REFINITIV

DELTA REPORT

10-Q

ALNY - ALNYLAM PHARMACEUTICALS,

10-Q - SEPTEMBER 30, 2024 COMPARED TO 10-Q - JUNE 30, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	1341
CHANGES	127
DELETIONS	796
ADDITIONS	418

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2024 September 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-36407

ALNYLAM PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**77-0602661**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
675 West Kendall Street, Henri A. Termeer Square Cambridge, MA	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 551-8200
(Registrant's Telephone Number, Including Area Code)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	x	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

At July 26, 2024 October 25, 2024, the registrant had 128,380,513 128,980,917 shares of Common Stock, $0.01 par value per share, outstanding.

ALNYLAM PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of complying with those safe harbor provisions. All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our views with respect to the potential for approved and investigational RNAi therapeutics, including ONPATTRO, AMVUTTRA, GIVLAARI, OXLUMO, Leqvio® (inclisiran), fitusiran and zilebesiran;
- our plans for additional global regulatory filings and the continuing product launches of ONPATTRO, AMVUTTRA, GIVLAARI, OXLUMO and our collaborator's collaborators' plans with respect to Leqvio and fitusiran;
- our ability to obtain regulatory approval of AMVUTTRA (vutrisiran) for the treatment of ATTR amyloidosis with cardiomyopathy;
- our expectations regarding the potential market size for, and the successful commercialization of, ONPATTRO, AMVUTTRA, GIVLAARI, OXLUMO, Leqvio, fitusiran or any future products;
- our ability to obtain and maintain regulatory approvals and pricing and reimbursement for ONPATTRO, AMVUTTRA, GIVLAARI, OXLUMO or any future products, and our collaborators' ability with respect to Leqvio and fitusiran;

- the progress of our research and development programs, including programs in both rare and prevalent diseases;
- the potential for improved product profiles to emerge from our new technologies, including our IKARIA platform, and our ability to expand our product engine to include extrahepatic tissues;
- our current and anticipated clinical trials and expectations regarding the reporting of data from these trials;
- the timing of regulatory filings and interactions with, or actions or advice of, regulatory authorities, 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 or the timing or likelihood of regulatory approvals;
- the status of our manufacturing operations and any delays, interruptions or failures in the manufacture and supply of ONPATTRO, AMVUTTRA, GIVLAARI, OXLUMO or any of our product candidates (or other products or product candidates being developed and commercialized by our collaborators), by our or their contract manufacturers or by us or our collaborators;
- the impact of any future pandemics or public health emergencies on, among other things, our financial performance, business and operations, including manufacturing, supply chain, research and development activities and pipeline programs, and other potential impacts to our business;
- our progress continuing to build and leverage global commercial infrastructure;
- the possible impact of any competing products on the commercial success of ONPATTRO, AMVUTTRA, GIVLAARI, OXLUMO, Leqvio and Leqvio, fitusiran, as well as our product candidates, and, our, or with respect to Leqvio or fitusiran, our collaborators', ability to compete against such products;
- our ability to manage our growth and operating expenses;
- our views and plans with respect to our 5-year *Alnylam P5x25* strategy and our intentions to achieve the metrics associated with this strategy, including to become a top-tier biotech company by the end of 2025, and our ability to successfully execute on our *Alnylam P5x25* strategy;
- our belief that our current cash balance should enable us to achieve a self-sustainable profile without the need for future equity financing;
- our expectations regarding the length of time our current cash, cash equivalents and marketable equity and debt securities will support our operations based on our current operating plan;
- our dependence on third parties for development, manufacture and distribution of products;
- our expectations regarding our corporate collaborations, including potential future licensing fees and milestone and royalty payments under existing or future agreements;
- our ability to obtain, maintain and protect our intellectual property;
- our ability to attract and retain qualified key management and scientists, development, medical and commercial staff, consultants and advisors;
- the outcome of litigation, including our patent infringement suits against Pfizer, Inc., BioNTech SE and Moderna, Inc., or of other legal proceedings or government investigations;
- regulatory developments in the United States, or U.S., and foreign countries;
- the impact of laws and regulations;
- developments relating to our competitors and our industry;
- our ability to satisfy our payment obligations, and to service the interest on, or to refinance our indebtedness, including our convertible notes, or to make cash payments in connection with any conversion of our convertible notes, to the extent required; and
- our expectations regarding the effect of the capped call transactions and the anticipated market activities of the option counterparties and/or their respective affiliates.

These forward-looking statements reflect management's current views with respect to future events and with respect to our business and future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Other sections of this Quarterly Report on Form 10-Q may include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for management to predict all risk factors, nor can we assess the impact of all risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You are advised, however, to consult any further disclosure we make in our reports filed with the Securities and Exchange Commission, or SEC.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (Unaudited)

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

(Unaudited)

	June 30, 2024	December 31, 2023
	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Current assets:		
Current assets:		
Cash and cash equivalents		
Cash and cash equivalents		
Cash and cash equivalents		
Marketable debt securities		
Marketable equity securities		
Accounts receivable, net		
Inventory		
Prepaid expenses and other current assets		
Total current assets		
Total current assets		
Total current assets		
Property, plant and equipment, net		
Operating lease right-of-use assets		
Restricted investments		
Other assets		
Total assets		
LIABILITIES AND STOCKHOLDERS' DEFICIT		
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current liabilities:		
Current liabilities:		
Accounts payable		
Accounts payable		
Accounts payable		
Accrued expenses		
Operating lease liability		
Deferred revenue		
Liability related to the sale of future royalties		
Total current liabilities		
Operating lease liability, net of current portion		
Deferred revenue, net of current portion		
Convertible debt		
Liability related to the sale of future royalties, net of current portion		
Other liabilities		
Total liabilities		
Commitments and contingencies (Note 13)	Commitments and contingencies (Note 13)	Commitments and contingencies (Note 13)
Stockholders' deficit:		
Preferred stock, $0.01 par value per share, 5,000 shares authorized and no shares issued and outstanding as of June 30, 2024 and December 31, 2023		
Preferred stock, $0.01 par value per share, 5,000 shares authorized and no shares issued and outstanding as of June 30, 2024 and December 31, 2023		

Preferred stock, $0.01 par value per share, 5,000 shares authorized and no shares issued and outstanding as of June 30, 2024 and December 31, 2023	
Common stock, $0.01 par value per share, 250,000 shares authorized; 128,021 shares issued and outstanding as of June 30, 2024; 125,794 shares issued and outstanding as of December 31, 2023	
Stockholders' equity (deficit):	
Preferred stock, $0.01 par value per share, 5,000 shares authorized and no shares issued and outstanding as of September 30, 2024 and December 31, 2023	
Preferred stock, $0.01 par value per share, 5,000 shares authorized and no shares issued and outstanding as of September 30, 2024 and December 31, 2023	
Preferred stock, $0.01 par value per share, 5,000 shares authorized and no shares issued and outstanding as of September 30, 2024 and December 31, 2023	
Common stock, $0.01 par value per share, 250,000 shares authorized; 128,841 shares issued and outstanding as of September 30, 2024; 125,794 shares issued and outstanding as of December 31, 2023	
Additional paid-in capital	
Accumulated other comprehensive loss	
Accumulated deficit	
Total stockholders' deficit	
Total liabilities and stockholders' deficit	
Total stockholders' equity (deficit)	
Total liabilities and stockholders' equity (deficit)	

The accompanying notes are an integral part of these condensed consolidated financial statements.

ALNYLAM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE LOSS (LOSS) INCOME
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,						
	Three Months Ended September 30,		Nine Months Ended September 30,						
	2024	2024	2023	2024	2023	2024	2023	2024	2023
Statements of Operations									
Revenues:									
Revenues:									
Revenues:									
Net product revenues									
Net product revenues									
Net product revenues									
Net revenues from collaborations									
Royalty revenue									
Total revenues									
Operating costs and expenses:									
Cost of goods sold									
Cost of goods sold									
Cost of goods sold									
Cost of collaborations and royalties									
Research and development									
Selling, general and administrative									
Total operating costs and expenses									
Income (loss) from operations									
(Loss) income from operations									
Other (expense) income:									
Interest expense									
Interest expense									

Interest expense
Interest income
Other expense, net
Total other expense, net
Total other expense, net
Total other expense, net
Loss before income taxes
(Loss) income before income taxes
Provision for income taxes
Net loss
Net (loss) income
Net loss per common share - basic and diluted
Net loss per common share - basic and diluted
Net loss per common share - basic and diluted
Net (loss) income per common share - basic
Net (loss) income per common share - basic
Net (loss) income per common share - basic
Net (loss) income per common share - diluted
Weighted-average common shares - basic
Weighted-average common shares - basic
Weighted-average common shares - basic
Weighted-average common shares - diluted
Weighted-average common shares used to compute basic and diluted net loss per common share
Weighted-average common shares used to compute basic and diluted net loss per common share
Weighted-average common shares used to compute basic and diluted net loss per common share
Statements of Comprehensive Loss
Statements of Comprehensive Loss
Statements of Comprehensive Loss
Net loss
Net loss
Net loss
Other comprehensive (loss) income:
Unrealized (loss) gain on marketable securities
Unrealized (loss) gain on marketable securities
Unrealized (loss) gain on marketable securities
Foreign currency translation (loss) gain
Statements of Comprehensive (Loss) Income
Statements of Comprehensive (Loss) Income
Statements of Comprehensive (Loss) Income
Net (loss) income
Net (loss) income
Net (loss) income
Other comprehensive income (loss):
Unrealized gain on marketable securities
Unrealized gain on marketable securities
Unrealized gain on marketable securities
Foreign currency translation gain (loss)
Defined benefit pension plans, net of tax
Total other comprehensive (loss) income
Comprehensive loss
Total other comprehensive income (loss)
Comprehensive (loss) income

The accompanying notes are an integral part of these condensed consolidated financial statements.

ALNYLAM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT EQUITY (DEFICIT)
(In thousands)
(Unaudited)

	Common Stock Shares	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance as of December 31, 2023											
Balance as of December 31, 2023											
Balance as of December 31, 2023											
Exercise of common stock options, net of tax withholdings											
Issuance of common stock under equity plans											
Stock-based compensation charges											
Other comprehensive loss											
Net loss											
Balance as of March 31, 2024											
Exercise of common stock options, net of tax withholdings											
Issuance of common stock under equity plans											
Stock-based compensation charges											
Other comprehensive loss											
Net loss											
Balance as of June 30, 2024											
Exercise of common stock options, net of tax withholdings											
Issuance of common stock under equity plans											
Stock-based compensation charges											
Other comprehensive income											
Net loss											
Balance as of September 30, 2024											

The accompanying notes are an integral part of these condensed consolidated financial statements.

ALNYLAM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT EQUITY (DEFICIT)
(In thousands)
(Unaudited)

	Common Stock Shares	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
Balance as of December 31, 2022											
Balance as of December 31, 2022											
Balance as of December 31, 2022											
Exercise of common stock options, net of tax withholdings											

Issuance of common stock under equity plans	
Stock-based compensation charges	
Other comprehensive income	
Net loss	
Balance as of March 31, 2023	
Exercise of common stock options, net of tax withholdings	
Issuance of common stock under equity plans	
Stock-based compensation charges	
Other comprehensive income	
Net loss	
Balance as of June 30, 2023	
Exercise of common stock options, net of tax withholdings	
Issuance of common stock under equity plans	
Stock-based compensation charges	
Other comprehensive income	
Other comprehensive income	
Other comprehensive income	
Net income	
Balance as of September 30, 2023	

The accompanying notes are an integral part of these condensed consolidated financial statements.

ALNYLAM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cash flows from operating activities:				
Net loss				
Net loss				
Net loss				
Non-cash adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization				
Depreciation and amortization				
Depreciation and amortization				
Amortization and interest accretion related to operating leases				
Non-cash interest expense on liability related to the sale of future royalties				
Stock-based compensation expense				
Realized and unrealized loss on marketable equity securities				
Change in fair value of development derivative liability				
Change in fair value of development derivative liability				
Change in fair value of development derivative liability				
Other				
Other				
Other				
Changes in operating assets and liabilities:				
Accounts receivable, net				

Accounts receivable, net	
Accounts receivable, net	
Inventory	
Prepaid expenses and other assets	
Accounts payable, accrued expenses and other liabilities	
Operating lease liability	
Deferred revenue	
Net cash provided by (used in) operating activities	
Net cash provided by operating activities	
Cash flows from investing activities:	
Purchases of property, plant and equipment	
Purchases of property, plant and equipment	
Purchases of property, plant and equipment	
Purchases of marketable securities	
Sales and maturities of marketable securities	
Proceeds from maturity of restricted investments	
Purchases of restricted investments	
Net cash used in investing activities	
Net cash used in investing activities	
Other investing activities	
Net cash used in investing activities	
Cash flows from financing activities:	
Proceeds from exercise of stock options and other types of equity, net	
Proceeds from exercise of stock options and other types of equity, net	
Proceeds from exercise of stock options and other types of equity, net	
Proceeds from development derivative, net	
Proceeds from development derivative, net	
Proceeds from development derivative, net	
(Repayment of) proceeds from development derivative, net	
(Repayment of) proceeds from development derivative, net	
(Repayment of) proceeds from development derivative, net	
Net cash provided by financing activities	
Net cash provided by financing activities	
Net cash provided by financing activities	
Effect of exchange rate changes on cash, cash equivalents and restricted cash	
Net increase (decrease) in cash, cash equivalents and restricted cash	
Net increase in cash, cash equivalents and restricted cash	
Cash, cash equivalents and restricted cash, beginning of period	
Cash, cash equivalents and restricted cash, end of period	
Supplemental disclosure of cash flows:	
Cash paid for interest	
Cash paid for interest	
Cash paid for interest	

The accompanying notes are an integral part of these condensed consolidated financial statements.

