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): May 1, 2019

Alnylam Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-36407	77-0602661
(State or Other Juris-diction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

300 Third Street, Cambridge, MA	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))

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 May 1, 2019, Alnylam Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter ended March 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 May 1, 2019.

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: May 1, 2019

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ Manmeet S. Soni
Manmeet S. Soni
Senior Vice President, Chief Financial Officer

Exhibit 99.1

Alnylam Pharmaceuticals Reports First Quarter 2019 Financial Results and Highlights Recent Period Activity

– Achieved First Quarter 2019 ONPATTRO® Global Net Product Revenues of $26.3 Million with Over 400 Patients on Commercial Product Worldwide –

– Achieved Positive Results in ENVISION Phase 3 Study of Givosiran –

– Formed Broad Collaboration with Regeneron to Discover, Develop and Commercialize RNAi Therapeutics Focused on Ocular and Central Nervous System (CNS) Diseases –

– Strengthened Balance Sheet with New Equity-Based Capital and Partnership-Based Funding –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 1, 2019--Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today reported its consolidated financial results for the first quarter 2019 and reviewed recent business highlights.

“The first quarter of 2019 and recent weeks were a remarkable period of advancement for Alnylam toward our goal of building a leading biopharmaceutical company. Specifically, we demonstrated good progress in global commercialization of ONPATTRO, continued success in our R&D efforts with positive Phase 3 results for givosiran, and a strong commitment to future pipeline growth through our landmark ocular and CNS disease alliance with Regeneron. In addition, we significantly strengthened our balance sheet through both an equity offering in January and partnership-based equity funding and cash that we’ll receive upon closing of the Regeneron transaction,” said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. “We believe we are now well positioned to achieve our *Alnylam 2020* goal of building a multi-product, global biopharma company with a deep clinical pipeline for future growth and a robust product engine for sustainable innovation, a profile rarely achieved in our industry. Moreover, as evidenced by the success of our ONPATTRO launch and the results of our givosiran Phase 3 study in porphyria, we believe we’re delivering on our most important goal of bringing potentially transformative medicines to patients.”

“In the first quarter, we made significant progress in our global commercialization of ONPATTRO, as we advanced our efforts to help patients secure access to this important new medicine. With over 400 patients on commercial product, we’re very pleased with our team’s launch execution in over 10 countries where ONPATTRO is now available, and we look forward to continued growth in all existing and many new countries in the months to come. Of note, we saw strong new patient demand in the U.S. and EU in the first quarter, beyond the initial stages of our launch that had been largely driven by conversion of patients from our expanded access program as well as patients known to clinical study sites,” said Barry Greene, President of Alnylam. “As we reported last night, we believe an important highlight in our commercialization efforts is the innovation we’ve demonstrated with regard to patient access. Indeed, with 10 value-based agreements now completed in the U.S. and with favorable HTA ratings and reimbursement outcomes in key EU countries, we’re advancing our goal to ensure that ONPATTRO reaches all patients in need.”

First Quarter 2019 and Recent Significant Corporate Highlights

Commercial Performance in First Quarter 2019

- Achieved global net product revenues for the first quarter of 2019 of $26.3 million for ONPATTRO.
- Attained over 400 patients worldwide on commercial ONPATTRO treatment since launch as of March 31, 2019.
- Received 77 Start Forms in the U.S. in the first quarter, with over 90 percent from newly identified patients not previously treated in the ONPATTRO Expanded Access Program.
    - Start Forms in the first quarter came from a diverse range of prescribing physician specialties, including 55 percent from cardiologists and 35 percent from neurologists, with 65 percent of patients covered by Medicare.
    - In addition, the Company reports continued strength in the number of U.S. patients receiving ONPATTRO from channels outside of its Alnylam Assist patient hub where the Company does not receive Start Forms.
- Reported continued progress with value-based agreements (VBAs) with commercial payers in the U.S. and with market access efforts globally.
    - Since launch, Alnylam has achieved access to ONPATTRO, if prescribed, for greater than 90 percent of U.S. lives across commercial, Medicare, Medicaid, and other government payer categories. In addition, Alnylam has completed definitive VBAs with 10 commercial U.S. payers to date.
    - In the EU, Alnylam reported favorable Health Technology Assessment (HTA) ratings from health authorities in several countries, including in France (“ASMR III”), Germany (“considerable benefit”), Italy (“innovation status”), and the Netherlands where a first-of-its-kind VBA was reached with all health insurers to reimburse ONPATTRO. The Company remains on track with pricing and reimbursement procedures in nearly all EU markets, and encouraging discussions with authorities have progressed significantly over the quarter.

