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): August 6, 2020 (August 3, 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 August 6, 2020, Alnylam Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2020. 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 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b)

On August 3, 2020, Barry E. Greene resigned from his position as the Company's President, effective September 30, 2020, following seventeen years of service, initially as Chief Operating Officer, then as President and Chief Operating Officer, and most recently as President. In connection with his resignation, Mr. Greene and the Company will enter into a written agreement not later than September 30, 2020, which will contain the material terms under which Mr. Greene will provide consulting services to the Company, on an as needed basis, for a two-year period following the effective date of his resignation, as well as certain other terms relating to Mr. Greene's departure.

(c)

Yvonne L. Greenstreet, MBChB, MBA, has been appointed to the position of President of the Company, effective October 1, 2020, in addition to her existing position as the Company's Chief Operating Officer.

Dr. Greenstreet, 57, has served as the Company's Chief Operating Officer since September 2016. Prior to joining the Company, Dr. Greenstreet most recently served as the founder and Managing Director of Highgate LLC, from January 2014 to August 2016. Prior to that time, Dr. Greenstreet served as the Senior Vice President and Head of Medicines Development at Pfizer Inc., a multinational pharmaceutical company, from December 2010 to November 2013. Prior to joining Pfizer, Dr. Greenstreet worked for 18 years at GlaxoSmithKline plc, or GSK, a multinational pharmaceutical, biologics, vaccines and consumer healthcare company, where she served in various positions, most recently as Senior Vice President and Chief of Strategy for Research and Development and as a member of GSK's Product Management Board. Dr. Greenstreet currently serves on the Scientific Advisory Committee of the Bill and Melinda Gates Foundation and serves as a director of Pacira Pharmaceuticals and American Funds.

Item 7.01. Regulation FD Disclosure

On August 6, 2020, the Company issued a press release announcing Mr. Greene's resignation. A copy of this press release is furnished as Exhibit 99.2 to this Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.2 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of 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 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 exhibits shall be deemed to be furnished, and not filed:

99.1	Press Release dated August 6, 2020.
99.2	Press Release dated August 6, 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.

Date: August 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 Second Quarter 2020 Financial Results and Highlights Recent Period Activity

− Achieved Second Quarter 2020 ONPATTRO® Global Net Product Revenues of $66.5 Million, with More Than 1,050 Patients on Commercial Product Worldwide –

− Achieved Second Quarter 2020 GIVLAARI® Global Net Product Revenues of $11.0 Million with More Than 100 Patients on Commercial Product Worldwide –

– Presented Complete Results from ILLUMINATE-A Phase 3 Study of Lumasiran and Completed Filings of New Drug Application and Marketing Authorisation Application –

− Completed $2 Billion Strategic Financing Collaboration with Blackstone, Enabling Achievement of Self-Sustainable Financial Profile without Need for Future Equity Offerings –

– Increased Midpoint of Guidance Range for 2020 ONPATTRO Revenue, Narrowing Range from $270-$300 million to $280-$300 million –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--August 6, 2020--Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today reported its consolidated financial results for the second quarter 2020 and reviewed recent business highlights.

“In the second quarter of 2020, the world experienced unprecedented challenges as it continued to confront the COVID-19 pandemic. While the pandemic continues in some countries and states, our global commercialization strategy is now enabling some customer-facing activities to resume in most markets as we enter the third quarter. We are very pleased with our ONPATTRO and GIVLAARI commercial performance in the second quarter, in the face of the ongoing pandemic, and believe it reflects strong demand for our products as well as our team’s unwavering commitment to assure access to these RNAi therapeutics for patients around the world,” said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. “In the quarter, we also continued advancing our robust late-stage pipeline of investigational RNAi therapeutics, where, notably, we presented full results from the ILLUMINATE-A Phase 3 study and completed regulatory filings for lumasiran, and continued enrollment in our APOLLO-B and HELIOS-B Phase 3 studies of patisiran and vutrisiran, respectively. Further, a key business highlight in the second quarter was our completion of a landmark strategic financing collaboration with Blackstone, which we believe will secure our ability to achieve a self-sustainable financial profile without the need for future equity financing. These and other achievements position us to realize our *Alnylam 2020* vision of building a multi-product, global biopharma company with a deep clinical pipeline to fuel continued growth and a robust, organic product engine to drive sustainable innovation and further value creation.”