ALNYLAM PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. NATURE OF BUSINESS

Alnylam Pharmaceuticals, Inc. (also referred to as Alnylam, the Company, we, our or us) commenced operations on June 14, 2002 as a biopharmaceutical company seeking to develop and commercialize novel therapeutics based on ribonucleic acid interference, or RNAi. We are committed to the advancement of our company strategy of building a multi-product, global, commercial biopharmaceutical company with a deep and sustainable clinical pipeline of RNAi therapeutics for future growth and a robust, organic research engine

for sustainable innovation and great potential for patient impact. Since inception, we have focused on discovering, developing and commercializing RNAi therapeutics by establishing and maintaining a strong intellectual property position in the RNAi field, establishing strategic collaborations with leading pharmaceutical and life sciences companies, generating revenues through licensing agreements, and ultimately developing and commercializing RNAi therapeutics globally, either independently or with our strategic collaborators. We have devoted substantially all of our efforts to business planning, research, development, manufacturing and commercial efforts, acquiring, filing and expanding intellectual property rights, recruiting management and technical staff, and raising capital.

In early 2021, we launched our *Alnylam P5x25* strategy, which focuses on our planned transition to a top-tier biotech company by the end of 2025. With *Alnylam P5x25*, we aim to deliver transformative rare and prevalent disease medicines for patients around the world through sustainable innovation, while delivering exceptional financial performance.

As of June 30, 2024 September 30, 2024, we have five marketed products, including one product commercialized by a collaborator, and multiple late-stage investigational programs advancing towards potential commercialization. We currently generate worldwide product revenues from four commercialized products, ONPATTRO, AMVUTTRA, GIVLAARI and OXLUMO, primarily in the United States, or U.S., and Europe.

2. BASIS OF PRESENTATION AND PRINCIPLES OF CONSOLIDATION

The accompanying condensed consolidated financial statements of Alnylam are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, applicable to interim periods and, in the opinion of management, include all normal and recurring adjustments that are necessary to state fairly the results of operations for the reported periods. Our condensed consolidated financial statements have also been prepared on a basis substantially consistent with, and should be read in conjunction with, our audited consolidated financial statements for the year ended December 31, 2023, which were included in our Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on February 15, 2024. The year-end condensed consolidated balance sheet data was derived from our audited financial statements but does not include all disclosures required by GAAP. The results of our operations for any interim period are not necessarily indicative of the results of our operations for any other interim period or for a full fiscal year.

The accompanying condensed consolidated financial statements reflect the operations of Alnylam and our wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Our significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2023. There have been no material changes to our significant accounting policies during the six-month nine-month period ended June 30, 2024 September 30, 2024.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. In our condensed consolidated financial statements, we use estimates and assumptions related to our inventory valuation and related reserves, liability related to the sale of future royalties, development derivative liability, income taxes, deferred tax asset valuation allowances, revenue recognition, research and development expenses, and stock-based compensation. compensation expense. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Liquidity

Based on our current operating plan, we believe that our cash, cash equivalents and marketable securities as of June 30, 2024 September 30, 2024, will be sufficient to satisfy our working capital and operating needs for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q.

ALNYLAM PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2023-09, Improvements to Income Tax Disclosures, which requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. We are currently evaluating the disclosure requirements related to this new standard.

In November 2023, the FASB issued Accounting Standards Update ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. We are currently evaluating the disclosure requirements related to this new standard.

3. NET PRODUCT REVENUES

Net product revenues, classified based on the geographic region in which the product is sold, consist of the following:

		Three Months Ended June 30,		Six Months Ended June 30,						
		Three Months Ended September 30,		Nine Months Ended September 30,						
(In thousands)	(In thousands)	2024	2023	2024	2023	(In thousands)	2024	2023	2024	2023
ONPATTRO										
United States										
United States										
United States										

Europe	
Rest of World	
Total	
AMVUTTRA	
AMVUTTRA	
AMVUTTRA	
United States	
United States	
United States	
Europe	
Rest of World	
Total	
GIVLAARI	
GIVLAARI	
GIVLAARI	
United States	
United States	
United States	
Europe	
Rest of World	
Total	
OXLUMO	
OXLUMO	
OXLUMO	
United States	
United States	
United States	
Europe	
Rest of World	
Total	
Total net product revenues	
Total net product revenues	
Total net product revenues	

ALNYLAM PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

The following table presents the balance of our receivables related to our net product revenues:

(In thousands)	(In thousands)	As of June 30, 2024	As of December 31, 2023	(In thousands)	As of September 30, 2024	As of December 31, 2023
Receivables included in “Accounts receivable, net”						

4. NET REVENUES FROM COLLABORATIONS

Net revenues from collaborations consist of the following:

		Three Months Ended June 30,		Six Months Ended June 30,					
		Three Months Ended September 30,		Nine Months Ended September 30,					
(In thousands)	(In thousands)	2024	2023	2024	2023	(In thousands)	2024	2023	2024	2023
Roche										
Regeneron Pharmaceuticals										
Novartis AG										

Other
Total

The following table presents the balance of our receivables and contract liabilities related to our collaboration agreements:

(In thousands)	(In thousands)	As of June 30, 2024	As of December 31, 2023	(In thousands)	As of September 30, 2024	As of December 31, 2023
Receivables included in “Accounts receivable, net”						
Contract liabilities included in “Deferred revenue”						
Contract liabilities included in “Deferred revenue”						
Contract liabilities included in “Deferred revenue”						

We recognized revenue of $200.0 million $19.5 million and $228.7 million $248.6 million in the three and six nine months ended June 30, 2024 September 30, 2024, respectively, and revenue of $4.8 million $50.5 million and $10.3 million $42.0 million in the three and six nine months ended June 30, 2023 September 30, 2023, respectively, that was included in the contract liability balance at the beginning of the applicable period.

To determine revenue recognized in the period from contract liabilities, we first allocate revenue to the individual contract liability balance outstanding at the beginning of the period until the revenue exceeds that balance. If additional consideration is received on those contracts in subsequent periods, we assume all revenue recognized in the reporting period first applies to the beginning contract liability as opposed to a portion applying to the new consideration for the period.

The following table provides research and development expenses incurred by type, for which we recognize net revenues, that are directly attributable to our collaboration agreements, by collaborator:

	Three Months Ended June 30,						Three Months Ended September 30,					
	2024			2024			2023			2024			2023		
(In thousands)	(In thousands)	Clinical and Manufacturing	External Services	Other	Clinical and Manufacturing	External Services	Other	(In thousands)	Clinical and Manufacturing	External Services	Other	Clinical and Manufacturing	External Services	Other
Roche														
Regeneron Pharmaceuticals														
Other														
Total														

ALNYLAM PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

	Six Months Ended June 30,						Nine Months Ended September 30,					
	2024			2024			2023			2024			2023		
(In thousands)	(In thousands)	Clinical and Manufacturing	External Services	Other	Clinical and Manufacturing	External Services	Other	(In thousands)	Clinical and Manufacturing	External Services	Other	Clinical and Manufacturing	External Services	Other
Roche														
Regeneron Pharmaceuticals														
Other														
Total														

The research and development expenses incurred for the agreements included in the table above consist of costs incurred for (i) clinical and preclinical manufacturing expenses, including manufacturing of clinical and preclinical product, (ii) external services, including consulting services and lab supplies and services, and (iii) other expenses, including professional services, facilities and overhead allocations, and a reasonable estimate of compensation and related costs as billed to our counterparties, for which we recognize net revenues from collaborations. For the three and six nine months ended June 30, 2024 September 30, 2024 and 2023, we did not incur material selling, general and administrative expenses related to our collaboration agreements.

Product Collaborations

Roche

On July 21, 2023, or the Effective Date, we entered into a Collaboration and License Agreement, or the Roche Agreement, with F. Hoffmann-La Roche Ltd. and Genentech, Inc., or, collectively, Roche, pursuant to which we and Roche established a worldwide, strategic collaboration for the joint development of zilebesiran. Zilebesiran is our investigational small interfering RNA, or siRNA, therapeutic targeting liver-expressed angiotensinogen, which is currently in Phase 2 clinical development for the treatment of hypertension.

Under the Roche Agreement, we granted to Roche (i) co-exclusive rights to develop zilebesiran worldwide and commercialize zilebesiran in the U.S., referred to as the Co-Commercialization Territory, (ii) exclusive rights to commercialize zilebesiran outside of the U.S., referred to as the Roche Territory, and (iii) non-exclusive rights to manufacture zilebesiran for the development and commercialization of zilebesiran in the Roche Territory. In connection with the Roche Agreement, Roche made an upfront, non-refundable payment to us of $310.0 million.

We lead the global clinical development for zilebesiran. We are responsible for forty percent (40%) and Roche is responsible for the remaining sixty percent (60%) of development costs incurred in the conduct of development activities that support regulatory approval of zilebesiran globally. We and Roche share equally (50/50) all costs incurred in connection with development activities that are conducted to support regulatory approval of zilebesiran solely in the Co-Commercialization Territory if incremental development activities are needed. Roche is solely responsible for all costs incurred in the conduct of development activities that are conducted primarily to support regulatory approval in the Roche Territory. Upon regulatory approval, Roche has the exclusive right to commercialize zilebesiran in the Roche Territory and will pay us tiered, low double-digit royalties based on net sales of zilebesiran on a country-by-country basis during the applicable royalty term. We and Roche will co-commercialize zilebesiran in the Co-Commercialization Territory and share equally (50/50) profits and losses (including commercialization costs).

Roche has the right to terminate the Roche Agreement for any or no reason at all upon prior written notice, notice; however, if the termination notice occurs after the achievement of the first development milestone and before the achievement of the third development milestone, Roche is required to pay us a termination fee of $50.0 million. In addition, either party may terminate the Roche Agreement for a material breach by, or insolvency of, the other party, subject to a cure period. Unless earlier terminated pursuant to its terms, the Roche Agreement will remain in effect until expiration on a country-by-country basis (a) in the Roche Territory, upon expiration of the applicable royalty term in the applicable country and (b) in the Co-Commercialization Territory, upon expiration of the term of the co-commercialization efforts.

We evaluated the Roche Agreement and concluded that the Roche Agreement had elements that were within the scope of Accounting Standards Codification, or ASC, 606, *Revenue from Contracts with Customers* and ASC 808, *Collaborative Arrangements*.

As of the Effective Date, we identified the following promises in the Roche Agreement that were evaluated under the scope of ASC 606: delivery of (i) a co-exclusive license to develop zilebesiran worldwide and commercialize zilebesiran within the Co-Commercialization Territory, a non-exclusive license to manufacture zilebesiran in the Roche Territory solely for purposes of developing and commercializing zilebesiran in the Roche Territory, and an exclusive license to commercialize zilebesiran in the Roche Territory, collectively referred to as Roche License Obligation, (ii) development services, including the manufacture of

of clinical supply, that support regulatory approval of zilebesiran, referred to as the Roche Development Services Obligation, and (iii) a technology transfer of the existing manufacturing process for zilebesiran, referred to as the Roche Technology Transfer Obligation. The three performance obligations under the Roche Agreement are collectively referred to as the Roche Performance Obligations.

We also evaluated whether certain options outlined within the Roche Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options convey a material right to Roche and therefore were not considered separate performance obligations within the Roche Agreement.

We assessed the above promises and determined that the Roche License Obligation, Roche Development Services Obligation and Roche Technology Transfer Obligation were reflective of a vendor-customer relationship and therefore represented performance obligations within the scope of ASC 606. The Roche License Obligation was considered functional intellectual property and distinct from other promises under the contract as Roche can benefit from the licenses on its own or together with other readily available resources. As the licenses were delivered at the same time, they were considered one performance obligation at contract inception. The Roche Development Services Obligation was considered distinct as Roche could benefit from the development services together with the licenses transferred by us at the inception of the agreement. The development services are not expected to significantly modify or customize the initial intellectual property as zilebesiran was in Phase 2 clinical development at contract inception. The Roche Technology Transfer Obligation was distinct as Roche can benefit from the manufacturing license transferred by us at the inception of the agreement given the advancements of our RNAi platform and our utilization of third-party contract manufacturing organizations to manufacture zilebesiran. Therefore, each represents a separate performance obligation within the contract with a customer under the scope of ASC 606 at contract inception.

We consider the collaborative activities associated with the co-commercialization of zilebesiran in the U.S. to be a separate unit of account within the scope of ASC 808 as we and Roche are both active participants in the commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the arrangement.

We determined the transaction price under ASC 606 at the inception of the Roche Agreement was $857.0 million, consisting of the $310.0 million upfront payment and $547.0 million additional variable consideration attributed to cost reimbursement from development and manufacturing services and technology transfer related to the Roche Performance Obligations. We determined that any variable consideration related to development and regulatory milestones was deemed to be fully constrained at inception and therefore excluded from the initial transaction price due to the high degree of uncertainty and risk associated with these potential payments as we determined that we could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized would not occur. We also determined that royalties and sales milestones relate solely to the licenses of intellectual property and were therefore excluded from the transaction price under the sales- or usage-based royalty exception of ASC 606.

We developed the estimated standalone selling price at inception for each of the Roche Performance Obligations with the objective of determining the price at which we would sell such an item if it were to be sold regularly on a standalone basis. We developed the estimated standalone selling price for the Roche License Obligation primarily based on the probability-weighted present value of expected future cash flows associated with each underlying license or activity. In developing such estimates, we applied judgment in determining the forecasted revenues, taking into consideration the applicable market conditions and relevant entity-specific factors, the probability of success, the time needed to develop zilebesiran and the discount rate. We developed the estimated standalone selling price for the services and clinical supply included in the Roche Development Services Obligation and the Roche Technology Transfer Obligation primarily based on the level of efforts necessary to perform the service and the costs for full-time equivalent employees and expected resources to be committed plus a reasonable margin.