R&D Highlights

- Advanced patisiran (the non-branded name for ONPATTRO), an intravenously administered investigational RNAi therapeutic in development for the treatment of ATTR amyloidosis.
  - Obtained alignment with the U.S. Food and Drug Administration (FDA) on the design of APOLLO-B, a randomized, double-blind, placebo-controlled Phase 3 study of patisiran in hereditary and wild-type ATTR amyloidosis patients with cardiomyopathy, with the goal of starting the trial in mid-2019.
- Advanced vutrisiran (ALN-TTRsc02), a subcutaneously administered investigational RNAi therapeutic in development for the treatment of ATTR amyloidosis.
  - Continued enrollment in the HELIOS-A Phase 3 study of vutrisiran in hereditary ATTR amyloidosis patients with plans to initiate additional Phase 3 studies, including in hereditary and wild-type ATTR amyloidosis cardiomyopathy, in late 2019.
- Advanced givosiran, an investigational RNAi therapeutic in development for the treatment of acute hepatic porphyria (AHP).
  - Achieved positive results in the ENVISION Phase 3 study and presented data at the European Association for the Study of the Liver (EASL) 54th Annual International Liver Congress.
  - On track to complete submission of a New Drug Application (NDA) and submit a Marketing Authorisation Application (MAA) for givosiran in mid-2019.
- Advanced lumasiran, an investigational RNAi therapeutic in development for the treatment of primary hyperoxaluria type 1 (PH1).
  - Continued enrollment in the ILLUMINATE-A Phase 3 study of lumasiran in PH1 patients aged six or older with mild-to-moderate renal impairment, and remain on track to report results by year-end 2019.
  - Presented new positive results from the ongoing Phase 2 open-label extension (OLE) study of lumasiran at the International Society of Nephrology (ISN) 2019 Annual Meeting.
  - Initiated ILLUMINATE-B, a global Phase 3 pediatric study of lumasiran in PH1 patients under six years of age.
- Alnylam's partner, The Medicines Company, announced in April that the Independent Data Monitoring Committee for ongoing inclisiran Phase 3 clinical trials (ORION 9, 10, and 11) conducted its sixth planned review of safety and efficacy data from the ORION trials and recommended that the trials continue without modification.
  - The safety database for inclisiran now provides more than 3,000 patient-years of exposure to an RNAi therapeutic, representing the industry's most comprehensive body of safety data for an RNA therapeutic.
- Alnylam's partner, Sanofi, continues enrollment in the ATLAS Phase 3 program with fitusiran in patients with hemophilia A or B with and without inhibitors.
- Advanced early- and mid-stage RNAi clinical pipeline.
  - Initiated a Phase 2 study of cemdisiran, an investigational RNAi therapeutic targeting complement C5 for the treatment of complement-mediated diseases, in IgA nephropathy.
  - Filed a Clinical Trial Authorisation (CTA) application and received approval to initiate a Phase 1 study of ALN-AGT, an investigational RNAi therapeutic targeting angiotensinogen (AGT) for the treatment of hypertension in high unmet need populations, including patients with resistant or refractory hypertension, chronic kidney disease or heart failure.

Additional Business Highlights

- Announced a broad collaboration with Regeneron Pharmaceuticals, Inc. to discover, develop, and commercialize RNAi therapeutics focused on ocular and CNS diseases. Subject to Hart-Scott-Rodino (HSR) clearance, the Company anticipates closing this transaction during the second quarter of 2019.
- Announced the conclusion of the research and option phase of the Company's 2014 collaboration with Sanofi focused on advancing RNAi therapeutics for rare genetic diseases.
- Entered into a collaboration with 23andMe to support the addition of a new Genetic Health Risk report for Hereditary Amyloidosis (TTR-related), which will help 23andMe customers who have opted in to receive such reports learn more about their genetic risk for the three most common TTR variants in the United States (V122I, V30M, and T60A). Read more about the report here.