Second Quarter 2020 and Recent Significant Corporate Highlights

Commercial Performance

ONPATTRO®

- Achieved global net product revenues for the second quarter of 2020 of $66.5 million.
- Attained over 1,050 patients worldwide on commercial ONPATTRO treatment as of June 30, 2020.
- Continued strong market access in the U.S., with over 15 value-based agreements (VBAs) to date with commercial payers and confirmed access for over 98% of covered U.S. lives.
- Continued progress with market access efforts across the CEMEA region (**C**anada, **E**urope, **M**iddle **E**ast, and **A**frica), with recent launches in Spain and Italy.
    - The Company announces today that it has achieved agreement on pricing and reimbursement in France, completing patient access for ONPATTRO in all major European markets in under 2 years following approval.

GIVLAARI®

- Achieved global net product revenues for the second quarter of 2020 of $11.0 million.
- Since launch, received over 85 Start Forms in the U.S. and attained over 100 patients globally on commercial GIVLAARI treatment from launch through June 30, 2020.
- Received marketing authorization approval for GIVLAARI in Brazil for the treatment of acute hepatic porphyria in adults.
- Continued strong progress with market access in the U.S., with seven completed VBAs with commercial payers, and confirmed access for over 75% of covered U.S. lives.
- Continued progress with market access efforts across the CEMEA region, with a successful launch in Germany, commencement of cohort ATU supply in France, and named patient sales in other countries.
    - Received an Improvement of Medical Benefit (ASMR) score of II from Haute Autorité de Santé (HAS) in France, concluding that GIVLAARI offers significant additional therapeutic value. Only two new commercial medicines received a similar ASMR score in 2019.

- Continued work with physicians in multiple regions to support requests for pre-approval access to GIVLAARI in an Expanded Access Program (EAP) in accordance with local requirements.

R&D Highlights

- Advanced **patisiran** (the non-proprietary name for ONPATTRO), 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.
  - Presented additional clinical data with patisiran – including 24-month results from the global open-label extension (OLE) study and results from an open-label study in post-orthotopic liver transplant hATTR amyloidosis patients – and published findings from an evaluation of patisiran with concomitant use of TTR stabilizers.

- Presented new 12-month interim data from the ENVISION Phase 3 study of **givosiran** (the non-proprietary name for GIVLAARI) in acute hepatic porphyria (AHP).
  - In addition, published pivotal results from the ENVISION Phase 3 study in *The New England Journal of Medicine*.
  - Submitted a Marketing Authorization Application (MAA) for givosiran in Switzerland and Israel.

- Advanced **lumasiran**, an investigational RNAi therapeutic in development for the treatment of primary hyperoxaluria type 1 (PH1).
  - Completed the rolling submission of a New Drug Application (NDA) to the Food and Drug Administration (FDA) and submitted an MAA to the European Medicines Agency (EMA), with both applications now accepted.
    - The FDA also granted Priority Review for the NDA and set an action date of December 3, 2020 under the Prescription Drug User Fee Act (PDUFA).
    - The EMA granted an accelerated assessment for the lumasiran MAA.
  - Received a positive scientific opinion from the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) through the Early Access to Medicines Scheme (EAMS).
  - Presented complete results from the ILLUMINATE-A Phase 3 study.
  - Continued treating patients in ILLUMINATE-B, a global Phase 3 pediatric 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.
  - Continued enrollment in the ILLUMINATE-C Phase 3 study of lumasiran for the treatment of advanced PH1 in patients of all ages.

- Advanced **vutrisiran**, a subcutaneously administered investigational RNAi therapeutic in development for the treatment of ATTR amyloidosis.
  - Continued treating patients in the fully enrolled HELIOS-A Phase 3 study of vutrisiran in hATTR amyloidosis patients with polyneuropathy, and remain on track to report topline results in early 2021.
  - Received Fast Track Designation from the FDA for the treatment of the polyneuropathy of hATTR amyloidosis in adults.
  - Continued enrollment in the HELIOS-B Phase 3 study in ATTR amyloidosis patients with cardiomyopathy.

- Alnylam's partner, Novartis, continued advancing **inclisiran**, potentially the first and only siRNA cholesterol-lowering treatment, which is undergoing review for approval in the U.S. and EU.
  - Published results from the completed ORION Phase 3 pivotal trials in *The New England Journal of Medicine*, showing durable and potent LDL-C reduction achieved with inclisiran, with a safety profile similar to placebo.

