair value of liability obligation	—	—	9,422	—
Gain on litigation settlement	—	—	—	20,564
Total other income	21,490	9,276	54,178	53,999
Loss before income taxes	(276,583)	(211,080)	(885,253)	(760,674)
Benefit (provision) for income taxes	398	(361)	(863)	(823)
Net loss	$ (276,185)	$ (211,441)	$ (886,116)	$ (761,497)
Net loss per common share - basic and diluted	$ (2.47)	$ (2.09)	$ (8.11)	$ (7.57)
Weighted-average common shares used to compute basic and diluted net loss per common share	111,750	101,066	109,264	100,590
Comprehensive loss:				
Net loss	$ (276,185)	$ (211,441)	$ (886,116)	$ (761,497)
Unrealized (loss) gain on marketable securities, net of tax	(214)	179	558	1,220
Foreign currency translation	(2,624)	—	(343)	—
Defined benefit pension plans, net of tax	691	—	(3,520)	—
Comprehensive loss	$ (278,332)	$ (211,262)	$ (889,421)	$ (760,277)

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Reconciliation of GAAP to Non-GAAP Research and development:				
GAAP Research and development	$ 201,301	$ 131,036	$ 655,114	$ 505,420
Less: Stock-based compensation expenses	(34,786)	(12,972)	(88,930)	(80,509)
Non-GAAP Research and development	$ 166,515	$ 118,064	$ 566,184	$ 424,911
Reconciliation of GAAP to Non-GAAP Selling, general and administrative:				
GAAP Selling, general and administrative	$ 156,277	$ 108,688	$ 479,005	$ 382,359
Less: Stock-based compensation expenses	(31,411)	(15,001)	(85,911)	(77,243)
Non-GAAP Selling, general and administrative	$ 124,866	$ 93,687	$ 393,094	$ 305,116
Reconciliation of GAAP to Non-GAAP Operating expenses:				
GAAP Operating expenses	$ 369,754	$ 241,389	$ 1,159,181	$ 889,581
Less: Stock-based compensation expenses	(66,197)	(27,973)	(174,841)	(157,752)
Non-GAAP Operating expenses	$ 303,557	$ 213,416	$ 984,340	$ 731,829
Reconciliation of GAAP to Non-GAAP Net loss:				
GAAP Net loss	$ (276,185)	$ (211,441)	$ (886,116)	$ (761,497)
Add: Stock-based compensation expenses	66,197	27,973	174,841	157,752
Less: Change in fair value of liability obligation	—	—	(9,422)	—
Less: Gain on litigation settlement	—	—	—	(20,564)
Less: Gain on equity securities investment	(11,267)	—	(11,267)	—
Non-GAAP Net loss	$ (221,255)	$ (183,468)	$ (731,964)	$ (624,309)
Reconciliation of GAAP to Non-GAAP Net loss per common share-basic and diluted:				
GAAP Net loss per common share - basic and diluted	$ (2.47)	$ (2.09)	$ (8.11)	$ (7.57)
Add: Stock-based compensation expenses	0.59	0.27	1.60	1.57
Less: Change in fair value of liability obligation	—	—	(0.09)	—
Less: Gain on litigation settlement	—	—	—	(0.21)
Less: Gain on equity securities investment	(0.10)	—	(0.10)	
Non-GAAP Net loss per common share - basic and diluted	$ (1.98)	$ (1.82)	$ (6.70)	$ (6.21)

Please note that the figures presented above may not sum exactly due to rounding

ALNYLAM PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts)

	December 31, 2019	December 31, 2018
Cash, cash equivalents and marketable debt and equity securities	$ 1,536,162	$ 1,084,155
Restricted investments	14,825	44,825
Accounts receivable, net	43,011	18,760
Inventory	56,348	24,068
Prepaid expenses and other assets	98,412	82,336
Property, plant and equipment, net	425,179	320,658
Operating lease right-of-use lease assets	221,197	—
Total assets	$ 2,395,134	$ 1,574,802
Accounts payable, accrued expenses and other liabilities	$ 256,415	$ 177,392
Total deferred revenue	396,204	3,954
Total deferred rent	—	61,491
Operating lease liability	303,823	—
Long-term debt	—	30,000
Total stockholders' equity 112.2 million shares issued and outstanding at December 31, 2019; 101.2 million shares issued and outstanding at December 31, 2018	1,438,692	1,301,965
Total liabilities and stockholders' equity	$ 2,395,134	$ 1,574,802

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, 2018.

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