We allocated the variable consideration related to the estimated reimbursements for the Roche Development Services Obligation and the Roche Technology Transfer Obligation to each performance obligation as the terms of the variable payment relate specifically to our efforts to satisfy the performance obligation and allocating the variable amount of consideration entirely to the respective performance obligation is consistent with the allocation objective of ASC 606 when considering all of the performance obligations and payment terms in the contract. We allocated the fixed upfront consideration of $310.0 million entirely to the Roche License Obligation as the value of the fixed consideration together with the expected value of the remaining development and regulatory milestones, sales-based milestones, and royalties, all of which are either currently constrained at inception or subject to the sales- or usage-based royalty exception, approximates the standalone selling price of the Roche License Obligation. Therefore, allocating the fixed upfront consideration entirely to the Roche License Obligation is consistent with the allocation objective of ASC 606 when considering all of the performance obligations and payment terms in the contract.

The Roche License Obligation was satisfied at a point in time upon transfer of the license to Roche. Control of the licenses was transferred on the Effective Date and Roche could begin to use and benefit from the licenses. For the Roche Development

Services Obligation, we measure proportional performance over time using an input method based on cost incurred relative to the total estimated cost of the obligation, on a quarterly basis, by determining the proportion of effort incurred as a percentage of total effort we expect to expend. This ratio is applied to the transaction price allocated to the obligation. Management has applied significant judgment in the process of developing our estimates. We re-evaluate the transaction price as of the end of each reporting period.

As of June 30, 2024 September 30, 2024, the total transaction price was determined to be $922.0 million, an increase of $65.0 million from December 31, 2023. The increase is due to the achievement of the development milestone for the first patient dosed in the KARDIA-3 Phase 2 study. clinical trial.

The following tables provide a summary of the transaction price allocated to each performance obligation, in addition to revenue activity during the period, in thousands:

Performance Obligations	Transaction Price Allocated		Revenue Recognized During						Transaction Price Allocated					
	Performance Obligations	As of June 30, 2024	Three Months Ended June 30,		Six Months Ended June 30,		Revenue Recognized During		Performance Obligations	As of September 30, 2024	Three Months Ended September 30,		Nine Months Ended September 30,	
			2024	2023	2024	2023					2024	2023	2024	2023
Roche License Obligation														
Roche Development Services Obligation														
Roche Technology Transfer Obligation														
	$													

As of June 30, 2024 September 30, 2024, the aggregate amount of the transaction price allocated to the Roche Performance Obligations that was unsatisfied was $503.1 million $488.2 million, which is expected to be recognized through the term of the Roche Agreement as the services are performed.

Regeneron Pharmaceuticals, Inc.

Overview

In 2019, we entered into a global, strategic collaboration with Regeneron Pharmaceuticals, Inc., or Regeneron, to discover, develop and commercialize RNAi therapeutics for a broad range of diseases by addressing therapeutic targets expressed in the eye and central nervous system, or CNS, in addition to a select number of targets expressed in the liver, which we refer to as the Regeneron Collaboration. The Regeneron Collaboration is governed by a Master Agreement, referred to as the Regeneron Master Agreement. In connection with the Regeneron Master Agreement, we and Regeneron entered into (i) a co-co collaboration agreement covering the continued development of cemdisiran, our C5 siRNA, currently in development for C5 complement-mediated diseases, as a monotherapy, or the C5 Co-Co Collaboration Agreement, and (ii) a license agreement to evaluate anti-C5 antibody-siRNA combinations for C5 complement-mediated diseases including evaluating the combination of Regeneron's pozelimab and cemdisiran, or the C5 License Agreement. The Master Agreement, the C5 Co-Co Collaboration Agreement and the C5 License Agreement were accounted for as a single arrangement because the agreements were negotiated together.

In November 2022, Regeneron exercised its right under the C5 Co-Co Collaboration Agreement to opt-out of the further development and commercialization of cemdisiran monotherapy. As a result of Regeneron's decision to opt-out, the licenses granted to Regeneron under the C5 Co-Co Collaboration Agreement reverted to us, we had the sole right to continue to develop and commercialize cemdisiran monotherapy, and Regeneron no longer shared in the costs on any monotherapy program. Regeneron remained eligible to receive tiered, double-digit royalties on net sales of cemdisiran as a monotherapy.

In June 2024, we entered into an amended and restated C5 License Agreement, or the Amended C5 License Agreement, which terminated the C5 Co-Co Collaboration Agreement and granted Regeneron a worldwide license to cemdisiran as a monotherapy in addition to the license to cemdisiran in combination with anti-C5 antibodies. Through the Amended C5 License Agreement, Regeneron is now solely responsible for development, manufacturing and commercialization of cemdisiran as a monotherapy and in combination with anti-C5 antibodies. As part of the Amended C5 License Agreement, we will provide manufacturing technology transfer services for cemdisiran to Regeneron. Regeneron provided us with an upfront payment of $10.0 million, and we will receive certain milestone payments upon receipt of regulatory approval for cemdisiran as a monotherapy, and tiered double-digit royalties on net sales. The Amended C5 License Agreement did not change our rights to receive low double-digit royalties and commercial milestones of up to $325.0 million on any potential product sales if cemdisiran is used as part of a combination product.

Under the terms of the Regeneron Collaboration, we are working exclusively with Regeneron to discover RNAi therapeutics for eye and CNS diseases for an initial research period of up to seven years, which we refer to as the Initial

Research Term. Regeneron has an option to extend the Initial Research Term (referred to as the Research Term Extension

ALNYLAM PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Period, and together with the Initial Research Term, the Research Term) for up to an additional five years, for a research term extension fee of $300.0 million. The Regeneron Collaboration also covers a select number of RNAi therapeutic programs designed to target genes expressed in the liver.

Regeneron leads development and commercialization for all programs targeting eye diseases (subject to limited exceptions), entitling us to certain potential milestone and royalty payments pursuant to the terms of a license agreement, the form of which has been agreed upon by the parties. We and Regeneron are alternating leadership on CNS and liver programs, with the lead party retaining global development and commercial responsibility. For such CNS and liver programs, both we and Regeneron have the option at lead candidate selection to enter into a co-co collaboration agreement, the form of which has been agreed upon by the parties, whereby both companies will share equally all costs of, and profits from, all development and commercialization activities under the program. If the non-lead party elects to not enter into a co-co collaboration agreement with respect to a given CNS or liver program, we and Regeneron will enter into a license agreement with respect to such program and the lead party will be the “Licensee” for the purposes of the license agreement. If the lead party for a CNS or liver program elects to not enter into the co-co collaboration agreement, then we and Regeneron will enter into a license agreement with respect to such program and leadership of the program will transfer to the other party and the former non-lead party will be the “Licensee” for the purposes of the license agreement.

In connection with the Regeneron Master Agreement, we remain eligible to receive an additional $100.0 million in milestone payments upon achievement of certain criteria during early clinical development for an eye program. In addition, we and Regeneron are continuing to advance programs nominated during the Initial Research Term, and Regeneron has the right to nominate up to six additional targets per year during this period. For each of these programs, Regeneron will provide us with $2.5 million in funding at program initiation and an additional $2.5 million at lead candidate identification. If Regeneron exercises the option to extend the research term, Regeneron will retain the right to nominate up to six additional targets per year, and we will remain eligible to achieve $2.5 million in funding at each program initiation and an additional $2.5 million at each lead candidate identification during the Research Term Extension Period.

For any license agreement subsequently entered into, the licensee will generally be responsible for its own costs and expenses incurred in connection with the development and commercialization of the collaboration products. The licensee will pay to the licensor certain development and/or commercialization milestone payments totaling up to $150.0 million for each collaboration product. In addition, following the first commercial sale of the applicable collaboration product under a license agreement, the licensee is required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the licensor based on the aggregate annual net sales of the collaboration product, subject to customary reductions.

For any co-co collaboration agreement subsequently entered into, we and Regeneron will share equally all costs of, and profits from, development and commercialization activities. Reimbursement of our share of costs will be recognized as a reduction to research and development expense in the condensed consolidated statements of operations and comprehensive loss. (loss) income. In the event that a party exercises its opt-out right, the lead party will be responsible for all costs and expenses incurred in connection with the development and commercialization of the collaboration products under the applicable co-co collaboration agreement, subject to continued sharing of costs through defined points. If a party exercises its opt-out right, following the first commercial sale of the applicable collaboration product under a co-co collaboration agreement, the lead party is required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the other party based on the aggregate annual net sales of the collaboration product and the timing of the exercise of the opt-out right, subject to customary reductions and a reduction for opt-out transition costs.

Contract Modification

We In June 2024, we determined the Amended C5 License Agreement does not meet the requirements to account for the contract modification as a separate contract under ASC 606 because the consideration exchanged for the additional distinct goods and services does not reflect the standalone selling price. Therefore, we have accounted for the Amended C5 License Agreement and Regeneron Master Agreement as a single combined contract. The modification date was determined to be the June 2024 effective date of the Amended C5 License Agreement.

Our performance obligations subsequent to the contract modification include: (i) a research license and research services, collectively referred to as the Research Services Obligation; (ii) a worldwide license to cemdisiran for combination therapies, and manufacturing and development service obligations, collectively referred to as the C5 License Obligation; (iii) a worldwide license to cemdisiran for monotherapies, referred to as the C5 Monotherapy Obligation, and (iv) a technology transfer of the existing manufacturing process for cemdisiran, referred to as the Regeneron Technology Transfer Obligation.

The Amended C5 License Agreement did not change the Research Services Obligation or the C5 License Obligation, which were both performance obligations at the inception of our global, strategic collaboration with Regeneron prior to the contract modification. The Amended C5 License Agreement resulted in two additional performance obligations which are the C5 Monotherapy Obligation and the Regeneron Technology Transfer Obligation. The C5 Monotherapy Obligation is considered

ALNYLAM PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

C5 Monotherapy Obligation and the Regeneron Technology Transfer Obligation. The C5 Monotherapy Obligation is considered functional intellectual property and distinct from other promises as Regeneron can benefit from the cemdisiran monotherapy license on its own or together with other readily available resources and the license is separately identifiable from the other promises in the contract. The Regeneron Technology Transfer Obligation is distinct as Regeneron can benefit from the cemdisiran monotherapy license transferred

by us without the technology transfer given cemdisiran is in an advanced stage of clinical development and our utilization of third-party contract manufacturing organizations to manufacture cemdisiran. Therefore, the C5 Monotherapy Obligation and the Regeneron Technology Transfer Obligation each represent a separate performance obligation.

As of the modification date, we established a new transaction price of $329.7 million, which represents the remaining deferred revenue as of the modification date of $260.3 million, variable consideration of $59.4 million, which relates to estimated reimbursements and milestones for the Research Services Obligation, C5 License Obligation and Regeneron Technology Transfer Obligation, and the $10.0 million upfront payment related to the Amended C5 License Agreement. We allocated the $59.4 million of variable consideration to the respective performance obligation as the terms of the variable payments relate specifically to our efforts to satisfy the performance obligations and allocating the variable amount of consideration entirely to the respective performance obligations is consistent with the allocation objective of ASC 606 when considering all of the performance obligations and payment terms in the contract.

We determined that any variable consideration related to regulatory milestones were was deemed to be fully constrained and therefore excluded from the transaction price due to the high degree of uncertainty and risk associated with these potential payments and we determined that we could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized would not occur. We determined that royalties and sales-based milestones relate solely to the license of intellectual property and were therefore excluded from the transaction price under the sales-or usage-based royalty exception of ASC 606.

As of the modification date, the transaction price for each performance obligation is as follows, in thousands:

Performance Obligations	Standalone Selling Price	Fixed Consideration	Variable Consideration Allocated	Total Transaction Price
Research Services Obligation	$ 78,820	$ 45,469	$ 30,000	$ 75,469
C5 License Obligation	$ 53,745	31,004	25,386	56,390
C5 Monotherapy Obligation	$ 332,000	191,520	—	191,520
Regeneron Technology Transfer Obligation	$ 4,000	2,307	4,000	6,307
		$ 270,300	$ 59,386	$ 329,686

The fixed consideration was allocated to the obligations based on the relative estimated standalone selling prices of each obligation, over which management has applied significant judgment. We developed the estimated standalone selling prices for the remaining Research Services Obligation, the remaining C5 License Obligation and the new Regeneron Technology Transfer Obligation primarily based on the level levels of efforts effort necessary to perform the services and the costs for full-time equivalent employees and expected resources to be committed plus a reasonable margin. We developed the estimated standalone selling price for the cemdisiran monotherapy license granted under the C5 Monotherapy Obligation using the adjusted market assessment approach based on a discounted cash flow model that establishes the forecasted earnings during the commercial period for cemdisiran as a monotherapy adjusted for probability of success.

The transaction price of $191.5 million allocated to the C5 Monotherapy Obligation performance obligation was recognized immediately as this obligation was satisfied at a point in time upon transfer of the license to Regeneron. Control of the license was transferred in June 2024 and Regeneron could begin to use and benefit from the license.

A cumulative catch-up adjustment was recognized for the remaining Research Services and the remaining C5 License Obligation as of the contract modification date to reflect the measure of progress and transaction price following the modification. The cumulative catch-up adjustment for the remaining Research Services and the remaining C5 License Obligation was not significant.

For the Research Services Obligation, the C5 License Obligation, and the Regeneron Technology Transfer Obligation, we measure proportional performance over time using an input method based on cost incurred relative to the total estimated costs for each of the identified obligations by determining the proportion of effort incurred as a percentage of total effort we expect to expend. This ratio is applied to the transaction price allocated to each obligation. Management has applied significant judgment in the process of developing our estimates. Any changes to these estimates will be recognized in the period in which they change as a cumulative catch-up. We re-evaluate the transaction price as of the end of each reporting period. The transaction price remaining related to our unsatisfied performance obligations period and as of June 30, 2024 increased $31.6 million from the contract

modification date primarily related September 30, 2024, the total transaction price was determined to our Research Services Obligation. After the contract modification date, the estimated timing of our underlying research activities to complete our obligations, and the resulting milestones we expect to achieve, changed. be $166.7 million. Revenue recognized under this agreement is accounted for as collaboration revenue.