- Alnylam's partner, Sanofi, continued enrollment in the ATLAS Phase 3 program for **fitusiran** in patients with hemophilia A or B with and without inhibitors, with topline results expected in H1 2021.
  - Presented updated interim results at the World Federation of Hemophilia meeting from a Phase 2 OLE study of fitusiran in patients with hemophilia A and B with and without inhibitors.

- Advanced early- and mid-stage RNAi therapeutic pipeline programs.
  - In collaboration with Regeneron, advanced **cemdisiran**, an investigational RNAi therapeutic for the treatment of complement-mediated diseases.
    - Continued enrollment in a Phase 2 clinical trial of cemdisiran monotherapy in patients with IgA nephropathy, with topline results expected in 2021.
    - Regeneron filed a Clinical Trial Application (CTA) in The Netherlands to initiate a Phase 1 study of cemdisiran in combination with **pozelimab**, an anti-C5 monoclonal antibody, in normal healthy volunteers and patients with paroxysmal nocturnal hemoglobinuria (PNH).
  - Alnylam's partner, Vir Biotechnology, presented positive interim data from the ongoing Phase 2 trial in patients and results from the Phase 1 trial in healthy volunteers of **ALN-HBV02 (VIR-2218)**, an investigational RNAi therapeutic for the treatment of chronic hepatitis B virus (HBV) infection.
  - Reported positive initial topline results from the ongoing Phase 1 study of **ALN-AGT** in hypertension, demonstrating acceptable safety, and clinically significant blood pressure lowering with durability enabling a quarterly or less frequent dosing regimen. Additional Phase 1 results are expected to be presented at a scientific meeting later in 2020, pending abstract acceptance.
  - Filed a Clinical Trial Application (CTA) for **ALN-HSD**, an investigational RNAi therapeutic targeting HSD17B13 in development for the treatment of nonalcoholic steatohepatitis (NASH). ALN-HSD is being advanced in collaboration with Regeneron.
  - Selected a Development Candidate (DC), **ALN-COV (VIR-2703)**, for SARS-CoV-2 – the virus that causes COVID-19 – with a plan for accelerated filing of an IND around year-end 2020.

- Continued progress advancing investigational RNAi therapeutics for CNS and ocular diseases, including **ALN-APP**, in development for the treatment of hereditary cerebral amyloid angiopathy (hCAA) and autosomal dominant Alzheimer's Disease (ADAD), which remains on track for a CTA filing in 2021. The Company announces today that Regeneron has exercised its co-development/co-commercialization option on the ALN-APP program, which Alnylam will lead.

Additional Business Updates

- Barry Greene, President of Alnylam, announced his intention to transition from Alnylam to pursue new opportunities at the end of the third quarter. Yvonne Greenstreet, Chief Operating Officer, will assume an expanded role as President and Chief Operating Officer on October 1, 2020.
- Entered into a strategic financing collaboration with Blackstone under which Alnylam will receive up to $2 billion that is expected to enable Alnylam to achieve a self-sustainable financial profile without the need for future equity financing.
- Entered into an agreement with Dicerna to develop and commercialize investigational RNAi therapeutics for the treatment of alpha-1 antitrypsin (A1AT) deficiency-associated liver disease, and completed a non-exclusive cross-licensing agreement with Dicerna regarding the companies' respective intellectual property for Alnylam's lumasiran and Dicerna's nedosiran investigational programs for the treatment of primary hyperoxaluria.
- Expanded infectious disease collaboration with Vir to include the development and commercialization of RNAi therapeutics targeting up to three host factor targets for SARS-CoV-2, including angiotensin converting enzyme-2 (ACE2), transmembrane protease, serine 2 (TMPRSS2), and potentially a third host factor target to emerge from Vir's functional genomics work.
- Formed a Distribution Agreement with taiba Middle East to commercialize Alnylam's RNAi therapeutics in the Gulf states.

Upcoming Events

In mid- and late 2020, Alnylam intends to:

- Achieve regulatory approval for ONPATTRO in Israel.
- File a new drug application for GIVLAARI in Japan and achieve regulatory approval for GIVLAARI in Canada.
- Report topline results from the ILLUMINATE-B Phase 3 study of lumasiran in PH1 patients less than six years of age with preserved renal function.
- Present additional clinical results from the ongoing Phase 1 trial of ALN-AGT.
- Initiate a Phase 1 trial of ALN-HSD.
- Achieve regulatory approvals for lumasiran in U.S. and EU.
- Alnylam's partner Novartis expects an FDA action date for inclisiran in late 2020.
- Alnylam's partner Regeneron plans to initiate a Phase 1 study of cemdisiran in combination with pozelimab.

