UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. ALNYLAM PHARMACEUTICALS, INC., JOHN M. MARAGANORE, and MANMEET S. SONI, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff _____ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Alnylam Pharmaceuticals, Inc. ("Alnylam" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Alnylam securities between

February 15, 2018 and September 12, 2018, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Alnylam is a global biopharmaceutical company developing therapeutics based on RNA interference ("RNAi"). RNAi is a naturally occurring biological pathway within cells for sequence-specific silencing and regulation of gene expression. Alnylam purports to harness the RNAi pathway to develop a potential new class of innovative medicines, known as RNAi therapeutics. RNAi therapeutics are comprised of small interfering RNA, or siRNA, and function upstream of today's medicines by potently silencing messenger RNA, or mRNA, that encode for disease-causing proteins, thus preventing them from being made.

3. In December 2017, Alnylam submitted its first new drug application ("NDA") and marketing authorization application ("MAA") for Onpattro (patisiran) to the U.S. Food and Drug Administration ("FDA"). Patisiran is an intravenously administered RNAi therapeutic targeting transthyretin ("TTR") for the treatment of hereditary ATTR amyloidosis. It is designed to target and silence specific messenger RNA, potentially blocking the production of TTR protein before it is made.

4. Alnylam's stock trades on the NASDAQ Global Select Market ("NASDAQ") under the ticker symbol "ALNY."

5. In August 2018, patisiran received FDA approval for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults, having been reviewed

by the FDA under Priority Review and previously granted Breakthrough Therapy and Orphan Drug Designations.

6. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Alnylam overstated the efficacy and safety of its Onpattro (patisiran) lipid complex injection; and (ii) as a result, Alnylam's public statements were materially false and misleading at all relevant times.

7. On September 12, 2018, Nomura/Instinet analyst Christopher Marai stated that a review document released by the FDA's Center for Drug Evaluation and Research "highlights greater risk" with respect to certain trials of Alnylam's ONPATTRO (patisiran) lipid complex injection, as well as "a limited market opportunity in TTRcardiomyopathy, and a potential platform safety risk." Specifically, Marair asserted that "[t]he document highlights FDA reviewers' concerns over cardiac deaths in patients treated with ONPATTRO and suggests that the drug should be limited to patients with polyneuropathy only *(i.e.*, not patients with cardiac manifestations and polyneuropathy). Furthermore, we believe some comments on the lack of cardiac efficacy call into question claims made by [Alnylam] in this regard."

8. On this news, Alnylam's stock price fell $5.60 per share, or over 5.5%, to close at $94.75 per share on September 12, 2018.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act.

7. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as the Company's securities are traded on the NASDAQ, located within this Judicial District.

11. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities Exchange.

PARTIES

12. Plaintiff, as set forth in the attached Certification, acquired Alnylam securities at artificially inflated prices during the Class Period and were damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Alnylam is incorporated in Delaware and its principal executive offices are located at 300 Third Street, Cambridge, Massachusetts 02142. The Company's securities are traded on the NASDAQ under the symbol "ALNY."

14. Defendant John M. Maraganore ("Maraganore") has served as the Chief Executive Officer ("CEO") of Alnylam at all relevant times.

15. Defendant Manmeet S. Soni ("Soni") has served as the Chief Financial Officer ("CFO") of Alnylam at all relevant times.

16. The Defendants referenced above in ¶¶ 14-15 are sometimes referred to herein as the "Individual Defendants."

17. The Individual Defendants possessed the power and authority to control the contents of Alnylam SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

18. Alnylam is a global biopharmaceutical company developing novel therapeutics based on RNA interference. RNAi is a naturally occurring biological pathway within cells for sequence-specific silencing and regulation of gene expression. Alnylam purports to harness the RNAi pathway to develop a potential new class of innovative medicines, known as RNAi therapeutics. RNAi therapeutics are comprised of small interfering RNA, or siRNA, and function upstream of today's medicines by potently silencing messenger RNA, or mRNA, that encode for disease-causing proteins, thus preventing them from being made.