The following tables provide a summary of the transaction price allocated, deferred revenue as of the balance sheet date, and revenue recognized during the period for the remaining unsatisfied performance obligations, in thousands:

Performance Obligations	Transaction Price Allocated	Transaction Price Allocated	Transaction Price Allocated
Research Services Obligation			
Research Services Obligation			
Research Services Obligation			
C5 License Obligation			

C5 License Obligation			
C5 License Obligation			
Regeneron Technology Transfer Obligation			
Regeneron Technology Transfer Obligation			
Regeneron Technology Transfer Obligation			
			$
			$
			$
		Revenue Recognized During	
		Revenue Recognized During	
		Revenue Recognized During	
		Three Months Ended June 30,	
		Three Months Ended June 30,	
		Three Months Ended June 30,	
		Three Months Ended September 30,	
		Three Months Ended September 30,	
		Three Months Ended September 30,	
	Performance Obligations		
	Performance Obligations		
	Performance Obligations		
Research Services Obligation			
Research Services Obligation			
Research Services Obligation			
C5 License Obligation			
C5 License Obligation			
C5 License Obligation			
		$	
		$	
		$	

As of June 30, 2024 September 30, 2024, the aggregate amount of the transaction price allocated to the remaining Research Services Obligation, C5 License Obligation, and Regeneron Technology Transfer Obligation that was unsatisfied was $152.2 $133.3 million, which is expected to be recognized through the term of the Regeneron Collaboration as the services are performed. Deferred revenue related to the Regeneron Collaboration is classified as either current or non-current in the condensed consolidated balance sheets based on the period the revenue is expected to be recognized.

Novartis AG

2013 Collaboration with The Medicines Company

In February 2013, we and The Medicines Company, or MDCO, entered into a license and collaboration agreement with The Medicines Company, or MDCO, pursuant to which we granted to MDCO an exclusive, worldwide license to develop, manufacture and commercialize RNAi therapeutics targeting proprotein convertase subtilisin/kexin type 9 for the treatment of hypercholesterolemia and other human diseases, including inclisiran. We refer to this agreement, as amended through the date hereof, as the MDCO License Agreement. In 2020, Novartis AG, or Novartis, completed its acquisition of MDCO and assumed all of MDCO's rights and obligations under the MDCO License Agreement.

As of June 30, 2024 September 30, 2024, we have earned $120.0 million of milestones and we could be entitled to receive an additional $60.0 million commercialization milestone. In addition, we are entitled to royalties ranging from 10% up to 20% based on annual worldwide net sales of licensed products by Novartis, its affiliates and sublicensees, subject to reduction under specified circumstances.

Other

In addition to the collaboration agreements discussed above, we have various other collaboration agreements that are not individually significant to our operating results or financial condition at this time. Pursuant to the terms of those agreements, we may be required to pay, or we may receive, additional amounts contingent upon the occurrence of various future events (e.g., upon the achievement of various development and commercial milestones) which in the aggregate could be significant. We may also incur, or be reimbursed for, significant research and development costs. In addition, if any products related to these collaborations are approved for sale, we may be required to pay, or we may receive, royalties on future sales. The payment or receipt of these amounts, however, is contingent upon the occurrence of various future events. Due to the uncertainty of pharmaceutical development and the high historical failure rates generally associated with drug development and commercialization, it is possible we may not receive any such payments under all of our existing collaboration and license agreements, including the agreements described within this note.

5. FAIR VALUE MEASUREMENTS

The following tables present information about our financial assets and liabilities that are measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value:

(In thousands)	(In thousands)	As of June 30, 2024	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	(In thousands)	As of September 30, 2024	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets										
Cash equivalents:										
Cash equivalents:										
Cash equivalents:										
Money market funds										
Money market funds										
Money market funds										
Commercial paper										
U.S. treasury securities										
Commercial paper										
Marketable debt securities:										
Marketable debt securities:										
Marketable debt securities:										
U.S. treasury securities										
U.S. treasury securities										
U.S. treasury securities										
U.S. government-sponsored enterprise securities										
Corporate notes										
Commercial paper										
Municipal securities										
Municipal securities										
Municipal securities										
Marketable equity securities										
Restricted cash (money market funds)										
Total financial assets										
Financial liabilities										
Development derivative liability										
Development derivative liability										
Development derivative liability										

(In thousands)	As of December 31, 2023	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 166,059	$ 166,059	$ —	$ —
U.S. treasury securities	30,712	—	30,712	—
Commercial paper	2,685	—	2,685	—
Corporate notes	762	—	762	—
Marketable debt securities:				
U.S. treasury securities	862,022	—	862,022	—
U.S. government-sponsored enterprise securities	441,341	—	441,341	—

Corporate notes	252,350	—	252,350	—
Commercial paper	56,216	—	56,216	—
Certificates of deposit	3,587	—	3,587	—
Marketable equity securities	11,178	11,178	—	—
Restricted cash (money market funds)	1,210	1,210	—	—
Total financial assets	$ 1,828,122	$ 178,447	$ 1,649,675	$ —
Financial liabilities				
Development derivative liability	$ 324,941	$ —	$ —	$ 324,941

For the six nine months ended June 30, 2024 September 30, 2024 and 2023, there were no transfers into or out of Level 3 financial assets or liabilities. The carrying amounts reflected on our condensed consolidated balance sheets for cash, accounts receivable, net, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

ALNYLAM PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

6. MARKETABLE DEBT SECURITIES

We invest our excess cash balances in marketable debt securities and at each balance sheet date presented, we classify all of our investments in debt securities as available-for-sale and as current assets as they represent the investment of funds available for current operations. We did not record any impairment charges related to our marketable debt securities during the three and six nine months ended June 30, 2024 September 30, 2024 or 2023.

The following tables summarize our marketable debt securities:

	As of June 30, 2024					As of September 30, 2024				
(In thousands)	(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities										
U.S. government-sponsored enterprise securities										
Corporate notes										
Commercial paper										
Municipal securities										
Municipal securities										
Municipal securities										
Total										

	As of December 31, 2023			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 892,237	$ 1,085	$ (588)	$ 892,734
U.S. government-sponsored enterprise securities	440,915	1,000	(574)	441,341
Corporate notes	252,487	945	(320)	253,112
Commercial paper	58,901	—	—	58,901
Certificates of deposit	3,587	—	—	3,587
Total	$ 1,648,127	$ 3,030	$ (1,482)	$ 1,649,675

The fair values of our marketable debt securities by classification in the condensed consolidated balance sheets were as follows:

(In thousands)	(In thousands)	As of June 30, 2024	As of December 31, 2023	(In thousands)	As of September 30, 2024	As of December 31, 2023
Marketable debt securities						
Cash and cash equivalents						
Total						

7. OTHER BALANCE SHEET DETAILS

Inventory

The components of inventory are summarized as follows:

(In thousands)	(In thousands)	As of June 30, 2024	As of December 31, 2023	(In thousands)	As of September 30, 2024	As of December 31, 2023

Raw materials	
Work in process	
Finished goods	
Total inventory	

As of June 30, 2024 September 30, 2024 and December 31, 2023, we had $36.4 million $39.4 million and $36.3 million of long-term inventory, respectively, included within other assets in our condensed consolidated balance sheets as we anticipate it being consumed beyond our normal operating cycle.

ALNYLAM PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within our condensed consolidated balance sheets that sum to the total of these amounts shown in the condensed consolidated statements of cash flows:

	As of June 30,		As of September 30,	
(In thousands)	**(In thousands) 2024**	**2023**	**(In thousands) 2024**	**2023**
Cash and cash equivalents				
Total restricted cash included in other assets				
Total cash, cash equivalents, and restricted cash shown in the condensed consolidated statements of cash flows				

Accumulated Other Comprehensive (Loss) Income

The following tables summarize the changes in accumulated other comprehensive (loss) income, by component:

(In thousands)	**Loss on Investment in Joint Venture**	**Defined Benefit Pension Plans**	**Unrealized (Losses) Gains from Debt Securities**	**Foreign Currency Translation Adjustment**
(In thousands)				
Balance as of December 31, 2023				
Other comprehensive loss before reclassifications				
Amounts reclassified from accumulated other comprehensive loss				
Net other comprehensive (income) loss				
Balance as of June 30, 2024 September 30, 2024				

(In thousands)	
Balance as of December 31, 2022	
Other comprehensive income before reclassifications	
Amounts reclassified from other comprehensive income	
Net other comprehensive income	
Balance as of June 30, 2023	

(In thousands)	
Balance as of December 31, 2022	
Other comprehensive (loss) income before reclassifications	
Amounts reclassified from accumulated other comprehensive loss	
Net other comprehensive (loss) income	
Balance as of September 30, 2023	

Amounts reclassified out of accumulated other comprehensive (loss) income relate to settlements of marketable debt securitie

8. CONVERTIBLE DEBT

Convertible Senior Notes Due 2027

In 2022, we commenced a private offering of $900.0 million in aggregate principal amount of 1% Convertible Senior Notes du indenture, dated September 15, 2022, or the Indenture. The Indenture includes customary covenants and sets forth certain event

The Notes will mature on September 15, 2027, unless earlier converted, redeemed or repurchased. The Notes bear interest a reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecut reported sale price of our common stock and the conversion rate of the Notes on such trading day; (3) If if we call any or all of the

The conversion rate for the Notes will initially be 3.4941 shares of common stock per $1,000 principal amount of Notes, which

We may not redeem the Notes prior to September 20, 2025. We may redeem for cash equal to 100% of the principal amount periodically.

If we undergo a fundamental change, as defined in the Indenture, then subject to certain conditions, holders may require us conditions allowing holders of the Notes to convert were not met this quarter.

As of June 30, 2024 September 30, 2024 and December 31, 2023, the Notes are classified as a long-term liability, net of una 2024 September 30, 2024 and December 31, 2023 (Level 2). , respectively. The Notes were issued at par and costs associated w

Capped Call Transactions

In 2022, in connection with the pricing of the Initial Notes and the initial purchasers' exercise of their option to purchase the A 12, 2022, and is subject to certain adjustments under the terms of the Capped Call Transactions.

9. LIABILITY RELATED TO THE SALE OF FUTURE ROYALTIES

In April 2020, we entered into a purchase and sale agreement, or Purchase Agreement, with BX Bodyguard Royalties L.P. Agreement, together with the Royalty Interest, the Purchased Interest. If Blackstone Royalties does not receive payments in respe

Due to our continuing involvement and an obligation to repay BX Bodyguard Royalties L.P., we record the proceeds from this

commercial milestones due to us under the MDCO License Agreement as revenue on our condensed consolidated statement stat

In order to determine the amortization of the liability related to the sale of future royalties, we are required to estimate the tot and 8%, respectively. These estimates contain assumptions that impact both the amount recorded at execution and the interest e

As payments are made to Blackstone Royalties, the balance of the liability will be effectively repaid over the life of the Purchas we will prospectively adjust the amortization of the liability related to the sale of future royalties and the related interest expense.

As of June 30, 2024 September 30, 2024 and December 31, 2023, the carrying value of the liability related to the sale of fut considered Level 3 inputs.

The following table shows the activity with respect to the liability related to the sale of future royalties, in thousands:

Carrying value as of December 31, 2023	
Interest expense recognized	
Payments	
Carrying value as of June 30, 2024 September 30, 2024	

10. DEVELOPMENT DERIVATIVE LIABILITY

In August 2020, we entered into a co-development agreement, referred to as the Funding Agreement, with BXLS V Bodygua trial and $26.0 million to fund zilebesiran Phase 2 clinical trials. Furthermore, Blackstone Life Sciences has the right, but is not ob

As consideration for Blackstone Life Sciences' funding for vutrisiran clinical development costs, we have agreed to pay Blac consideration for Blackstone Life Sciences' funding for Phase 2 clinical development costs of zilebesiran, we have agreed to pay payable to Blackstone Life Sciences in 16 equal, quarterly payments over four years. As consideration for Blackstone Life Scienc

Our payment obligations under the Funding Agreement will be secured, subject to certain exceptions, by security interests in i

We and Blackstone Life Sciences each have the right to terminate the Funding Agreement in its entirety in the event of the ot Blackstone Life Sciences has the right to terminate the Funding Agreement in its entirety upon the occurrence of certain events commercialize vutrisiran is enjoined in a specified major market as a result of an alleged patent infringement. In certain terminati cardiomyopathy following termination.

We account for the Funding Agreement under ASC 815, Derivatives and Hedging, as a derivative liability, measured at fair va

As of June 30, 2024 September 30, 2024, the derivative liability is classified as a Level 3 financial liability in the fair value hi amyloidosis with cardiomyopathy, (iv) our cost of borrowing (11%), and (v) Blackstone Life Sciences' cost of borrowing (6%).

The following table presents the activity with respect to the development derivative liability, in thousands:

Carrying value as of December 31, 2023	
Amount received under the Funding Agreement	
Amount paid under the Funding Agreement	
Change in fair value of development derivative liability	
Carrying value as of June 30, 2024 September 30, 2024	

11. STOCK-BASED COMPENSATION

The following table summarizes stock-based compensation expenses included in operating costs and expenses on our conde

(In thousands)	
Research and development	
Selling, general and administrative	
Total stock-based compensation expense	
Capitalized stock-based compensation costs	
Total stock-based compensation charges	

12. NET LOSS (LOSS) INCOME PER COMMON SHARE

We compute basic net loss (loss) income per common share by dividing net loss (loss) income by the weighted-average num shares issuable upon the vesting of restricted stock units, the exercise of stock options (the proceeds of which are then assume common share is the same as basic net loss (loss) income per common share.