Upcoming Events in Mid-2019

- Alnylam expects to receive regulatory approvals for ONPATTRO in Japan and Canada.
- Alnylam plans to complete its rolling NDA submission and file an MAA for givosiran.
- Alnylam expects to complete enrollment in the ILLUMINATE-A Phase 3 study of lumasiran.
- The Company also expects to initiate the ILLUMINATE-C Phase 3 study of lumasiran in patients with impaired renal function.
- Alnylam expects to initiate the APOLLO-B Phase 3 study of patisiran in hereditary and wild-type ATTR amyloidosis patients with cardiomyopathy.
- Alnylam's partner, The Medicines Company, expects to report initial topline results from the inclisiran Phase 3 clinical trials in the third quarter.

Financial Results for the Quarter Ended March 31, 2019

"2019 is off to a strong start for Alnylam, as we ended the first quarter with a balance sheet of $1.3 billion. During the quarter, our financials were bolstered by encouraging ONPATTRO uptake as well as proceeds from our January equity financing, and subsequently enhanced with $800 million in additional cash expected to be received during the second quarter upon close of our recently announced collaboration with Regeneron," said Manmeet Soni, Chief Financial Officer of Alnylam. "This cash balance positions us for continued execution of potential commercial launches on a global scale, while accelerating the advancement of our promising pipeline of late- and early-stage programs."

Cash and Investments
At March 31, 2019, Alnylam had cash, cash equivalents and marketable debt securities and restricted investments of $1.29 billion, as compared to $1.13 billion at December 31, 2018.

In January 2019, Alnylam sold an aggregate of 5,000,000 shares of its common stock through an underwritten public offering at a price to the public of $77.50 per share. As a result of the offering, Alnylam received aggregate net proceeds of approximately $382 million.

Cash at March 31, 2019 excludes proceeds from the Regeneron collaboration, which was announced after the quarter end and is subject to customary closing conditions. On a *pro forma* basis, Alnylam has cash, cash equivalents and marketable debt securities and restricted investments of greater than $2 billion.

GAAP and Non-GAAP Net Loss
The net loss according to accounting principles generally accepted in the U.S. (GAAP) for the first quarter of 2019 was $181.9 million, or $1.73 per share on both a basic and diluted basis, as compared to a net loss of $141.2 million, or $1.41 per share on both a basic and diluted basis, for the same period in the previous year.

The non-GAAP net loss for the first quarter of 2019 was $149.9 million, or $1.42 per share on both a basic and diluted basis, as compared to a non-GAAP net loss of $121.6 million, or $1.22 per share on both a basic and diluted basis for the same period in the previous year.

See “Use of Non-GAAP Financial Measures” below for a description of non-GAAP financial measures and a reconciliation between GAAP and non-GAAP net loss appearing later in this press release.

ONPATTRO Revenues, Net
Net product revenues from sales of ONPATTRO were $26.3 million in the first quarter of 2019.

Net Revenues from Collaborators
Net revenues from collaborators were $7.0 million in the first quarter of 2019 as compared to $21.9 million in the first quarter of 2018.

GAAP and Non-GAAP Research and Development Expenses
GAAP research and development (R&D) expenses were $129.1 million in the first quarter of 2019 as compared to $96.9 million in the first quarter of 2018.

Non-GAAP R&D expenses were $113.0 million in the first quarter of 2019 as compared to $86.7 million in the first quarter of 2018. Non-GAAP R&D expenses exclude stock-based compensation expense. A reconciliation between GAAP and non-GAAP R&D expenses appears later in this press release.

GAAP and Non-GAAP Selling, General and Administrative Expenses
GAAP selling, general and administrative (SG&A) expenses were $89.6 million in the first quarter of 2019 as compared to $72.4 million in the first quarter of 2018.

Non-GAAP SG&A expenses were $73.7 million in the first quarter of 2019 as compared to $63.0 million in the first quarter of 2018. Non-GAAP SG&A expenses exclude stock-based compensation expense. A reconciliation between GAAP and non-GAAP SG&A expenses appears later in this press release.