19. Alnylam's pipeline of investigational RNAi therapeutics is focused in three Strategic Therapeutic Areas, or "STArs": Genetic Medicines; Cardio-Metabolic Diseases; and

Hepatic Infectious Diseases. Alnylam purports to be committed to the advancement of its "Alnylam 2020 strategy", which is to achieve a company profile with three marketed products and ten RNAi therapeutic clinical programs, including four in late stages of development, across its three STArs by the end of 2020.

20. In December 2017, Alnylam filed its NDA and MAA for Onpattro (patisiran). Patisiran is an intravenously administered RNAi therapeutic targeting transthyretin (TTR) for the treatment of hereditary ATTR amyloidosis. It is designed to target and silence specific messenger RNA, potentially blocking the production of TTR protein before it is made. Patisiran blocks the production of transthyretin in the liver, reducing its accumulation in the body's tissues in order to halt or slow down the progression of the disease.

21. In early February 2018, the FDA accepted Alnylam's NDA and granted its request for priority review, with an action date of August 11, 2018. If approved, Alnylam projected to launch patisiran and begin generating product revenues in 2018.

Materially False and Misleading Statements Issued During the Class Period

22. The Class Period begins on February 15, 2018, when the Company filed its annual report on Form 10-K for the fiscal year ended December 31, 2017 (the "2017 10-K") with the SEC, which contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

23. In the 2017 10-K, the Company discussed the its phase 3 clinical trial for patisiran, referred to as "APOLLO 3":

APOLLO Phase 3 Clinical Trial

Trial Design: Initiated in November 2013 and completed in September 2017, APOLLO is the largest pivotal study conducted to date in hATTR amyloidosis patients with polyneuropathy, with 225 patients enrolled, representing 39 TTR genotypes from across 19 countries. This randomized, double-blind, placebo-controlled, global study was designed to evaluate the efficacy and safety of patisiran in hATTR amyloidosis patients with polyneuropathy. The primary endpoint of the study was the change from baseline in the modified neuropathy impairment score, or mNIS+7, at 18 months. The mNIS+7 score is an evaluation of muscle weakness, sensory and autonomic function, and nerve conductance across a 304-point scale, where neuropathy progression leads to an increased score over time. A key secondary endpoint was the Norfolk Quality of Life Diabetic Neuropathy, or Norfolk QOL-DN, questionnaire, which is a validated instrument that measures clinical benefit. Additional secondary endpoints included: NIS-weakness, the subdomain of mNIS+7 assessing muscle strength; Rasch-built Overall Disability Scale, or R-ODS, a patient reported outcome measure of activities of daily living and disability; timed 10-meter walk test, assessing ambulatory ability and gait speed; modified body mass index, or mBMI, assessing nutritional status; and COMPASS-31, a patient questionnaire assessing autonomic disease symptoms. Exploratory endpoints measured the effects on cardiac structure and function. Patients were randomized 2:1, patisiran-to-placebo, with patisiran administered at 0.30 mg/kg once every three weeks for 18 months by intravenous infusion. 99 percent of patients who completed the APOLLO study rolled over into the Phase 3 OLE study, called the Global OLE.

Trial Results:

Efficacy: Patisiran met the primary endpoint of mNIS+7 change from baseline at 18 months relative to placebo, and all secondary study endpoints. Specifically:

- Patisiran treatment (N=148) resulted in a negative 6.0-point mean change (improvement) in mNIS+7 score from baseline at 18 months as compared to a 28.0-point mean increase (worsening) reported for the placebo group (N=77), resulting in a 34.0-point mean difference relative to placebo (p=9.26 x 10-24).
    - Improvement in mNIS+7 from patisiran treatment was also consistently observed across all defined patient subgroups, including age, sex, race, geographic region, baseline neuropathy impairment, genotype, prior TTR stabilizer use, baseline Familial Amyloid Polyneuropathy, or FAP, stage, and inclusion in the pre-specified cardiac subpopulation.
- Patisiran treatment resulted in a negative 6.7-point mean change (improvement) in Norfolk QoL-DN score from baseline at 18 months as compared to a 14.4-point mean increase (worsening) reported for the placebo group, resulting in a 21.1-point mean difference relative to placebo (p=1.10 x 10-10).