The following table sets forth the potential common shares (prior to consideration of the treasury stock or if-converted method

(In thousands)	**(In thousands)**	**(In thousands)**
Options to purchase common stock, inclusive of performance-based stock options		
Options to purchase common stock, inclusive of performance-based stock options		
Options to purchase common stock, inclusive of performance-based stock options		
Unvested restricted stock units, inclusive of performance-based restricted stock units		
Unvested restricted stock units, inclusive of performance-based restricted stock units		
Unvested restricted stock units, inclusive of performance-based restricted stock units		
Convertible debt		

Convertible debt

Convertible debt

Total

Total

Total

The following table sets forth the computation of basic and diluted net (loss) income per share:

(In thousands, except per share amounts)

Net (loss) income, as reported

Adjustment for the elimination of interest expense on the convertible debt

Net (loss) income, for use in diluted income per share

Weighted-average common shares - basic

Effect of dilutive securities:

Convertible debt

Options to purchase common stock, inclusive of performance-based stock options

Restricted stock units, inclusive of performance-based restricted stock units

Employee stock purchase program

Weighted-average common shares - diluted

Net (loss) income per common share - basic

Net (loss) income per common share - diluted

13. COMMITMENTS AND CONTINGENCIES

Technology License and Other Commitments

We have licensed from third parties the rights to use certain technologies and information in our research processes as well a

September 30, 2024, our commitments over the next five years to make fixed and cancellable payments under existing license ag

Legal Matters

From time to time, we may be a party to litigation, arbitration or other legal proceedings in the course of our business, includir proceedings, regardless of the merits, is inherently uncertain. In addition, litigation and related matters are costly and may divert t

Patent Infringement Lawsuits

In March 2022, we filed separate lawsuits in the U.S. District Court for the District of Delaware against (1) Pfizer, Inc. and cationic lipids that are foundational to the success of the mRNA COVID-19 vaccines.

We are seeking judgment that each of Pfizer and Moderna is infringing the '933 Patent, as well as damages adequate to

On May 23, 2022, Moderna filed a partial motion to dismiss, asserting an affirmative defense under Section 1498(a). We

contract ended in April 2022. Moderna responded on June 13, 2022, requesting a partial motion to dismiss those claims for sales

On May 27, 2022, Pfizer filed an answer to our complaint, denying the allegations, and asserting invalidity and non-infring

On July 12, 2022, we filed an additional lawsuit against each of Pfizer and Moderna seeking damages for infringement of

On February 8, 2023, we received notification from the U.S. Patent Office that a third patent would issue on February 28 well as a motion filed by Moderna to add certain invalidity arguments made by Pfizer in our case to supplement Moderna's invalid

On May 26, 2023, we filed additional lawsuits against Pfizer and Moderna in Delaware seeking damages for infringing the

On August 9, 2023, a Markman hearing was held in the U.S. District Court for the District of Delaware to consider the me
at which time the court construed the final claim term narrowly. Following the August 21, 2023 order, we and Moderna jointly agre

claim construction ruling initially did not affect one of the patents in the lawsuit filed against Moderna on May 26, 2023, but followi
we agreed to a judgment of non-infringement in the second case, which period runs from approximately September 2023 to Octol

The two separate suits against Pfizer are ongoing subject to the ruling on the third claim term, and in September 2023, w

On July 12, 2024, Acuitas Therapeutics, Inc., or Acuitas, and certain named employees, filed a Declaratory Judgment dec
granted. The court has not ruled on our motion to dismiss.

Indemnifications

In connection with license agreements we may enter with companies to obtain rights to intellectual property, we may be requi
the ordinary course of business, which contain typical provisions that obligate us to indemnify the other parties to such agreement
action taken by the officer or director while acting in such capacity, subject to certain limitations. These indemnification costs are c

Our maximum potential future liability under any such indemnification provisions is uncertain. We have determined that the es

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains management's discussion and analysis of our financial condition and results of operations and s

Overview

We are a global commercial-stage biopharmaceutical company developing novel therapeutics based on ribonucleic acid inte
implicated in the cause or pathway of disease, thus preventing them from being made. We believe this is a revolutionary approacl

Our research and development strategy is to target genetically validated genes that have been implicated in the cause or pat
clinical indications where there is a high unmet need, a genetically validated target, early biomarkers for the assessment of clinica

In early 2021, we launched our *Alnylam P5x25* strategy, which focuses on our planned transition to a top-tier biotech company

We currently have five marketed products and more than ten clinical programs, including several in late-stage development, a

AMVUTTRA is approved in the U.S. for the treatment of hereditary transthyretin-mediated amyloidosis, or hATTR amyloidos
vutrisiran (the non-branded generic name of AMVUTTRA) in patients with ATTR amyloidosis with cardiomyopathy and announced
using a Priority Review Voucher. Voucher, and on October 16, 2024, we announced that we had submitted a Type II Variation to th

ONPATTRO is approved by in the FDA U.S. for the treatment of the polyneuropathy of hATTR amyloidosis in adults and has a

GIVLAARI is approved in the U.S. for the treatment of adults with acute hepatic porphyria, or AHP, in the EU for the treatment

OXLUMO is approved in the U.S. for the treatment of primary hyperoxaluria type 1, or PH1, to lower urinary and plasma oxala

Leqvio (inclisiran), our fifth product, is being developed and commercialized by our collaborator Novartis AG, or Novartis, and
July 2023, the FDA

approved an expanded indication for Leqvio to include treatment of adults with high LDL-C and who are at increased risk of heart

In addition to our marketed products, as part of our *Alnylam P5x25* strategy, we have multiple drivers of future growth, includir
Roche, pursuant to which we established a worldwide, strategic collaboration for the joint development and commercialization of z
an add-on therapy in adult patients with high cardiovascular risk and uncontrolled hypertension despite treatment with two to four

We are also advancing mivelsiran (formerly ALN-APP), an investigational RNAi therapeutic targeting amyloid precursor prote
demonstration of gene silencing in the human brain using an RNAi therapeutic. In July 2024, we initiated dosing in the cAPPRicor

We have additional late-stage investigational programs advancing toward potential commercialization, including fitusiran for
geographic atrophy and as a monotherapy in a Phase 3 clinical trial in paroxysmal nocturnal hemoglobinuria.

In further support of our *Alnylam P5x25* strategy and in view of our evolving risk profile, we remain focused on the continued e
we work to execute on our strategy consistent with our values and in compliance with applicable laws and regulations, and to miti

Based on our expertise in RNAi therapeutics and broad intellectual property estate, we have formed collaborations with leadir

We have incurred significant losses since we commenced operations in 2002 and as of June 30, 2024 September 30, 2024, v establishment continued build-out of late-stage clinical and commercial capabilities, including global commercial operations, conti continue to fluctuate for the foreseeable future, therefore, period-to-period comparisons should not be relied upon as predictive of

We currently have programs focused on a number of therapeutic areas and, as of June 30, 2024 September 30, 2024, we ge portion of our total revenues in recent years has been derived from collaboration revenues from collaborations with Roche, Regen licensors, including royalties on sales of Leqvio made by our collaborator Novartis, as well as proceeds from the sale of equity or

Research and Development

Since our inception, we have focused primarily on drug discovery and development programs. Research and development ex

Our Product Pipeline

Our broad pipeline, including five approved products and multiple late and early-stage investigational RNAi therapeutics, add European Medicines Agency, or EMA, or any other health authority and no conclusions can or should be drawn regarding the safe

The table below represents our commercial products and late- and early-stage development programs as of August 1, 20

During the second third quarter of 2024 and recent period, we reported the following updates from our commercially approved

Commercial

Total TTR: ONPATTRO & AMVUTTRA

- We achieved global net product revenues for ONPATTRO and AMVUTTRA for the second third quarter of 2024 of $77.2 r

Total Rare: GIVLAARI & OXLUMO

- We achieved global net product revenues for GIVLAARI and OXLUMO for the second third quarter of 2024 of $62.1 millio

Late-Stage Clinical Development

- We reported positive topline results from submitted an sNDA to the HELIOS-B Phase 3 study FDA using a Priority Review
- We reported announced positive initial results from the KARDIA-2 multiple dose portion of the Phase 2 1 study of investiga
- Our collaboration partner, Sanofi, submitted regulatory filings for the investigational agent for hemophilia, fitusiran, in Chir

There is a risk that any drug discovery or development program may not produce revenue for a variety of reasons, including associated with developing drugs, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts n effect on our operations, financial position and liquidity. A discussion of some of the risks and uncertainties associated with compl

Strategic Collaborations

Our business strategy is to develop and commercialize a broad pipeline of RNAi therapeutic products directed towards transf

Below is a brief description of certain of our key collaborations.

Roche. In July 2023, we entered into the Roche Collaboration and License Agreement, pursuant to which we and Roche esta of zilebesiran outside of the U.S. Roche made an upfront payment of $310.0 million. In April 2024, we achieved the developmen remaining sixty percent (60%), of development costs incurred in the conduct of development activities that support regulatory ap outside of the U.S. during the royalty term. We and Roche will share equally (50/50) profits and losses (including commercializatio

Regeneron. In April 2019, we entered into a global, strategic collaboration with Regeneron to discover, develop and commerc

in addition to a select number of targets expressed in the liver, which we refer to as the Regeneron Collaboration. The Regeneron

Under the terms of the Regeneron Collaboration, we are working exclusively with Regeneron to discover RNAi therapeutics f directed clinical and pre-clinical pipeline programs that have not been collaborated.

Regeneron leads development and commercialization for all programs targeting eye diseases (subject to limited exceptions),

In August 2019, in connection with the Regeneron Master Agreement, we and Regeneron entered into (i) a co-co collaborat
Regeneron exercised its right under the C5 Co-Co Collaboration Agreement to opt-out of the further development and commercia

In June 2024, we entered into an amended and restated C5 License Agreement, or the Amended C5 License Agreement, w
upfront payment of $10.0 million and we will receive certain milestone payments upon receipt of regulatory approval for cemdisira

In May 2024, Regeneron notified us of its decision to opt-out of the further co-development of mivelsiran, an investigational R
share potential future profits from sales of mivelsiran with us, although we remain subject to certain financial obligations to Regen

Sanofi. We formed a broad strategic alliance with Sanofi in 2014. In January 2018, we and Sanofi amended our 2014 collal
commercialization of fitusiran and any back-up products. Under the Exclusive TTR License, Sanofi is eligible to receive (i) royaltie
the research and option phase and to amend and restate the AT3 License Terms to modify certain of the business terms. The mat

Novartis. In February 2013, we entered into an exclusive, worldwide license with MDCO (acquired by Novartis AG in January

We also have entered into license agreements to obtain rights to intellectual property in the field of RNAi. In addition, because

Critical Accounting Policies and Estimates

Our critical accounting policies are described in the “Management’s Discussion and Analysis of Financial Condition and Resu

Results of Operations

The following data summarizes the results of our operations:

(In thousands, except percentages)	(In thousands, except percentages)	Three Months Ended June 3 2024		2023	
Total revenues	Total revenues	$ 659,825	$	$ 318,754	$
Operating costs and expenses	Operating costs and expenses	$ 611,211	$	$ 548,585	$
Income (loss) from operations		$ 48,614		$ (229,831)	
(Loss) income from operations		$ (76,905)		$ 213,867	
Net loss					
Net loss					
Net loss		$ (16,889)		$ (276,024)	
Net (loss) income					
Net (loss) income					
Net (loss) income		$ (111,570)		$ 147,753	

Discussion of Results of Operations

Revenues

Total revenues consist of the following:

(In thousands, except percentages)	(In thousands, except percentages)	Three Months Ended June 30, 2024		2023		$ Change		
Net product revenues	Net product revenues	$410,088	$	$305,705	$	$104,383		34
Net revenues from collaborations	Net revenues from collaborations	227,338	5,844	5,844	221,494		221,494	
Royalty revenue	Royalty revenue	22,399	7,205	7,205	15,194		15,194	21
Total	Total	$659,825	$	$318,754	$	$341,071		107

* Indicates the percentage change period over period is greater than 500%.

Net Product Revenues

Net product revenues consist of the following, by product and region:

	Three Months Ended June 30,	Three Months Ended September 30,

(In thousands, except percentages)	(In thousands, except percentages)	2024		2023		$ Change	
ONPATTRO							
United States							
United States							
United States		$ 22,112	$	$ 25,560	$	$ (3,448)	
Europe	Europe	37,074	56,393	56,393	(19,319)		(1
Rest of World	Rest of World	18,058	9,505	9,505	8,553		
Total	Total	77,244	91,458	91,458	(14,214)		(1
AMVUTTRA							
AMVUTTRA							
AMVUTTRA							
United States							
United States							
United States		148,463	96,469	96,469	51,994		5
Europe	Europe	56,760	14,405	14,405	42,355		4
Rest of World	Rest of World	24,886	21,262	21,262	3,624		
Total	Total	230,109	132,136	132,136	97,973		9
GIVLAARI							
GIVLAARI							
GIVLAARI							
United States							
United States							
United States		41,225	35,196	35,196	6,029		
Europe	Europe	16,314	14,051	14,051	2,263		
Rest of World	Rest of World	4,588	8,652	8,652	(4,064)		(
Total	Total	62,127	57,899	57,899	4,228		
OXLUMO							
OXLUMO							
OXLUMO							
United States							
United States							
United States		15,744	8,794	8,794	6,950		
Europe	Europe	20,503	12,216	12,216	8,287		
Rest of World	Rest of World	4,361	3,202	3,202	1,159		
Total	Total	40,608	24,212	24,212	16,396		1
Total net product revenues							
Total net product revenues							
Total net product revenues		$ 410,088	$	$ 305,705	$	$ 104,383	

Net product revenues increased during the three and six nine months ended June 30, 2024 September 30, 2024, as compare

Net Revenues from Collaborations and Royalty Revenue

Net revenues from collaborations and royalty revenue consist of the following:

		Three Months Ended June 30,							Six Mo
(In thousands, except percentages)	(In thousands, except percentages)	2024		2023		$ Change		% Change	2024
Roche	Roche	$ 16,506	$	$ —	$	$ 16,506	N/A	N/A	$ 9
Regeneron Pharmaceuticals	Regeneron Pharmaceuticals	207,429	(2,837)	(2,837)	210,266	210,266	*	*	
Novartis AG	Novartis AG	2,304	8,627	8,627	(6,323)	(6,323)	(73)	(73)%	
Other									

Other									
Other		1,099	54	54	1,045	1,045	*	*	
Total net revenues from collaborations	Total net revenues from collaborations	$227,338	$	$ 5,844	$	$221,494	*	*	$ 34
Royalty revenue									
Royalty revenue									
Royalty revenue		$ 22,399	$	$ 7,205	$	$ 15,194	211	211 %	$33,021

* Indicates the percentage change period over period is greater than 500%.

