



August 22, 2024

VIA EDGAR

United States Securities and Exchange Commission
Division of Corporation Finance
100 F Street, N.E.
Washington, D.C. 20549
Attention: Frank Wyman, Angela Connell

Re: Alnylam Pharmaceuticals, Inc.
Form 10-K for the Year Ended December 31, 2023
Filed February 15, 2024
File No. 001-36407

Dear Mr. Wyman and Ms. Connell:

On behalf of Alnylam Pharmaceuticals, Inc. (the "Company," "we," or "our"), I am submitting this letter in response to comments from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") received by letter dated August 12, 2024, concerning the Company's Form 10-K for the year ended December 31, 2023, filed with the Commission on February 15, 2024.

To assist your review, the text of the Staff's comments is presented in italics below.

Form 10-K for the Year Ended December 31, 2023

Notes to Consolidated Financial Statements

4. Net Revenues from Collaborations, page 107

- We note your tabular disclosure at the bottom of page 107 that quantifies the research and development (R&D) expenses incurred by collaborator and type that are directly attributable to your collaboration agreements. Please explain to us how this disclosure relates to your net revenues from collaborations. Using the Roche collaboration as an example, your disclosure on page 110 indicates that you recognized collaboration revenue of \$24 million during 2023 related to your Development Services Obligation. Please***

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explain how this amount relates to the \$44.6 million in total R&D expenses attributed to the Roche collaboration as disclosed on page 107. In addition, to the extent applicable, please explain how the \$547 million additional variable consideration attributed to cost reimbursement from development and manufacturing services and technology transfer related to the Roche Performance Obligations was calculated.

Response to Comment #1:

The table at the bottom of page 107 discloses the type and amount of research and development (“R&D”) expenses incurred for the Company's collaborations. Each of our collaboration agreements has unique performance obligations and cost sharing mechanisms. For our collaboration with Regeneron Pharmaceuticals, Inc. (“Regeneron”), revenue is recognized on a cost-to-cost input method and the costs used to measure both costs incurred and total costs are only those that relate to these performance obligations. Under the Company’s Collaboration and License Agreement with F. Hoffmann-La Roche Ltd. and Genentech, Inc. (together, “Roche”), dated as of July 21, 2023 (the “Roche Agreement”), we are reimbursed based on a percentage of the cost related to the R&D performance obligation. As requested by the Staff, we explain this in more detail below using our collaboration with Roche as an example.

Roche

Under the Roche Agreement, the Company has a performance obligation under Accounting Standards Codification (“ASC”) 606 and is obligated to perform development services, including the manufacture of clinical supply to support the regulatory approval of zilebesiran (the “Roche Development Services Obligation”). The Company is responsible for 40% and Roche is responsible for 60% of the costs incurred to perform the Roche Development Services Obligation.

At inception of the Roche Agreement, based on the development plan agreed to by the Company and Roche (the “Development Plan”), the Company was able to estimate the development activities it will perform under the Roche Development Services Obligation and the reimbursement that it is entitled to receive from Roche. The Company used the expected value method and estimated the expected value amount as \$545 million. The estimated expected value amount represents 60% of the total cost (the Roche share) per the Development Plan based on the hours and costs expected to be incurred to perform all of the development activities until commercialization, risk adjusted based on the probability of successful completion of all of the phases which are contingent upon future regulatory events. The Company concluded it is probable that a significant reversal of cumulative revenue will not occur in the future if some amount of the variable payments are not ultimately paid, because the cost reimbursement amounts are only recognized as revenue as the Company performs the development activities under the Roche Development Services Obligation.

During the year ended December 31, 2023, the Company incurred \$45 million in R&D expenses related to the Roche collaboration and recognized collaboration revenue of \$24 million related to

the Roche Development Services Obligation. Of the \$45 million in R&D expenses incurred, approximately \$40 million related to the Roche Development Services Obligation.

The Company recognizes the consideration associated with the Roche Development Services Obligation using the cost-to-cost method which is based on cost incurred (the numerator in the cost-to-cost model) relative to the total estimated cost of the obligation (the denominator in the cost-to-cost model) to determine the proportion of effort incurred as a percentage of total effort the Company expects to expend. This ratio is applied to the transaction price allocated to the obligation. As of December 31, 2023, the Company is approximately 4% complete with the Roche Development Services Obligation and has recognized \$24 million of the \$545 million transaction price associated with this obligation.

As all costs in the cost-to-cost model are allowable for reimbursement from Roche, and the assumptions used to determine the total estimated cost of the obligation (denominator in the cost-to-cost model) are consistent with the assumptions used to determine the transaction price associated with the obligation, the collaboration revenue recognized will approximate 60% of the actual reimbursable costs incurred.