- In a pre-specified binary analysis of neurological improvement, 56 percent (95 percent confidence interval, or CI: 48.1, 64.1) of patisiran patients had an improvement in mNIS+7 (less than 0-point change compared to baseline at 18 months), while 4 percent (95 percent CI: 0.0, 8.2) of placebo patients had an improvement (p=1.82 x 10-15).
- Similarly, 51 percent (95 percent CI: 43.3, 59.4) of patisiran patients had an improvement in Norfolk QoL-DN (less than 0-point change compared to baseline at 18 months), versus 10 percent (95 percent CI: 3.6, 17.2) for placebo (p=1.95 x 10-10).
- Patisiran also demonstrated statistically significant and clinically meaningful improvements over placebo in all other secondary endpoints at 18 months.

Cardiac Subpopulation Results: Favorable and significant changes in several exploratory cardiac measures, including N-terminal pro b-type natriuretic peptide, or NT-proBNP, and certain echocardiographic parameters, were reported in patisiran-treated patients with pre-defined cardiac involvement (baseline left ventricular (LV) wall thickness ≥ 1.3 cm with no history of hypertension or aortic valve disease). Specifically:

- Patisiran treatment resulted in a median decrease (improvement) of 49.9 pg/ml in NT-proBNP levels as compared to a median increase (worsening) of 320 pg/ml reported for the placebo arm at 18 months (nominal p=7.74 x 10-8, based on analysis of log-transformed values).

- Regarding echocardiographic measures, patisiran treatment resulted in a mean 0.93 mm reduction (improvement) in left ventricular (LV) wall thickness (nominal p=0.0173) and a mean absolute 1.37 percent improvement in longitudinal strain (nominal p=0.0154) relative to placebo.

Safety and Tolerability: Patisiran showed an encouraging safety and tolerability profile relative to placebo with up to 18 months of dosing. Specifically:

• The most commonly reported adverse events, or AEs, that occurred more frequently in patisiran patients were peripheral edema (29.7 percent versus 22.1 percent in placebo) and infusion-related reactions, or IRRs (18.9 percent versus 9.1 percent in placebo). These were generally mild to moderate in severity and only one patient discontinued due to an IRR (0.7 percent).

• Compared to placebo, patisiran treatment was associated with fewer treatment discontinuations (4.7 versus 14.3 percent) and fewer study withdrawals (4.7 versus 11.7 percent) due to AEs.

• The incidence of serious adverse events, or SAEs, across the patisiran (36.5 percent) and placebo (40.3 percent) groups was similar.

> • SAEs reported in 2 or more patients in the patisiran group included: diarrhea (5.4 percent), cardiac failure, congestive cardiac failure, orthostatic hypotension, pneumonia, and atrioventricular block complete (2 percent each). These were all considered unrelated to patisiran, except for one SAE of diarrhea. SAEs occurred with similar frequency in the placebo group, except for diarrhea (1.3 percent in placebo group).
>
> • Deaths were recorded with a similar incidence across the patisiran (4.7 percent) and placebo (7.8 percent) treatment groups.
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> o No deaths were considered related to study drug.
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> • There were no safety signals with regard to hepatic or renal function, or evidence of thrombocytopenia, due to patisiran.

24. On May 4, 2018 the Company filed its quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2018 (the "1Q'18 10-Q") with the SEC, which contained signed certifications pursuant to SOX by the Individual Defendants, attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

25. Discussing the APOLLO Phase 3 trial, the 1Q'18 10-Q stated that:

> During the first quarter of 2018 and recent period, we reported the following updates from our late-stage clinical programs[,] ***[w]e continued to advance patisiran, an investigational RNAi therapeutic for the treatment of patients with hereditary ATTR amyloidosis, or hATTR, presenting new data from our APOLLO Phase 3 study, including results on the effects of patisiran on cardiomyopathy manifestations and a post-hoc analysis on the effects of patisiran on the composite rate of all-cause hospitalization and mortality***. We received acceptance from the FDA and the EMA of patisiran's NDA and MAA, respectively.