Net revenues from collaborations increased decreased during the three and six nine months ended June 30, 2024 September

- revenue recognized under our Roche Collaboration due to the recognition of $310.0 million of revenue upon the transfer
- revenue recognized under our Regeneron Collaboration. We Collaboration due to recognition of a cumulative catch-up ad

Partially offset by:

- revenue recognized under our Regeneron Collaboration as we modified our the collaboration with Regeneron in June 20 transferred in June 2024 and Regeneron could begin to use and benefit from zilebesiran KARDIA-3 clinical trial during the

Royalty revenue increased during the three and six nine months ended June 30, 2024 September 30, 2024, as compared to t

Recognition of our combined net revenues from collaborations and royalty revenue is dependent on a variety of factors includ

Operating Costs and Expenses

Operating costs and expenses consist of the following:

		Three Months Ended June 30,				
(In thousands, except percentages)	**(In thousands, except percentages)**	**2024**		**2023**		**$ Change**
Cost of goods sold	Cost of goods sold	$ 67,271	$	$ 75,336	$	$ (8,065)
Cost of goods sold as a percentage of net product revenues						
Cost of goods sold as a percentage of net product revenues						
Cost of goods sold as a percentage of net product revenues						
Cost of collaborations and royalties						
Cost of collaborations and royalties						
Cost of collaborations and royalties		1,401	10,034	10,034	(8,633)	(8,63
Research and development	Research and development	294,142	248,526	248,526	45,616	45,61
Selling, general and administrative	Selling, general and administrative	248,397	214,689	214,689	33,708	33,70
Total	Total	$ 611,211	$	$ 548,585	$	$ 62,626

Cost of goods sold

Cost of goods sold as a percentage of net product revenues decreased during the three and six nine months ended June 30 occur receive regulatory approval in 2024. the U.S. These decreases were partially offset by higher volume and royalty rates paya

We Excluding the one-time events in 2023 associated with cancelled manufacturing commitments and the impairment of ONP

Cost of collaborations and royalties

Cost of collaborations and royalties decreased during the three and six nine months ended June 30, 2024 September 30, 202

We expect cost of collaborations and royalties will continue to decrease during 2024, as compared to 2023, as a result of our

Research and development

Research and development expenses consist of the following:

		Three Months End
		Three Months Ended
(In thousands, except percentages)	**(In thousands, except percentages)**	**2024** **2023**

Clinical research and outside services	Clinical research and outside services	$ 119,496	$	$ 109,698	$
Compensation and related	Compensation and related	86,762	64,707	64,707	22,055
Occupancy and all other costs	Occupancy and all other costs	39,769	41,320	41,320	(1,551
Stock-based compensation	Stock-based compensation	48,115	32,801	32,801	15,314
Total	Total	$ 294,142	$	$ 248,526	$

For the three and six nine months ended June 30, 2024 September 30, 2024, the increase in research and development expe

- increased clinical trial expenses primarily associated with zilebesiran in the KARDIA-3 trial and mivelsiran in the cAPPRic
- increased costs associated with our preclinical activities as we continue to expand develop our R&D pipeline;
- increased clinical research expenses primarily associated with zilebesiran in the KARDIA-3 clinical trial pipeline of RNAi th
- increased expenses associated with our HELIOS-B clinical trial primarily driven by increased costs and fees leading up to
- increased employee compensation and related expenses to support our R&D research and development pipeline and dev
- increased stock-based compensation expense primarily due to the accounting for certain performance-based awards.

Offset Partially offset by:

- decreased expenses within other clinical programs, specifically the APOLLO-B Phase 3 clinical trial of patisiran due to the
- decreased expenses associated with the timing of manufacturing activities to support pre-clinical and clinical programs. pe

During the three and six nine months ended June 30, 2024 September 30, 2024 and 2023, in connection with advancing activ

The following table summarizes research and development expenses incurred, for which we recognize net revenue, that are

(In thousands)	(In thousand
Roche	
Regeneron Pharmaceuticals	
Other	
Total	

Selling, general and administrative

Selling, general and administrative expenses consist of the following:

		Three Months Ended		Three Months Ended Se	
(In thousands, except percentages)	(In thousands, except percentages)	2024		2023	
Compensation and related	Compensation and related	$ 96,538	$	$ 75,507	$
Consulting and professional services	Consulting and professional services	66,731	57,848	57,848	8,883
Occupancy and all other costs	Occupancy and all other costs	43,955	38,333	38,333	5,622
Stock-based compensation	Stock-based compensation	41,173	43,001	43,001	(1,828)
Total	Total	$ 248,397	$	$ 214,689	$

For the three and nine months ended June 30, 2024 September 30, 2024, the increase in selling, general and administrative e

We expect that research and development expenses combined with selling, general and administrative expenses will continu platform and pre-clinical pipeline, and prepare regulatory submissions. However, we expect that certain expenses will be variable

Other (Expense) Income

Other (expense) income consists of the following:

		Three Mo		
(In thousands, except percentages)	(In thousands, except percentages)	2024		
Interest expense	Interest expense	$(33,258)	$	$(3
Interest income	Interest income	29,182	21,075	
Other expense, net				
Realized and unrealized loss on marketable equity securities				
Realized and unrealized loss on marketable equity securities				
Realized and unrealized loss on marketable equity securities		(1,367)		

Realized and unrealized gains (losses) on marketable equity securities				
Realized and unrealized gains (losses) on marketable equity securities				
Realized and unrealized gains (losses) on marketable equity securities		(1,567)		(1
Change in fair value of development derivative liability	Change in fair value of development derivative liability	(55,642)	(30,215)	(3
Other	Other	1,304	(6,603)	
Total	Total	$(59,781)	$	$(4

Total other expense increased decreased during the three and six nine months ended June 30, 2024 September 30, 2024, as HELIOS-B clinical trial announced in June 2024, partially offset by an increase in interest income driven by higher market interest

Provision for Income Taxes

For the three and six months ended June 30, 2024, we We recorded a provision for income taxes of $5.7 $2.9 million and $8.1

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. As of June 30 valuation allowance attributable to Switzerland will no longer be needed. Release of all, or a portion, of the valuation allowance w

Liquidity and Capital Resources

The following table summarizes our cash flow activities:

(In thousands)	
Net cash provided by (used in):	
Operating activities	
Operating activities	
Operating activities	
Investing activities	
Financing activities	

Operating activities

Net cash provided by operating activities increased decreased during the six nine months ended June 30, 2024 September 30

Investing activities

Net cash used in investing activities decreased during the six nine months ended June 30, 2024 September 30, 2024, compar

Financing activities

Net cash provided by financing activities increased during the six nine months ended June 30, 2024 September 30, 2024, com

Additional Capital Requirements

We currently have programs focused in many therapeutic areas and, as of June 30, 2024 September 30, 2024, have receive activities relating to our research platform, our drug development programs, including clinical trial and manufacturing costs, the es

Our expected working and other capital requirements are described in our 2023 Annual Report on Form 10-K in “Part II, Item Form 10-K.

Based on our current operating plan, we believe that our cash, cash equivalents and marketable securities as of June 30, 202 funds earlier than we currently expect in order to continue to commercialize our approved products, and to develop, conduct clinic

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Financial market risks related to interest rates are described in our Annual Report on Form 10-K for the year ended Decembe

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Executive Vice Preside Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their ob

Changes in Internal Control

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2024 September 30,

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For a discussion of material pending legal proceedings, please read Note 13, Commitments and Contingencies, to our conde

ITEM 1A. RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the following risk factors in addition to operating result or financial condition could be materially and adversely affected. In these circumstances, the trading price of our

Our business is subject to numerous risks and uncertainties, discussed in more detail in the following section. These risks inc

Business Related Risks – Risks Related to Our Financial Results

- The marketing and sale of our approved products or any future products may be unsuccessful or less successful than ant
- We have a history of losses and may never become and remain profitable.
- We will require substantial funds to continue our research, development and commercialization activities.
- Any negative developments related to Leqvio could have a material adverse effect on our receipt of future royalties and m

Risks Related to Our Dependence on Third Parties

- We may be unable to maintain existing or enter into new collaborations with other companies that can provide business a
- If any collaborator materially amends, terminates or fails to perform its obligations under agreements with us, the develop
- We expect to incur significant costs as we continue to grow our manufacturing capabilities and resources and develop ma
- We rely on third parties to conduct our clinical trials, and if such third parties fail to fulfill their obligations, our development

Risks Related to Managing Our Operations

- If we are unable to attract and retain qualified key management and scientists, development, medical and commercial sta
- We may have difficulty expanding our operations successfully as we continue our evolution from a U.S.- and Europe-base

Industry Related Risks – Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candid

- Any product candidate we or our collaborators develop may fail in development or be delayed to a point where such prod
- We or our collaborators may be unable to obtain U.S. or foreign regulatory approval for our or our collaborated product ca
- Even if we or our collaborators obtain regulatory approvals, our products will be subject to ongoing regulatory oversight.
- We may incur significant liability if enforcement authorities allege or determine that we are engaging in commercial activiti
- Even if we or our collaborators receive regulatory approval to market our product candidates, the market may not be rece
- We are a multi-product commercial company and expect to continue to invest significant financial and management resou
- Any products we currently market or may develop in the future may become subject to unfavorable pricing regulations, thi

Risks Related to Patents, Licenses and Trade Secrets

- If we are not able to obtain and enforce patent protection for our discoveries, our ability to develop and commercialize our
- We license patent rights from third-party owners. If such owners do not properly or successfully obtain, maintain or enforc
- Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from develo
- If we become involved in intellectual property litigation or other proceedings related to a determination of rights, including
- If we fail to comply with our obligations under any licenses or related agreements, we may be required to pay damages a

Risks Related to Competition

- The pharmaceutical market is intensely competitive. If we or our collaborators are unable to compete effectively with exist
- We and our collaborators face competition from other companies that are working to develop novel drugs and technology

Risks Related to Our Common Stock

- Our stock price has been and may in the future be volatile, and an investment in our common stock could suffer a decline
- We expect that results from our and our collaborators' clinical development activities and the clinical development activitie

Risks Related to Our Convertible Notes

- We may not have sufficient cash flow from our business to pay our indebtedness.
- We may not have the ability to raise the funds necessary to settle for cash conversions of our 1% Convertible Senior Note
- The conditional conversion feature of the Notes, if triggered, may adversely affect our liquidity.

Risks Related to Our Financial Results

The marketing and sale of our approved products or any future products may be unsuccessful or less successful than a

Although we have commercially launched four products, we cannot predict whether we will successfully market and sell our a and efficacy results from our APOLLO-B clinical trial, in October 2023, the FDA issued a complete response letter, or CRL for our

To execute our business plan of building a profitable, top-tier biotech company by the end of 2025 and achieving our *Alnylam*

- execute product development activities and continue to leverage new technologies related to both RNAi and to the deliver
- build and maintain a strong intellectual property portfolio;
- gain regulatory acceptance for the development and commercialization of our product candidates and successfully marke
- attract and retain customers for our products;
- enter into and maintain successful collaborations; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing the objectives set forth above, we may not be able to develop product candidates, su

We have a history of losses and may never become and remain profitable.

We have experienced significant operating losses since our inception. As of June 30, 2024 September 30, 2024, we had a $775.3 million, $1.20 billion, respectively, in net product revenues from sales of ONPATTRO, AMVUTTRA, GIVLAARI and OXLU collaborations, including milestones and royalties on Leqvio sales, should enable us to achieve a self-sustainable profile without and Novartis. We cannot be certain that we will be able to maintain our existing collaborations, secure and maintain new collabora

To become and remain profitable, we must succeed in discovering, developing and commercializing novel product candidates even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we cann

We will require substantial funds to continue our research, development and commercialization activities, and if we requ

We have used substantial funds to develop our RNAi technologies and will require substantial funds to conduct further resear our product candidates.

We believe that our current cash, cash equivalents and marketable equity and debt securities, as well as revenue we expect number of factors, many of which are difficult to predict or are outside of our control, including:

- progress in our research and development programs, including programs in both rare and prevalent diseases, as well as
- the timing, receipt and amount of milestone, royalty and other payments, if any, from present and future collaborators, if a
- our ability to maintain and establish additional collaborations and/or new business initiatives;
- the potential for improved product profiles to emerge from our new technologies and our ability to successfully advance ou
- the resources, time and costs required to successfully initiate and complete our pre-clinical studies and clinical trials, obta
- our ability to establish, maintain and operate our own manufacturing facilities in a timely and cost-effective manner;
- our ability to manufacture, or contract with third parties for the manufacture of, our product candidates for clinical testing a
- the impact of any future pandemics or public health emergencies or the ongoing conflicts in the Middle East and Ukraine
- the resources, time and cost required for the preparation, filing, prosecution, maintenance and enforcement of patent clai
- the costs associated with legal activities, including litigation and government investigations, arising in the course of our bu
- the timing, receipt and amount of sales milestones and royalties, if any, from our approved products and our potential pro
- the outcome of the regulatory review process and commercial success of our products, including AMVUTTRA, and produ

If our estimates, predictions and financial guidance relating to these factors are incorrect, we may need to modify our operatin

The terms of any financing we may be required to pursue in the future may adversely affect the holdings or the rights of our st

If we require additional funding and are unable to obtain such funding on a timely basis, we may be required to significantly d
our own.