Financial Results for the Quarter Ended June 30, 2020

“We are extremely pleased with our financial results for the second quarter, particularly in the face of these challenging circumstances. Our team’s ability to swiftly adapt to virtual engagement with stakeholders and to support the transition of patients, where needed, to alternate sites of care, in addition to strong international results, led to commercial performance for both ONPATTRO and GIVLAARI that exceeded the initial expectations we communicated in May 2020. As a result, we are further revising our full-year revenue guidance for ONPATTRO, with an increase in the midpoint of our guidance as we narrow the range from $270-$300 million to $280-$300 million,” said Jeff Poulton, Chief Financial Officer of Alnylam. “Outside of our commercial performance, a key business highlight in the second quarter was our achievement of year-over-year improvement in our non-GAAP operating loss versus 2019. Driven by strong top-line year-over-year growth and disciplined investment in our operations, we continue to believe 2019 represents our peak operating loss year as we begin our journey towards a self-sustainable financial profile. In summary, we believe that we’re well positioned to effectively navigate through the pandemic and continue to deliver on the promise of RNAi therapeutics, bringing transformative therapies to patients with serious diseases around the world.”

Financial Highlights

(in thousands, except per share amounts)

	Three Months Ended June 30,	
	2020	**2019**
Net product revenues	$ 77,533	$ 38,231
ONPATTRO net product revenues	$ 66,535	$ 38,231
GIVLAARI net product revenues	$ 10,998	$ —
Net revenue from collaborations	$ 26,429	$ 6,483
Cost of goods sold	$ 19,929	$ 4,326
GAAP research and development expenses	$ 154,996	$ 163,890
Non-GAAP research and development expenses	$ 139,206	$ 148,608
GAAP selling, general and administrative expenses	$ 127,896	$ 112,769
Non-GAAP selling, general and administrative expenses	$ 109,611	$ 97,448
GAAP operating loss	$ (198,859)	$ (236,271)
Non-GAAP operating loss	$ (164,784)	$ (205,668)
GAAP net loss	$ (179,229)	$ (219,481)
Non-GAAP net loss	$ (191,328)	$ (198,300)
GAAP net loss per common share - basic and diluted	$ (1.56)	$ (2.02)
Non-GAAP net loss per common share - basic and diluted	$ (1.67)	$ (1.83)

	June 30, 2020	**December 31, 2019**
Cash, cash equivalents, marketable debt and equity securities and restricted investments	$ 1,950,289	$ 1,550,987

Net Product Revenues

- Net product revenues were $77.5 million in the second quarter 2020 representing 103% growth from the second quarter 2019 as a result of the addition of new patients on therapy and expansion into new markets for ONPATTRO, as well as the ongoing U.S. commercial launch and initial European launch of GIVLAARI.

Net Revenues from Collaborations

- Net revenues from collaborations were $26.4 million in the second quarter 2020, an increase from $6.5 million in the second quarter 2019, primarily due to increases in revenues recognized from our Regeneron and Vir collaborations.

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

- R&D expenses decreased in the second quarter 2020 compared to the same period in 2019 on a GAAP and non-GAAP basis primarily due to nonrecurring expenses in 2019 from license fees related to the execution of our collaboration agreement with Regeneron, as well as a decrease in expenses associated with material manufactured for clinical trials.
- SG&A expenses increased in the second quarter 2020 compared to the same period in 2019 on a GAAP and non-GAAP basis primarily due to increased investment in commercial and medical affairs activity to support the ongoing launches of ONPATTRO and GIVLAARI and initial launch preparation activities for lumasiran.

Cash and Investments

- Cash, cash equivalents, marketable debt and equity securities, and restricted investments were $1.95 billion at the end of the second quarter 2020 compared to $1.55 billion at the end of 2019. The increase was primarily due to $600.0 million in proceeds received in the second quarter of 2020 from the sale of future royalties and issuance of common stock to Blackstone and its affiliates, partially offset by cash used in our operations to support overall growth.