(Emphasis added.)

26. On August 2, 2018 the Company filed its quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2018 (the "2Q'18 10-Q") with the SEC, which contained signed certifications pursuant to SOX by the Individual Defendants, attesting to the accuracy of

financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

27. Discussing the APOLLO Phase 3 trial, the 2Q'18 10-Q stated that:

> During the second quarter of 2018 and recent period, we reported the following updates from our late-stage clinical programs:
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> - ***We continued to advance patisiran, an investigational RNAi therapeutic for the treatment of patients with hATTR amyloidosis***, announcing in July 2018 that we received a positive opinion from the CHMP in the EU recommending marketing authorisation of ONPATTRO (patisiran) for the treatment of hATTR amyloidosis in adult patients with Stage 1 or Stage 2 polyneuropathy. The EC decision on approval of patisiran is now expected in September 2018, and the recommended SmPC includes data from secondary and exploratory study endpoints in the APOLLO Phase 3 trial, including cardiac results. ***We believe we are on track in the United States with an August 11, 2018 PDUFA date for patisiran with the FDA***. On July 5, 2018, we published the APOLLO results in *The New England Journal of Medicine,* and we also presented additional data from the APOLLO Phase 3 study in July.

(Emphasis added.)

28. On August 10, 2018, the Company issued a press release titled: "Alnylam Announces First-Ever FDA Approval of an RNAi Therapeutic, ONPATTRO™ (patisiran) for the Treatment of the Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis in Adults"

> CAMBRIDGE, Mass.--(BUSINESS WIRE)--Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, announced today that the United States Food and Drug Administration (FDA) approved ONPATTRO™ (patisiran) lipid complex injection, a first-of-its-kind RNA interference (RNAi) therapeutic, for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults. ONPATTRO is the first and only FDA-approved treatment for this indication. hATTR amyloidosis is a rare, inherited, rapidly progressive and life-threatening disease with a constellation of manifestations. In addition to polyneuropathy, hATTR amyloidosis can lead to other significant disabilities including decreased ambulation with the loss of the ability to walk unaided, a reduced quality of life, and a decline in cardiac functioning. ***In the largest controlled study of hATTR amyloidosis, ONPATTRO was shown to improve polyneuropathy – with***

reversal of neuropathy impairment in a majority of patients – and to improve a composite quality of life measure, reduce autonomic symptoms, and improve activities of daily living.

"Alnylam was founded on the vision of harnessing the potential of RNAi therapeutics to treat human disease, and this approval heralds the arrival of an entirely new class of medicines. We believe today draws us ever-closer to achieving our Alnylam 2020 goals of becoming a fully integrated, multi-product biopharmaceutical company with a sustainable pipeline," said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. "With the potential for the sequential launches of several new medicines in the coming years, we believe we have the opportunity to meaningfully impact the lives of people around the world in need of new approaches to address serious diseases with significant unmet medical needs."

"Today's historic approval marks the arrival of a first-of-its kind treatment option for a rare and devastating condition with limited treatment options," said Akshay Vaishnaw, M.D., Ph.D., President of R&D at Alnylam. "We extend our deepest gratitude to the patients who participated in the ONPATTRO clinical trials and their families and caregivers who supported them. We are also grateful for the tireless efforts of the investigators and study staff, without whom this important milestone would not have been possible. We also look forward to working with the FDA to potentially expand the ONPATTRO indication in the future."

The FDA approval of ONPATTRO was based on positive results from the randomized, double-blind, placebo-controlled, global Phase 3 APOLLO study, the largest-ever study in hATTR amyloidosis patients with polyneuropathy. Results from the APOLLO study were published in the July 5, 2018, issue of The New England Journal of Medicine.