Although we sold a portion of the royalty stream and commercial milestones from the global sales of Leqvio by Novartis

In April 2020, we sold to BX Bodyguard Royalties L.P. (an affiliate of The Blackstone Group Inc.), or Blackstone Royalties, 50
January 1, 2030. As a result, any factor that has an adverse impact on sales of Leqvio could affect our ability to meet the $1.00 bi

Factors that could have an adverse impact on Leqvio sales include:

- competitors may develop new therapies or alternative formulations of products for HeFH and ASCVD;
- lack of acceptance of Leqvio by patients, the medical community or third party payors;
- any negative developments relating to Leqvio, such as safety, efficacy, or reimbursement issues;
- any disputes concerning patents or proprietary rights, or under license and collaboration agreements;
- foreign currency exchange rate fluctuations; and
- adverse regulatory or legislative developments that limit or prohibit the sale of Leqvio, such as restrictions on the use of L

If the revenues generated by sales of Leqvio are lower than expected, we may not receive commercial milestone payments a

If the estimates we make, or the assumptions on which we rely, in preparing our financial statements and/or our projecte

Our condensed consolidated financial statements have been prepared in accordance with accounting principles generally ac
under the circumstances. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct

Further, from time to time we issue financial guidance relating to our expectations regarding our combined product sales, coll
of, our publicly disclosed financial guidance or other expectations about our business, our stock price could decline.

The investment of our cash, cash equivalents and marketable securities is subject to risks which may cause losses and

As of June 30, 2024 September 30, 2024, we had $2.62 billion $2.78 billion in cash, cash equivalents and marketable securiti
We may realize losses in the fair value of these investments or a complete loss of these investments, which would have a negativ

Volatility in foreign currency exchange rates could have a material adverse effect on our operating results.

Our revenue from outside of the U.S. is expected to increase as our products, whether commercialized by us or our collabora
a negative impact on net income, but our overall expenses will decrease, having a positive impact. Any future volatility in foreign e

Changes in tax laws could adversely affect our business, prospects, operating results and financial condition.

Our business is subject to numerous international, federal, state, and other governmental laws, rules, and regulations that ma
tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent ye

Additionally, the Organization for Economic Co-operation and Development, or the OECD, the EC, and individual taxing juris
the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis and an

We may incur additional tax liabilities related to our operations.

We are subject to income tax in the U.S. and the foreign jurisdictions in which we operate. Significant judgment is required in
to particular tax issues on our tax returns. Consequently, tax assessments or judgments in excess of accrued amounts that we ha
Global Anti-Base Erosion Model have influenced tax laws in countries in which we operate, including the implementation of minim

Any future outbreaks of pandemics or public health emergencies, may directly or indirectly adversely affect our busines

In the future, we may experience disruptions from a pandemic or public health emergency that could impact our business ar
staffing shortages, raw material or other supply chain shortages, production slowdowns and disruptions in delivery systems, may

Additionally, timely completion of pre-clinical activities and initiation of planned clinical trials are dependent upon the availabil
could impact review, inspection and approval timelines.

While the ultimate impact of any pandemic or public health emergency on our business is uncertain, any negative impacts of s

Risks Related to Our Dependence on Third Parties

If we are unable to maintain our existing collaborations, or enter into new collaborations with other companies that can p

We do not currently have adequate capacity or capabilities to advance all opportunities arising from our growing pipeline of R

In such collaborations, we expect our current, and may expect our future, collaborators to provide substantial capabilities in c
example, we will rely entirely on (i) Regeneron for the development and commercialization of all programs targeting eye diseases
the sales of the applicable product. If our collaborators are not successful in their development and/or commercialization efforts,
approval milestone and potential U.S. royalties. As discussed above, under our agreement with Blackstone Royalties, if the reven

We may not be successful in entering into future collaborations on terms favorable to us due to various factors, including our
challenges or potential challenges to our intellectual property portfolio. Even when we succeed in securing such new collaboratior

Furthermore, any delay in entering into new collaboration agreements would have the potential to prevent or delay the develo

For certain product candidates, we have formed collaborations to fund all or part of the costs of drug development and comm develop these product candidates or other product candidates internally, or to bring such product candidates to market. In these c

If any collaborator materially amends, terminates or fails to perform its obligations under agreements with us, the develo

Our dependence on collaborators for capabilities and funding means that our business could be adversely affected if any co candidate. Our current collaborations allow, and we expect that any future collaborations will allow, either party to terminate the agreement is terminated by Novartis for convenience, Novartis must grant a license to us under certain technology developed in attract a new collaborator (potentially on less favorable terms for us than we have with our existing collaborator) or develop expan

In addition, if we have a dispute with a collaborator over the ownership of technology or other matters, or if a collaborator ter difficult for us to attract new collaborators and could adversely affect how we are perceived in the business and financial communi

Moreover, a collaborator, or in the event of a change in control of a collaborator or the assignment of a collaboration agreeme

- pursue alternative technologies or develop alternative products, either on its own or jointly with others, that may be compe
- pursue higher-priority programs or change the focus of its development programs, which could affect the collaborator's co
- if it has marketing rights, choose to devote fewer resources to the marketing of our product candidates, if any are approve

If any of these occur, the development and commercialization of one or more products or product candidates could be delaye

We expect to incur significant costs as we continue to grow our manufacturing capabilities and resources and develop r

We have been expanding our manufacturing capabilities, and in order to continue to commercialize our approved products, c required to be produced under current good manufacturing practice standards, or cGMP. During 2012, we developed cGMP capa future.

At the present time, we only have the capacity to manufacture limited quantities of clinical trial drug substance ourselves, and risks inherent in pharmaceutical manufacturing that could affect the ability of our CMOs to meet our delivery time requirements or timely manner, or at all.

In addition to the manufacture of synthetic siRNAs, we may have additional manufacturing requirements related to the techno time. We also have limited experience in such scale-up and manufacturing, requiring us to depend on a limited number of third p discovery and development efforts, as well as additional expense to us.

In developing manufacturing capabilities by building our own manufacturing facilities, we have incurred substantial expenditu with them on reasonable terms and in a timely manner, or at all. Given our dependence on a limited number of CMOs to supply material adverse impact on the research and development activities and potential commercialization of our or our collaborators' p

The manufacturing processes for our products and any other product candidates that we may develop is subject to the FDA candidates. For example, in April 2022, due to an amendment to our vutrisiran NDA submission to address a pending inspection

Additionally, in January 2024, the U.S. House of Representatives introduced the BIOSECURE ACT (H.R. 7085), which was s biotechnology company that is subject to the jurisdiction, direction, control, or operates on behalf of a foreign adversary's governm otherwise receive reimbursement from, the U.S. government. We do business with companies in China and it is possible some of

If the third parties we engage to supply materials or manufacture product candidates or products for preclinical testing or clini used to manufacture them, it could materially and adversely impact our business, prospects, operating results or financial conditio

To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we depend, and will number of ways, including:

- we or our current or future collaborators may not be able to initiate or continue clinical trials of product candidates that are
- we or our current or future collaborators may be delayed in submitting regulatory applications, or receiving regulatory app
- we may lose the cooperation of our collaborators;
- our facilities and those of our CMOs, and our products could be the subject of inspections by regulatory authorities that co
- we may be required to cease distribution or recall some or all batches, of our products or take action to recover clinical tri
- ultimately, we may not be able to meet the clinical and commercial demands for our product candidates and products.

We rely on third parties to conduct our clinical trials, and if such third parties fail to fulfill their obligations, our developm

We rely on independent clinical investigators, CROs, and other third-party service providers to assist us in managing, monitor other entities, some of which may be our competitors, which may draw their time and resources away from our programs. Althou scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and our CROs are

connection with the review of marketing applications. If we or any of our CROs fail to comply with applicable GCP requirements, with GCP regulations.

If our third-party service providers cannot adequately and timely fulfill their obligations to us for any reason, or if the quality a negatively impacted.

Before conducting clinical trials to demonstrate the safety and efficacy of our product candidates in humans in support of INI unable to complete such pre-clinical studies in a timely manner or at all.

Risks Related to Managing Our Operations

If we are unable to attract and retain qualified key management and scientists, development, medical and commercial st

We are highly dependent upon our senior management and our scientific, clinical, sales and medical staff. The loss of the ser

We have grown our workforce significantly over the past several years and anticipate additional employee growth in the futur and if we are not able to attract and retain qualified sales and marketing professionals, it would negatively impact our ability to cor

We may have difficulty expanding our operations successfully as we continue our evolution from a U.S.- and EU-based c

As we continue the commercial launches of our approved products and increase the number of product candidates we are de

We have grown our workforce significantly over the last several years and anticipate additional employee growth globally in unable to develop such additional infrastructure or obtain sufficient space to accommodate our growth in a timely manner and or operations continue to expand, we will need to successfully manage additional relationships with various collaborators, suppliers, existing systems and controls.

The use of social media presents risks and challenges.

We use social media to communicate about our clinical development programs and the diseases our investigational RNAi th creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory action reporting obligations or that we may not be able to defend our business in the face of the political and market pressures generate we could incur liability, face regulatory actions or incur other harm to our business.

Our business and operations could suffer in the event of system failures or unauthorized or inappropriate use of or acce

We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store a organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees and others. Cyber-attacks are of

The pervasiveness of cybersecurity incidents in general and the risks of cyber-crime are complex and continue to evolve. Alt contractors, consultants and collaborators are vulnerable to damage or interruption from computer viruses, unauthorized or inappr

pandemics or public health emergencies, terrorism, war (including the ongoing conflicts in Ukraine and the Middle East), and tele use or access to our systems were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or propr candidates could be delayed.

In addition, our increased use of cloud technologies heightens these third party and other operational risks, and any failure by

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates and the Commercial

Any product candidate we or our collaborators develop may fail in development or be delayed to a point where such pro

Before obtaining regulatory approval for the commercial distribution of our product candidates, we must conduct, at our own development, as well as several earlier-stage clinical programs. However, we may not be able to further advance any of our produ

If we enter into clinical trials, the results from nonclinical testing or early or late-stage clinical trials of a product candidate ma HELIOS-B will support approval of vutrisiran for the treatment of patients with ATTR amyloidosis with cardiomyopathy. There is a our approved products and our current product candidates employ novel delivery technologies that with the exception of inclisiran

Additionally, several of our planned and ongoing clinical trials utilize an “open-label” trial design. An “open-label” clinical trial is are receiving treatment. Accordingly, open-label clinical trials may be subject to a “patient bias” where patients perceive their sym future clinical trial results with any of our product candidates when studied in a blinded, controlled environment with a placebo or a

In addition, we, the FDA or other applicable regulatory authorities, or an institutional review board, or IRB, or similar foreign re FDA or foreign regulatory authority, to suspend or terminate the clinical trial, or, in the case of regulatory agencies, a refusal to ap

Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. We or our collaborators may experienc difficulties retaining trial participants, including as a result of the availability of existing approved treatments or other investigationa

Although our RNAi therapeutics have been generally well-tolerated in our clinical trials to date, new safety findings may emer
temporarily suspended dosing in all ongoing fitusiran studies pending further review of a fatal thrombotic SAE that occurred in a p

In addition, the occurrence of SAEs and/or AEs could also result in refusal by the FDA or a foreign regulatory authority to app

Clinical trials also require the review, oversight and approval of IRBs, or, outside of the U.S., independent ethics committees,
in support of a marketing application.

Our product candidates that may encounter problems during clinical trials that will cause us, an IRB, ethics committee or regu
of our other product candidates.

A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen ever

- our nonclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may
- delays in filing IND applications or comparable foreign applications or delays or failure in obtaining the necessary approva
- conditions imposed on us by an IRB or ethics committee, or the FDA or comparable foreign regulatory authorities regardi
- problems in engaging IRBs or ethics committees to oversee clinical trials or problems in obtaining or maintaining IRB or e
- delays in enrolling patients and volunteers into clinical trials, and variability in the number and types of patients and volunt
- disruptions caused by man-made or natural disasters or pandemics, epidemics or public health emergencies or other bus
- high drop-out rates for patients and volunteers in clinical trials;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours;
- inadequate supply or quality of product candidate materials or other materials necessary for the conduct of our clinical tria
- greater than anticipated clinical trial costs;
- serious and unexpected drug-related side effects experienced by patients taking our approved products, participants in ou
- poor or disappointing effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or records of any clinical or noncli
- failure of our third-party contractors or investigators to comply with regulatory requirements, including GCP and cGMP, or
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including the imposition
- interpretations of data by the FDA and similar foreign regulatory agencies that differ from ours.