Therefore, \$24 million of collaboration revenue recognized under the cost-to-cost model can also be calculated as the \$40 million of R&D expenses related to the Roche Development Services, multiplied by 60%, which is the Company's reimbursement amount from Roche.

The Company also has an obligation to perform a technology transfer of the existing manufacturing process for zilebesiran (the "Roche Technology Transfer Obligation"). The Company used the expected value method to estimate the expected value amount of \$2 million based on the estimated costs expected to be incurred to perform the technology transfer activities. The Company did not recognize any collaboration revenue for the Roche Technology Transfer Obligation in the year ended December 31, 2023.

Regeneron

The Company recognizes revenue related to its collaboration with Regeneron over time using an input-based method on costs incurred relative to the total expected costs to be incurred for each of the identified performance obligations ("percentage of completion"). The specific amount of collaboration revenue for the period is determined by applying the percentage of completion to the transaction price allocated to each performance obligation. Hence, the R&D costs disclosed in the table on page 107 determine the extent of progress toward completion of the R&D services, but our collaboration revenue is based on the consideration allocated to the performance obligation.

- 2. Please explain the circumstances that resulted in a reversal of revenue in the amount of \$15.5 million related to your Regeneron C5 License Obligation during 2023 as disclosed on page 113.***

Response to Comment #2:

During 2019, the Company entered into a global, strategic collaboration with Regeneron to discover, develop and commercialize RNAi therapeutics for a broad range of diseases. At the inception of the Regeneron collaboration, the Company identified an obligation to provide Regeneron with a worldwide license to cemdisiran for combination therapies, manufacturing and supply and development service obligations (the “C5 License Obligation”). The Company determined that the worldwide license to cemdisiran for combination therapies is not distinct from the manufacturing and supply and development service obligations as Regeneron cannot benefit on its own from the value of the license without receipt of the supply. Therefore, the C5 License Obligation is a single performance obligation.

The C5 License Obligation is satisfied over time using an input-based method based on costs incurred relative to the total expected costs to be incurred. The amount of revenue recognized during each period for the C5 License Obligation is impacted by changes in the percent complete for the period, which is driven by changes in either costs incurred to date (the numerator in the percentage calculation) or changes in total expected costs to be incurred (the denominator in the percentage calculation). Pursuant to ASC 606-10-25-35, as circumstances change over time, the Company updates its measure of progress to reflect any changes in the outcome of the performance obligation. Such changes to the Company’s measure of progress are accounted for as a change in accounting estimate.

During the fourth quarter of 2023, Regeneron increased the scope of the manufacturing and supply activities for the C5 License Obligation to support the potential future manufacturing of cemdisiran as a commercial drug. The Company assessed the facts and circumstances surrounding this change, which resulted from new information communicated by Regeneron, and determined that such change represents a change in estimate in the fourth quarter of 2023.

The total expected costs to be incurred to perform the C5 License Obligation increased in the fourth quarter of 2023 to reflect the additional hours and costs expected to be incurred by the Company to perform the manufacturing and supply activities. When completing the Company’s periodic update to its estimated costs to complete and, in turn, the cumulative progress toward completion of the C5 License Obligation, the Company used its updated estimate of total expected costs to be incurred as the denominator in the cost-to-cost model and recalculated the cumulative amount of revenue that should be recognized. That cumulative amount of revenue is compared to the cumulative amount of revenue recognized as of the prior period end (December 31, 2022). As indicated in the table below, as the estimate of total expected costs to be incurred in the denominator increased, the percentage of completion and the cumulative amount of revenue recognized decreased, resulting in the reversal of revenue in the amount of \$15.1 million.

(In thousands, except percentages)	December 31, 2022	December 31, 2023	Reversal of revenue during the year ended December 31, 2023
Inception-to-date costs incurred	\$27,178	\$32,415	
Expected costs to be incurred	\$31,392	\$58,270	
Percentage of completion	87 %	56 %	
Transaction price	\$97,185	\$124,106	
Inception-to-date revenue recognized	\$84,139	\$69,039	<u><u>\$(15,100)</u></u>

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Please do not hesitate to email me at jpoulton@alnylam.com or Gisele Dion, the Company's Chief Accounting Officer, at gdion@alnylam.com with any questions or further comments you may have regarding this filing or if you wish to discuss the above responses.

Sincerely,

/s/ Jeffrey V. Poulton

Jeffrey V. Poulton
Executive Vice President, Chief Financial Officer

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