In APOLLO, the safety and efficacy of ONPATTRO were evaluated in a diverse, global population of hATTR amyloidosis patients in 19 countries, with a total of 39 TTR mutations. Patients were randomized in a 2:1 ratio to receive intravenous ONPATTRO (0.3 mg per kg of body weight) or placebo once every 3 weeks for 18 months. The study showed that ONPATTRO improved measures of polyneuropathy, quality of life, activities of daily living, ambulation, nutritional status and autonomic symptoms relative to placebo in adult patients with hATTR amyloidosis with polyneuropathy. The primary endpoint of the APOLLO study was the modified Neuropathy Impairment Score +7 (mNIS+7), which assesses motor strength, reflexes, sensation, nerve conduction and postural blood pressure.

- Patients treated with ONPATTRO had a mean 6.0-point decrease (improvement) in mNIS+7 score from baseline compared to a mean 28.0-point increase (worsening) for patients in the placebo group, resulting in a

mean 34.0-point difference relative to placebo, after 18 months of treatment.

- While nearly all ONPATTRO-treated patients experienced a treatment benefit relative to placebo, 56 percent of ONPATTRO-treated patients at 18 months of treatment experienced reversal of neuropathy impairment (as assessed by mNIS+7 score) relative to their own baseline, compared to four percent of patients who received placebo.
- Patients treated with ONPATTRO had a mean 6.7-point decrease (improvement) in Norfolk Quality of Life Diabetic Neuropathy (QoL-DN) score from baseline compared to a mean 14.4-point increase (worsening) for patients in the placebo group, resulting in a mean 21.1-point difference relative to placebo, after 18 months of treatment.
- As measured by Norfolk QoL-DN, 51 percent of patients treated with ONPATTRO experienced improvement in quality of life at 18 months relative to their own baseline, compared to 10 percent of the placebo-treated patients.
- Over 18 months of treatment, patients treated with ONPATTRO experienced significant benefit vs. placebo for all other secondary efficacy endpoints, including measures of activities of daily living, walking ability, nutritional status, and autonomic symptoms.
- The most common adverse events that occurred more frequently with ONPATTRO than with placebo were upper respiratory tract infections and infusion-related reactions. To reduce the risk of infusion-related reactions, patients received premedications prior to infusion.

“FDA approval of ONPATTRO represents an entirely new approach to treating patients with polyneuropathy in hATTR amyloidosis and shows promise as a new era in patient care,” said John Berk, M.D., Associate Professor of Medicine at Boston University School of Medicine and assistant director of the Amyloidosis Center at Boston University School of Medicine. “Given the strength of the APOLLO data, including data showing the possibility of halting or improving disease progression in many patients, ONPATTRO holds tremendous promise for people living with this disease.”

“For years I have witnessed the tragic impact of hATTR amyloidosis on generations of families. Today, we celebrate the FDA approval of ONPATTRO,” said Muriel Finkel, President of Amyloidosis Support Groups. “It’s extremely gratifying to see promising science translate into a treatment option that will allow patients to potentially experience an improvement in their disease and an improvement in their overall quality of life.”

“Today’s approval is significant in so many respects. It means the hATTR amyloidosis community of patients, families, caregivers and healthcare professionals in the United States now has a treatment option that offers renewed hope,” said Isabelle Lousada, Founder and Chief Executive Officer of the

> Amyloidosis Research Consortium. "With an FDA-approved treatment now available, I am more optimistic than ever that we can increase awareness of this rare disease and encourage more people to get tested and receive the proper diagnosis."
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> ONPATTRO is expected to be available for shipment to healthcare providers in the U.S. within 48 hours.
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> Alnylam is committed to helping people access the medicines they are prescribed and will be offering comprehensive support services for people prescribed ONPATTRO through Alnylam Assist™. Visit AlnylamAssist.com for more information or call 1-833-256-2748.
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> ONPATTRO was reviewed by the FDA under Priority Review and had previously been granted Breakthrough Therapy and Orphan Drug Designations. On July 27, patisiran received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) for the treatment of hereditary transthyretin-mediated amyloidosis in adults with stage 1 or stage 2 polyneuropathy under accelerated assessment by the European Medicines Agency. The recommended Summary of Product Characteristics (SmPC) for the European Union (EU) includes data on secondary and exploratory endpoints. Expected in September, the European Commission will review the CHMP recommendation to make a final decision on marketing authorization, applicable to all 28 EU member states, plus Iceland, Liechtenstein and Norway. Regulatory filings in other markets, including Japan, are planned beginning in mid-2018.