2019 Updated Financial Guidance
Alnylam is updating its 2019 annual non-GAAP R&D expenses to be in the range of $550 to $590 million and non-GAAP SG&A expenses to be in the range of $390 to $410 million. Both non-GAAP R&D and non-GAAP SG&A expenses exclude stock-based compensation expenses. The increase in non-GAAP R&D guidance of $30 million is due primarily to third party obligations based on assumed closing of the Regeneron collaboration during the second quarter.

The Company expects its current cash, cash equivalents, and marketable debt securities will support company operations for multiple years based upon its current operating plan.

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 and the 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 litigation settlement because the Company believes this item is a one-time event 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.

The Company does not provide in this press release a reconciliation of its estimated 2019 non-GAAP R&D and non-GAAP SG&A expense guidance to the comparable GAAP measures because it is not able to estimate 2019 stock-based compensation expense without unreasonable efforts. The Company's stock-based compensation expense is subject to significant fluctuations from period to period due to variability in the probability of performance-based vesting events for stock options and restricted stock units and changes in the Company's stock price which materially impacts the recognition, timing of expense and fair value of these awards. In addition, the Company believes such reconciliations for its 2019 financial guidance would imply a degree of precision that would be confusing or misleading to investors.

Conference Call Information
Management will provide an update on the Company and discuss first quarter 2019 results as well as expectations for the future via conference call on Wednesday, May 1, 2019 at 8:30 am ET. To access the call, please dial 800-289-0438 (domestic) or 323-794-2423 (international) five minutes prior to the start time and refer to conference ID 4935120. 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 719-457-0820 (international) and refer to conference ID 4935120.

About ONPATTRO® (patisiran)
Patisiran, based on Nobel Prize-winning science, is an intravenously administered RNAi therapeutic targeting transthyretin (TTR) for the treatment of hereditary ATTR amyloidosis. It is designed to target and silence TTR messenger RNA, thereby blocking the production of TTR protein before it is made. Patisiran 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 disease. In August 2018, patisiran received FDA approval for the treatment of the polyneuropathy of hATTR amyloidosis in adults, as well as European Medicines Agency marketing authorization for the treatment of hATTR amyloidosis in adults with Stage 1 or Stage 2 polyneuropathy.

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, paracetamol, 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 respiratory-tract infection (29 percent) and infusion-related reactions (19 percent).

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 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/ocular diseases. Based on Nobel Prize-winning science, RNAi therapeutics represent a powerful, clinically validated approach for the treatment of diseases with high unmet need. ONPATTRO® (patisiran) is the first-ever RNAi therapeutic approved by the U.S. FDA for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults and by the EMA for the treatment of hATTR amyloidosis in adults with stage 1 or stage 2 polyneuropathy. Alnylam has a deep pipeline of investigational medicines, including six product candidates in Phase 3 studies. Looking forward, Alnylam will continue to execute 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. Headquartered in Cambridge, MA, Alnylam employs over 1,000 people worldwide. For more information, 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 with respect to the potential for RNAi therapeutics, including patisiran, vutrisiran, givosiran, lumasiran, inclisiran, fitusiran, cemdisiran, and ALN-AGT, its plans for additional global regulatory filings and product launches for ONPATTRO, its expectations regarding the status of pricing and reimbursement procedures outside the U.S., its expectations regarding the timing for the initiation of its APOLLO-B Phase 3 study of patisiran, its plans to initiate additional Phase 3 studies for vutrisiran in late 2019, its expectations regarding the complete submission of an NDA for givosiran with the FDA and the filing of an MAA for givosiran with the EMA, its expectations regarding the timing of topline results from its ILLUMINATE-A Phase 3 study of lumasiran, its plans to initiate the ILLUMINATE-C Phase 3 study of lumasiran, its expectations regarding the timing of topline results to be reported by The Medicines Company from the ORION-11, ORION-9 and ORION-10 studies of inclisiran, its expected range of 2019 annual non-GAAP R&D expenses and non-GAAP SG&A expenses, its expectations regarding the length of time its current cash, cash equivalents and marketable debt securities will support company operations based on its current operating plan, its expectations regarding its cash position following the closing of its alliance with Regeneron and the expected timing of such closing, and expectations regarding 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, Alnylam's ability to discover and develop novel drug candidates and delivery approaches, 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, obtaining, maintaining and protecting intellectual property, Alnylam's ability to enforce its intellectual property rights against third parties and defend its patent portfolio against challenges from third parties, obtaining and maintaining regulatory approval, pricing and reimbursement for products, progress in establishing a commercial and ex-United States infrastructure, successfully launching, marketing and selling its approved products globally, 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, 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 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 Annual Report on Form 10-K 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.