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

2020 Updated Financial Guidance

Full year 2020 financial guidance consists of the following:

Item	Provided 5/6/2020 ($ millions)	Updated 8/6/2020 ($ millions)
ONPATTRO net product revenues	$270 - $300	$280 - $300
GIVLAARI net product revenues	No guidance provided	Unchanged
Net revenues from collaborations	$100 - $150	Unchanged
GAAP R&D and SG&A expenses	$1,155 - $1,250	$1,130 - $1,225
Non-GAAP R&D and SG&A expenses*	$1,000 - $1,075	Unchanged

*Excludes $130-$150 million (previously $155-175 million) of stock-based compensation and costs associated with the strategic financing collaboration from estimated GAAP R&D and SG&A expenses.

The strategic financing collaboration with Blackstone under which Alnylam will receive up to $2 billion is expected to enable Alnylam’s achievement of a self-sustainable financial profile without need for future equity financings.

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 expenses, unrealized gain on marketable equity securities, costs associated with our strategic financing collaboration, a gain on contractual settlement, and a gain on the change in fair value of a liability obligation. 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 unrealized gain on marketable equity securities, costs associated with our strategic financing collaboration, the gain on contractual settlement, and a gain on the change in fair value of a liability obligation because the Company believes these items are non-recurring transactions 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 second quarter 2020 results as well as expectations for the future via conference call on Thursday, August 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 was 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, Switzerland and Brazil 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. 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® (patisiran). In a controlled clinical study, 19% of ONPATTRO-treated patients experienced IRRs, compared to 9% 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%) and infusion-related reactions (19%).

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) approved in the United States and Brazil for the treatment of adults with acute hepatic porphyria (AHP). GIVLAARI is also approved in the European Union for the treatment of AHP in adults and adolescents aged 12 years and older. In the pivotal study, givosiran was shown to significantly reduce the rate of porphyria attacks that required hospitalizations, urgent healthcare visits or intravenous 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 aminolevulinic acid synthase 1 (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, 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, Switzerland and Brazil, and GIVLAARI® (givosiran), approved in the U.S., EU and Brazil. Alnylam has a deep pipeline of investigational medicines, including six 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 is headquartered in Cambridge, MA. For more information about our people, science and pipeline, please visit www.alnylam.com and engage with us on Twitter at @Alnylam or on LinkedIn.