(Emphasis added.)

29. The statements referenced in ¶¶ 22-27 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Alnylam overstated the efficacy and safety of its Onpattro (patisiran) lipid complex injection; and (ii) as a result, Alnylam's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

30. On August 10, 2018, the FDA's Center for Drug Evaluation and Research ("CDER") issued its Multi-Discipline Review/Summary of ONPATTRO (patisiran) (application number: 210922Orig1s000). The CDER report, a 485-page, highly technical document, included, *inter alia*, the following findings:

- "Although there was a higher percentage of total deaths in the placebo group of Study 004 [(i.e., Apollo)], . . . ***there was a higher percentage of cardiac deaths in the patisiran group***.";

- "***Study ALN-TTR02-004 [(i.e., Apollo)] does not provide any cardiac efficacy data***. Imaging and serum biomarkers such as global longitudinal strain and NT-proBNP do not measure how a patient feels, functions, or survives, nor are they known to predict how a patient feels, functions, or survives and hence do not measure a clinical benefit.";

- "Based on the mechanism of action of patisiran, it is theoretically possible that it might be beneficial for the non-polyneuropathy symptoms in patients with hATTR. ***However, any such benefits have not been established in the current development program.*** Although the applicant included a cardiac subpopulation in the placebo-controlled Study 004 and measured some cardiac biomarkers, as discussed in Section 6.1, the FDA cardiology consultant concluded that 'Study ALN-TTR02-004 does not provide any cardiac efficacy data'"; and

- "we recommend that, if approved, the indication in the label should explicitly state that Onpattro is intended ***solely*** for treatment of Familial Amyloid Polyneuropathy[.]"

(Emphases added.)

31. Notwithstanding the FDA's findings, Alnylam continued to tout the efficacy of Onpattro. On August 30, 2018, the Company issued a press release titled: "Alnylam Receives Approval of ONPATTRO™ (patisiran) in Europe", touting the APOLLO Phase 3 trial:

> The EC decision was based on the evaluation of the effects of patisiran in hATTR amyloidosis patients with polyneuropathy and its safety profile as demonstrated in the APOLLO Phase 3 study. The Summary of Product Characteristics (SmPC) includes data from APOLLO on primary and secondary endpoints, as well as exploratory cardiac endpoints. The European Medicines Agency reviewed patisiran under the accelerated assessment procedure that is granted to medicines judged to be of major interest for public health and therapeutic innovation.

About Apollo
The marketing authorization for patisiran was based on positive results from the randomized, double-blind, placebo-controlled, global Phase 3 APOLLO study, the largest-ever study in hATTR amyloidosis patients with polyneuropathy. Results from the APOLLO study were published in the July 5, 2018, issue of *The New England Journal of Medicine*.

In APOLLO, the safety and efficacy of patisiran were evaluated in a diverse, global population of hATTR amyloidosis patients in 19 countries, with a total of 39 TTR mutations. Patients were randomized in a 2:1 ratio to receive intravenous patisiran (0.3 mg per kg of body weight) or placebo once every 3 weeks for 18 months. The study showed that patisiran improved measures of polyneuropathy, quality of life, activities of daily living, ambulation, nutritional status and autonomic symptoms relative to placebo in adult patients with hATTR amyloidosis with polyneuropathy. The primary endpoint of the APOLLO study was the modified Neuropathy Impairment Score +7 (mNIS+7), which assesses motor strength, reflexes, sensation, nerve conduction and postural blood pressure.