With the exception of ONPATTRO (patisiran), none of Alnylam’s investigational therapeutics have been approved by the U.S. Food and Drug Administration, European Medicines Agency, or any other regulatory authority and no conclusions can or should be drawn regarding the safety or effectiveness of such investigational therapeutics.

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

	Three Months Ended March 31,	
	2019	**2018**
Revenues:		
Product revenues, net	$ 26,291	$ —
Net revenues from collaborators	7,003	21,899
Total revenues	33,294	21,899
Cost and expenses:		
Cost of goods sold	3,347	—
Research and development	129,127	96,857
Selling, general and administrative	89,608	72,447
Total costs and expenses	222,082	169,304
Loss from operations	(188,788)	(147,405)
Other income (expense):		
Interest income	7,525	5,794
Other income	43	335
Total other income	7,568	6,129
Loss before income taxes	(181,220)	(141,276)
(Provision) benefit for income taxes	(695)	62
Net loss	$ (181,915)	$ (141,214)
Net loss per common share - basic and diluted	$ (1.73)	$ (1.41)
Weighted-average common shares used to compute basic and diluted net loss per common share	105,400	99,979
Comprehensive loss:		
Net loss	$ (181,915)	$ (141,214)
Unrealized gain (loss) on marketable securities, net of tax	360	(420)
Comprehensive loss	$ (181,555)	$ (141,634)

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

	Three Months Ended March 31,	
	2019	**2018**
Reconciliation of GAAP to Non-GAAP Research and development:		
GAAP Research and development	$ 129,127	$ 96,857
Less: Stock-based compensation expenses	(16,125)	(10,137)
Non-GAAP Research and development	$ 113,002	$ 86,720
Reconciliation of GAAP to Non-GAAP Selling, general and administrative:		
GAAP Selling, general and administrative	$ 89,608	$ 72,447
Less: Stock-based compensation expenses	(15,907)	(9,447)
Non-GAAP Selling, general and administrative	$ 73,701	$ 63,000
Reconciliation of GAAP to Non-GAAP Operating costs and expenses:		
GAAP Operating costs and expenses	$ 222,082	$ 169,304
Less: Stock-based compensation expenses	(32,032)	(19,584)
Non-GAAP Operating costs and expenses	$ 190,050	$ 149,720
Reconciliation of GAAP to Non-GAAP Net loss:		
GAAP Net loss	$ (181,915)	$ (141,214)
Add: Stock-based compensation expenses	32,032	19,584
Non-GAAP Net loss	$ (149,883)	$ (121,630)
Reconciliation of GAAP to Non-GAAP Net loss per common share-basic and diluted:		
GAAP Net loss per common share - basic and diluted	$ (1.73)	$ (1.41)
Add: Stock-based compensation expenses	0.31	0.19
Non-GAAP Net loss per common share - basic and diluted	$ (1.42)	$ (1.22)

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

	March 31, 2019	December 31, 2018
Cash, cash equivalents and marketable debt securities	$1,244,537	$ 1,082,949
Restricted investments	44,825	44,825
Accounts receivable, net	33,801	18,760
Inventory	32,001	24,068
Prepaid expenses and other assets	90,711	83,542
Property, plant and equipment, net	341,712	320,658
Operating lease right-of-use lease assets	226,412	—
Total assets	$2,013,999	$ 1,574,802
Accounts payable, accrued expenses and other liabilities	$ 134,616	$ 177,392
Total deferred revenue	3,120	3,954
Total deferred rent	—	61,491
Long-term debt	30,000	30,000
Total operating lease liability	299,277	—
Total stockholders' equity (106.4 million shares issued and outstanding at March 31, 2019; 101.2 million shares issued and outstanding at December 31, 2018)	1,546,986	1,301,965
Total liabilities and stockholders' equity	$2,013,999	$ 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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