Alnylam Forward Looking Statements

Various statements in this release concerning Alnylam's expectations, plans and prospects, including, without limitation, expectations regarding the direct or indirect effects on Alnylam's business, activities and prospects as a result of the COVID-19 pandemic, or delays or interruptions resulting therefrom and the success of Alnylam's mitigation efforts, Alnylam's views and plans with respect to the potential for RNAi therapeutics, including ONPATTRO, GIVLAARI, lumasiran, patisiran, vutrisiran, inclisiran, fitusiran, cemdisiran, ALN-HBV02, ALN-AGT, ALN-HSD, ALN-COV and ALN-APP, 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, its expectations regarding continued progress supporting pre-approval access to GIVLAARI in its EAP program, the advancement of lumasiran and inclisiran through regulatory review and toward the market, the expected timing for the presentation of topline ILLUMINATE-B Phase 3 results for lumasiran, the achievement of additional pipeline milestones, including relating to ongoing clinical studies of vutrisiran, the expected timing for filing INDs or CTAs for ALN-COV and ALN-APP, the initiation of Phase 1 clinical studies of ALN-HSD by Alnylam and cemdisiran and pozelimab by Regeneron, its expectations relating to continued ONPATTRO and GIVLAARI revenue growth and the further revised expected range of ONPATTRO net product revenues for 2020, the expected range for net revenues from collaborations for 2020, the revised expected range of 2020 aggregate annual non-GAAP and GAAP R&D and SG&A expenses, Alnylam's belief that the funding provided by Blackstone should enable Alnylam to achieve a self-sustainable profile without the need for future equity financing, and expectations regarding the achievement of its "Alnylam 2020" strategic plan announced in 2015 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 direct or indirect impact of the COVID-19 global pandemic or any future pandemic, such as the scope and duration of the outbreak, government actions and restrictive measures implemented in response, material delays in diagnoses of rare diseases, initiation or continuation of treatment for diseases addressed by Alnylam products, or in patient enrollment in clinical trials, potential supply chain disruptions, and other potential impacts to Alnylam's business, the effectiveness or timeliness of steps taken by Alnylam to mitigate the impact of the pandemic, and Alnylam's ability to execute business continuity plans to address disruptions caused by the COVID-19 or any future pandemic; Alnylam's ability to discover and develop novel drug candidates and delivery approaches and successfully demonstrate the efficacy and safety of its product candidates, including vutrisiran, ALN-AGT, ALN-HSD, ALN-APP and ALN-COV; 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, including ONPATTRO, GIVLAARI, inclisiran, lumasiran and vutrisiran; 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 inclisiran, 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 and achieving net product revenues for ONPATTRO within its further revised expected range during 2020; 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 within the reduced ranges of guidance provided by Alnylam through the implementation of further discipline in operations to moderate spend and its ability to achieve a self-sustainable financial profile in the future without the need for future equity financing; Alnylam's ability to establish and maintain strategic business alliances and new business initiatives, including completing an agreement for funding by Blackstone of certain R&D activities for vutrisiran and ALN-AGT; Alnylam's dependence on third parties, including Regeneron, for development, manufacture and distribution of certain products, including eye and CNS products and ALN-APP, Ironwood, for assistance with the education about and promotion of GIVLAARI, and Vir for the development of ALN-COV and other potential RNAi therapeutics targeting SARS-CoV-2 and host factors for SARS-CoV-2; 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Statements of Operations				
Revenues:				
Net product revenues	$ 77,533	$ 38,231	$ 149,471	$ 64,522
Net revenues from collaborations	26,429	6,483	53,967	13,486
Total revenues	103,962	44,714	203,438	78,008
Operating costs and expenses:				
Cost of goods sold	$ 19,929	$ 4,326	$ 33,231	$ 7,673
Research and development	154,996	163,890	324,567	293,017
Selling, general and administrative	127,896	112,769	254,657	202,377
Total operating costs and expenses	302,821	280,985	612,455	503,067
Loss from operations	(198,859)	(236,271)	(409,017)	(425,059)
Other income:				
Interest expense	(27,248)	—	(27,248)	—
Interest income	3,165	8,781	8,645	16,306
Other income (expense)	45,039	(453)	68,071	(410)
Change in fair value of liability obligation	—	9,422	—	9,422
Total other income	20,956	17,750	49,468	25,318
Loss before income taxes	(177,903)	(218,521)	(359,549)	(399,741)
Provision for income taxes	(1,326)	(960)	(1,901)	(1,655)
Net loss	$ (179,229)	$ (219,481)	$ (361,450)	$ (401,396)
Net loss per common share - basic and diluted	$ (1.56)	$ (2.02)	$ (3.18)	$ (3.75)
Weighted-average common shares used to compute basic and diluted net loss per common share	114,911	108,576	113,830	106,997

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

	Three Months Ended	
	June 30, 2020	**June 30, 2019**
Reconciliation of GAAP to Non-GAAP research and development:		
GAAP Research and development	154,996	163,890
Less: Stock-based compensation expenses	(15,790)	(15,282)
Non-GAAP Research and development	139,206	148,608
Reconciliation of GAAP to Non-GAAP selling, general and administrative:		
GAAP Selling, general and administrative	127,896	112,769
Less: Stock-based compensation expenses	(17,965)	(15,321)
Less: Costs associated with the strategic financing collaboration	(320)	—
Non-GAAP Selling, general and administrative	109,611	97,448
Reconciliation of GAAP to Non-GAAP operating loss:		
GAAP operating loss	(198,859)	(236,271)
Add: Stock-based compensation expenses	33,755	30,603
Add: Costs associated with the strategic financing collaboration	320	—
Non-GAAP operating loss	(164,784)	(205,668)
Reconciliation of GAAP to Non-GAAP net loss:		
GAAP net loss	(179,229)	(219,481)
Add: Stock-based compensation expenses	33,755	30,603
Add: Costs associated with the strategic financing collaboration	320	—
Less: Unrealized gain on marketable equity securities	(45,532)	—
Less: Gain on contractual settlement	(642)	—
Less: Change in Fair value of liability contribution	—	(9,422)
Non-GAAP net loss	(191,328)	(198,300)
Reconciliation of GAAP to Non-GAAP net loss per common share- basic and diluted:		
GAAP net loss per common share - basic and diluted	(1.56)	(2.02)
Add: Stock-based compensation expenses	0.29	0.28
Add: Costs associated with the strategic financing collaboration	—	—
Less: Unrealized gain on marketable equity securities	(0.39)	—
Less: Gain on contractual settlement	(0.01)	—
Less: Change in Fair value of liability contribution	—	(0.09)
Non-GAAP net loss per common share - basic and diluted	(1.67)	(1.83)