- Patients treated with patisiran had a mean 6.0-point decrease (improvement) in mNIS+7 score from baseline compared to a mean 28.0-point increase (worsening) for patients in the placebo group, resulting in a mean 34.0-point difference relative to placebo, after 18 months of treatment.
- While nearly all patisiran-treated patients experienced a treatment benefit relative to placebo, 56 percent of patisiran-treated patients at 18 months of treatment experienced improvement of neuropathy impairment (as assessed by mNIS+7 score) relative to their own baseline, compared to four percent of patients who received placebo.
- Patients treated with patisiran had a mean 6.7-point decrease (improvement) in Norfolk Quality of Life Diabetic Neuropathy (QoL-DN) score from baseline compared to a mean 14.4-point increase (worsening) for patients in the placebo group, resulting in a mean 21.1-point difference relative to placebo, after 18 months of treatment.
- As measured by Norfolk QoL-DN, 51 percent of patients treated with patisiran experienced improvement in quality of life at 18 months relative to their own baseline, compared to 10 percent of the placebo-treated patients.
- Over 18 months of treatment, patients treated with patisiran experienced significant benefit vs. placebo for all other secondary efficacy endpoints, including measures of activities of daily living, walking ability, nutritional status, and autonomic symptoms.
- Patisiran was associated with favorable effects on exploratory endpoints related to cardiac structure and function in the prespecified subpopulation of patients with cardiac involvement.
- The incidence and severity of adverse events were similar in patients receiving patisiran and placebo. The most common adverse events that

> occurred more frequently with patisiran than with placebo were peripheral oedema and infusion-related reactions. To reduce the risk of infusion-related reactions, patients received premedications prior to infusion.

32. Then, on September 12, 2018, Nomura/Instinet analyst Christopher Marai issued a report that conveyed to the market the full significance of the Onpattro review document released by the FDA CDER, stating that it "highlights greater risk" with respect to certain trials of Alnylam's ONPATTRO (patisiran) lipid complex injection, as well as "a limited market opportunity in TTRcardiomyopathy, and a potential platform safety risk."

33. Specifically, Marair asserted that "[t]he document highlights FDA reviewers' concerns over cardiac deaths in patients treated with ONPATTRO and suggests that the drug should be limited to patients with polyneuropathy only *(i.e.*, not patients with cardiac manifestations and polyneuropathy). Furthermore, ***we believe some comments on the lack of cardiac efficacy call into question claims made by [Alnylam] in this regard***." (Emphasis added.) Marair concluded that "the ONPATTRO review document highlights greater risk for ALNY's ONPATTRO/TTRsc02 trials, a limited market opportunity in TTRcardiomyopathy, and a potential platform safety risk."

34. On this news, Alnylam's stock price fell $5.60, or over 5.5%, to close at $94.75 per share on September 12, 2018.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Alnylam securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their

immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Alnylam securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Alnylam or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Alnylam;

- whether the Individual Defendants caused Alnylam to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Alnylam securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

41. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Alnylam securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Alnylam securities between the time the Defendants failed to disclose or misrepresented

material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

42. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

43. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

44. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

45. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

46. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of

Alnylam securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Alnylam securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

47. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Alnylam securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Alnylam finances and business prospects.

48. By virtue of their positions at Alnylam , Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

49. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers

and/or directors of Alnylam, the Individual Defendants had knowledge of the details of Alnylam internal affairs.

50. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Alnylam. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Alnylam businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Alnylam securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Alnylam business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Alnylam securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

51. During the Class Period, Alnylam securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Alnylam securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff

and the Class, the true value of Alnylam securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Alnylam securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

52. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

53. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

54. Plaintiff repeats and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

55. During the Class Period, the Individual Defendants participated in the operation and management of Alnylam, and conducted and participated, directly and indirectly, in the conduct of Alnylam business affairs. Because of their senior positions, they knew the adverse non-public information about Alnylam misstatement of income and expenses and false financial statements.

56. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Alnylam

financial condition and results of operations, and to correct promptly any public statements issued by Alnylam which had become materially false or misleading.

57. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Alnylam disseminated in the marketplace during the Class Period concerning Alnylam results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Alnylam to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Alnylam within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Alnylam securities.

58. Each of the Individual Defendants, therefore, acted as a controlling person of Alnylam. By reason of their senior management positions and/or being directors of Alnylam, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Alnylam to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Alnylam and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

59. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Alnylam.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.