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)
(Unaudited)

	June 30, 2020	December 31, 2019
Cash, cash equivalents and marketable debt and equity securities	$ 1,925,564	$ 1,536,162
Restricted investments	24,725	14,825
Accounts receivable, net	69,115	43,011
Inventory	77,418	56,348
Prepaid expenses and other assets	108,745	98,412
Property, plant and equipment, net	439,126	425,179
Operating lease right-of-use lease assets	229,674	221,197
Receivable related to the sale of future royalties	500,000	—
Total assets	$ 3,374,367	$ 2,395,134
Accounts payable, accrued expenses and other liabilities	$ 256,166	$ 256,415
Total deferred revenue	389,117	396,204
Operating lease liability	315,065	303,823
Liability related to the sale of future royalties	1,014,293	—
Total stockholders' equity (115.6 million shares issued and outstanding at June 30, 2020; 112.2 million shares issued and outstanding at December 31, 2019)	1,399,726	1,438,692
Total liabilities and stockholders' equity	$ 3,374,367	$ 2,395,134

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, 2019.

Contacts

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

Josh Brodsky
(Investors)
617-551-8276

Exhibit 99.2

Alnylam Announces Planned Transition of Barry Greene, President

- Greene to Pursue New Opportunities at End-Q3, While Remaining a Consultant for Up to Two Years to Ensure Orderly Transition -

- Yvonne Greenstreet to be Named President and Chief Operating Officer; Company Initiates Search for a Chief Commercial Officer -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--August 6, 2020--Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, announced today that after 17 years, Barry Greene, President, has decided to leave the Company at the end of the third quarter to pursue outside interests in the biopharmaceutical industry. Mr. Greene will remain a consultant to the Company for up to two years to ensure an orderly transition, while the search for a new Chief Commercial Officer is underway. In addition, Dr. Yvonne Greenstreet, MBChB, MBA, who currently serves as Chief Operating Officer, has been named President and Chief Operating Officer effective October 1, 2020.

“It has been my tremendous privilege to serve as President of Alnylam for such a long period of time. I’m very proud of what we’ve been able to accomplish during my 17 years, having built a global, fully integrated, multi-product company that is recognized for excellence in R&D, and for our commercial strength and innovation as well,” said Barry Greene. “As I consider my next move, I plan to remain close to the science, medicine, and patients. I am fully confident Alnylam will achieve its goals with quality and excellence, and I’m grateful to have been a part of creating an entirely new class of medicines for patients. I will continue to support Alnylam in this transition and have no doubts about the Company’s future prospects as a top tier biopharmaceutical company.”

“I know that I speak for everyone at Alnylam in thanking Barry for his exceptional contributions and dedication to the Company, to patients and to our employees. We all owe him tremendous gratitude for his outstanding leadership and track record that have contributed to the delivery of a new class of medicines for patients and enabled life-changing advances in science and healthcare,” said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. “We respect his decision to pursue other interests and strongly believe that he will continue to be a highly impactful leader in life sciences. We are, however, pleased that he will remain involved with Alnylam as a consultant sharing his in-depth knowledge, extensive network and experience. Furthermore, as we conduct the search for a Chief Commercial Officer, we anticipate no impact to our ongoing commercial execution.”

“I would like to thank all of the employees, investigators, customers, partners, patient advocates and other stakeholders, as well as the Management Board and Alnylam Board of Directors, for your contributions, loyalty, guidance and collaboration over the years. I’m departing with the greatest admiration and respect as I take on the next chapter in my career,” added Mr. Greene.

“After nearly four very successful years at Alnylam and more than twenty years of experience across all facets of the biopharmaceutical sector, we are thrilled to have Yvonne step into an expanded role as President and Chief Operating Officer, given her strong command of our business, strategic perspective and proven ability to drive results,” added Dr. Maraganore. “Alnylam is on a positive trajectory and we are very well-positioned to continue building on our strong momentum. Yvonne has the leadership, track record, and breadth of experience that make her uniquely suited for this role. I look forward to our continued close partnership in this next phase of Alnylam’s evolution.”

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.

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Alnylam Forward Looking Statements

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