Even if we successfully complete clinical trials of our product candidates, any given product candidate may not prove to be a s

We or our collaborators may be unable to obtain U.S. or foreign regulatory approval for our or our collaborated product c

Our and our collaborated product candidates are subject to extensive governmental regulations relating to, among other thin
uncertain and subject to unanticipated delays. It is possible that the product candidates we and our collaborators are developing
regulatory approval. For example, although we reported positive results from the APOLLO-B Phase 3 clinical trial of patisiran in pa

The time required to obtain FDA and other regulatory approvals is unpredictable but typically takes many years following the
approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations,

Because the product candidates we or our collaborators are developing represent a new class of drug, the FDA and its foreig
development of our or our collaborated product candidates. In addition, because there may be approved treatments for some of t
effective than existing approved products. Interruption or delays in the operations of the FDA, EMA and comparable foreign regula

In addition, during the COVID-19 public health emergency, a number of companies announced receipt of complete response lett
Leqvio (the trade name under which inclisiran is marketed in the U.S.) in December 2021. This delay in the approval of Leqvio res
other data or information in connection with the regulatory review of our or our collaborators' product candidates, including by issu

Any delay or failure in obtaining required approvals for our product candidates or our collaborated product candidates could h
to limitations on the approved uses for which we or our collaborators may market the product or the labeling or other restrictions,
certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain sa
restrictions may limit the size of the market for our products and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials,

Even if we or our collaborators obtain regulatory approvals, our marketed products will be subject to ongoing regulatory

Following any initial regulatory approval of a product we or our collaborators may develop, including with respect to our four
receive for ONPATTRO, AMVUTTRA, GIVLAARI and OXLUMO, as well as any regulatory approvals we receive for any of our

requirements for any clinical trials that we conduct post-approval. In addition, we are conducting, and intend to continue to conduc

The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on nev side effects or known side effects could be observed as being more frequent or severe than in clinical trials or earlier post-marketi

- sales of our approved products may be lower than originally anticipated;

- regulatory approvals for our approved products may be restricted or withdrawn;
- we may decide, or be required, to send product warning letters or field alerts to physicians, pharmacists and hospitals;
- additional nonclinical studies or clinical trials, changes in labeling, adoption of a REMS plan, or changes to manufacturing
- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences could reduce or eliminate sales of our approved products, increase our expenses and impair ou

The CMO and manufacturing facilities we use to make our approved products and certain of our current product candidates, connection with any subsequent applications for regulatory approval of one or more of our products filed in other territories. The c for the treatment of hATTR-amyloidosis with polyneuropathy in adults, which delayed our PDUFA goal date and AMVUTTRA's FI materials, or we may contract a third party to manufacture this material for us. Reliance on CMOs entails risks to which we would

If we or our collaborators, CMOs or service providers fail to comply with applicable continuing regulatory requirements in the U and criminal prosecution.

We may incur significant liability if enforcement authorities allege or determine that we are engaging in commercial activ

Physicians have the discretion to prescribe approved drug products for uses that are not described in the product's labeling a false or misleading labeling or promotional materials, including by their agents. Manufacturers and their agents may not promote uses and the promotion of products for which marketing approval has not been obtained, and if in the future we are found to have condition. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litig

Notwithstanding regulations related to product promotion, the FDA and other regulatory authorities allow companies to engag proven, it could harm our reputation or divert financial and management resources from our core business, and would have a mat

In addition to our medical education efforts, we also offer patient support services to assist patients receiving treatment with o and/or the federal False Claims Act, or FCA, face significant liability, including civil and administrative penalties, criminal sanctions

As described below, we remain focused on our global compliance program, which is designed to support the execution of thes

Even if we or our collaborators receive regulatory approval to market our product candidates, the market may not be rec

The product candidates that we are developing are based upon relatively new technologies or therapeutic approaches, and o

Other factors we believe will materially affect market acceptance of our products include:

- the timing of our receipt of any marketing approvals, the terms of any approvals and the countries in which approvals are
- the safety and efficacy of our product candidates, as demonstrated in clinical trials and as compared with alternative treat
- relative convenience, dosing regimen and ease of administration of our product candidates;
- the willingness of patients to accept potentially new routes of administration or new or different therapeutic approaches ar
- the success of our physician education programs;
- the availability of adequate government and third-party payor reimbursement;
- the pricing of our products, particularly as compared to alternative treatments, and the market perception of such prices a
- availability of alternative effective treatments for the diseases that our product candidates we develop are intended to trea

For example, ONPATTRO utilizes an intravenous mode of administration with pre-medication that physicians and/or patients physicians and patients and their caregivers. Vutrisiran, if approved for the treatment of ATTR amyloidosis with cardiomyopathy, c

We are a multi-product commercial company and expect to continue to invest significant financial and management resc

We received our first product approval in August 2018 and have established capabilities for marketing, sales, market access capabilities as part of our core product strategy initially in the U.S., Europe and Japan, with expansion ongoing globally, which has

and for future products we successfully develop with respect to which we retain development and commercialization rights, we co

- scaling and retaining our global sales, marketing and administrative infrastructure and capabilities;
- hiring, training, managing and supervising our personnel worldwide;
- the cost of further developing, or leveraging an established, marketing or sales force, which may not be justifiable in light
- our direct sales and marketing efforts may not be successful.

If we are unable to continue to develop and scale our own global marketing, sales, market access and distribution capabilities

The patient populations suffering from hATTR amyloidosis with polyneuropathy, ATTR amyloidosis with cardiomyopathy

Our estimates regarding the potential market size for ONPATTRO, AMVUTTRA, GIVLAARI, OXLUMO or any future products improve diagnosis, it could have a material adverse effect on our business, prospects, operating results or financial condition, and

Any products we currently market or may develop in the future may become subject to unfavorable pricing regulations,

The regulations that govern marketing approvals, coverage, pricing and reimbursement for new drugs vary widely from countr our approved products and as several of our product candidates move through late stages of development. However, a number impact the revenues we are able to generate from the sale of the product in that country and potentially in other countries due to r

We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare and legislative inquiries into prescription drugs, and proposed and enacted federal and state legislation and regulations designed to, among othe

At the federal level, for example, the Inflation Reduction Act, or IRA, includes several provisions that will impact our business treatment of Stargardt Disease would cause us to lose the orphan exemption for AMVUTTRA from Medicare price negotiation. As IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbu

Furthermore, the Biden administration has indicated that lowering prescription drug prices is a priority, but we do not know the drug, and establishing new approach for administering outcomes-based agreements for cell and gene therapies. We do not know to seek new measures to control drug costs.

At the state level, governments have become increasingly aggressive in passing legislation and implementing regulations des toward Florida facilitating importation of certain prescription drugs from Canada. Importation of drugs from Canada and the Mos approved, or put pressure on our product pricing. We cannot predict what healthcare reform initiatives may be adopted in the futu business, prospects, operating results and financial condition and our ability to develop drug candidates.

Our ability to commercialize our approved products or any future products successfully also will depend in part on the extent such product(s) or any future products on a competitive basis or realize an appropriate return on our investment in product deve acquiring the product. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be countries where they may be sold at lower prices than in the U.S. In particular, governments in certain markets such as in EU, regulations may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products fo

Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insuranc deliver results in the real world setting comparable to those demonstrated in our clinical trials, and the agreements are structured return on investment could be adversely affected. In addition, we have stated publicly that we intend to grow through continued products in the future.

Insurers are increasingly adopting programs and policies that limit access to medications and increase out-of-pocket costs f legislation or regulatory action could restrict or otherwise negatively affect these co-pay coupon programs and patient support pro

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and a

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. laws are interpreted broadly and prohibit companies and their officers, directors, employees, agents, contractors, and other third- permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and em consequences.

We remain focused on these laws and the activities they regulate and as detailed below, maintain a global compliance progra

Governments outside the U.S. may impose strict price controls, which may adversely affect our revenues.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the U.S. In these countries, pricin unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

In some countries, including Member States of the EU, or Japan, the pricing of prescription drugs may be subject to governm developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursem pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenue

If we or our collaborators, CMOs or service providers fail to comply with healthcare laws and regulations, or legal obliga

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of any pr

- The U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willf actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violation

- The U.S. federal false claims laws, including the FCA, which prohibit, among other things, individuals or entities from kno when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fra
- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remu
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created, among other provision willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statemen
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, including its implementir
- Federal “sunshine” requirements imposed by the Affordable Care Act on drug, device, biological and medical supply mar nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their im
- Federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government

- Federal statutory and regulatory requirements applicable to pricing and sales of products to federal government agencies
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that
- State and foreign laws comparable to each of the above federal laws, including in the EU laws prohibiting giving healthca programs, patient data privacy and security.
- European privacy laws including Regulation 2016/679, known as the General Data Protection Regulation, or the EU GDP
- The California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or, collectively, implement (including through rule making) and enforce the CCPA. The CCPA provides for civil penalties for violations, as
- Furthermore, comprehensive privacy laws similar to the CCPA have been enacted in more than ten other states and pro private right of action. The effects of the CCPA and other state privacy laws are potentially significant and may require us

Some state laws also require pharmaceutical manufacturers to comply with the pharmaceutical industry’s voluntary complian our compliance efforts.

If our operations are found to be in violation of any of the aforementioned requirements, we may be subject to penalties, inclu which could materially and adversely affect our business, prospects, operating results or financial condition. We remain focused information, see the Risk Factor captioned “We may incur significant liability if enforcement authorities allege or determine that we applicable laws and regulations may be costly to us in terms of money, time and resources.

If we or our collaborators, CMOs or service providers fail to comply with applicable federal, state or foreign laws or regulati imprisonment.

Moreover, federal, state and foreign laws or regulations are subject to change, and while we, our collaborators, CMOs and/or

Third party patient assistance programs that receive financial support from companies have become the subject of enhance criteria and do not link aid to use of a donor’s product. However, donations to patient assistance programs have received negative charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we do so, a

We are subject to governmental regulation and other legal obligations related to privacy, data protection and informatior

The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for “spec

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member State ensure compliance with the data protection regime. The GDPR (i) requires us to inform data subjects of how we process their pe records of our processing activities and document data protection impact assessments where there is high risk processing, (vi) im

Significantly, the GDPR imposes strict rules on the transfer of personal data out of the EEA and UK to the U.S. or other regi invalidated the EU-U.S. Privacy Shield on the grounds that the Privacy Shield failed to offer adequate protections to EU personal if such standard is not met. Subsequent guidance published by the European Data Protection Board, or EDPB, in June 2021 des when implementing the new SCCs. However, there continue to be concerns about whether the SCCs and other mechanisms will issued in its wake) casts doubt on the legality of EU-U.S. data flows in general. Any inability to transfer, or burdensome restriction UK. On March 25, 2022, the EC and the U.S. announced a political agreement on a new “Trans-Atlantic Data Privacy Framewor under the new framework, and the EC stated that as a result personal data can flow safely from the EU to US companies particip Data Privacy Framework.

EEA Member States have adopted implementing national laws to implement the GDPR which may partially deviate from the the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime. The anticipated

We are subject to the supervision of local data protection authorities in those jurisdictions in which we are monitoring the beh diligence to ensure that they have sufficient technical and organizational security measures in place.

We are also subject to evolving European privacy laws on electronic marketing and cookies. The EU is in the process of repla the Council of EU on November 22, 2019; it is not clear when, or even if, new regulations will be adopted. We are also subject to

Compliance with U.S. and international data protection laws and regulations requires that we take on more onerous obligatior individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this infor

Our ability to obtain services, reimbursement or funding from the federal government may be impacted by possible redu

Under the Budget Control Act of 2011, the failure of Congress to enact deficit reduction measures of at least $1.2 trillion for th these reductions will stay in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These

Previous actions taken by Congress to reduce spending, disagreements in Congress over government funding levels, high-l activities, which may delay our ability to develop, market and sell our approved products and any other products we may develop.

If we fail to comply with our obligations under the 340B Drug Pricing Program or other U.S. governmental pricing progra

We participate in the 340B Drug Pricing Program, Medicaid Drug Rebate Program, and a number of other federal and state g occur frequently and program requirements are often ambiguous. We may be or become subject to penalties as a result of our fai

There is a substantial risk of product liability claims in our business. If we are unable to obtain sufficient insurance, a pr

Our business exposes us to significant potential product liability risks that are inherent in the development, testing, manufactu serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of a and sale of our approved products. Any insurance we have or may obtain may not provide sufficient coverage against potential lia

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standa

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failure As discussed in the Risk Factor captioned “If we or our collaborators, CMOs or service providers fail to comply with healthcare la Employee misconduct could also involve the improper use of, including improper trading based upon, information obtained in the identified potential concerns. It is not always possible, however, to identify and deter employee misconduct, and the precautions results and financial condition, including the imposition of significant fines or other sanctions.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business, p

Our research, development and manufacturing involve the use of hazardous materials, chemicals and various radioactive co facilities comply with the relevant guidelines of the City of Cambridge, the town of Norton, the Commonwealth of Massachusetts environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to b

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Related to Patents, Licenses and Trade Secrets

If we are not able to obtain and enforce patent protection for our discoveries, our ability to develop and commercialize o

Our success depends, in part, on our ability to protect proprietary compositions, methods and technologies that we develop u filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for subject matter commercialize future products, or continue to develop product candidates in our pipeline being developed by us or our collaborato

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. In addition, we may re collaborators to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation or circumvent

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology com upon by patent offices, courts and lawmakers. Moreover, there are periodic discussions in the U.S. Congress and in international from a first-to-invent to a first-to-file system. If we fail to file an invention before a competitor files on the same invention, we no lor

Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allow

Failure to obtain and maintain broad patent scope and all available regulatory exclusivities and to maximize patent term resto

We license patent rights from third-party owners. If such owners do not properly or successfully obtain, maintain or enfo

We are a party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful for our

Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licens protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale,

Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from deve

RNAi is a relatively new scientific field, the commercial exploitation of which has resulted in many different patents and pate manufacture and commercialization of RNAi therapeutics.

Specifically, we have a portfolio of patents, patent applications and other intellectual property covering, among other things: fu

As the field of RNAi therapeutics is maturing, patent applications are being fully processed by national patent offices around th has filed an opposition in the European Patent Office, or EPO, against our owned patent EP 2723758, with claims directed to RN which is directed to RNAi compositions and methods for silencing ketohexokinase, seeking to revoke the patent. An oral hearing h

in February 2023, a third party filed an opposition with the EPO against our owned patent EP 3366775, titled “Modified RNA Ag
ZL201380063930.5 remained valid as a whole, and patent No. ZL201810143112.0 remained valid based on the amended versic
uncertain and may adversely affect our business, prospects, operating results and financial condition if we are not successful in d
results and financial condition and on our ability to successfully compete in the field of RNAi.

There are many issued and pending patents that claim aspects of oligonucleotide chemistry and modifications that we may ne
proceeding or otherwise based upon the asserting party’s belief that we may need such patents for our siRNA therapeutic candida
rules that we need such patent rights that have been asserted against us, we may be unable to market our products, including Of
patents. There were also a number of related actions brought by us or Silence in connection with this intellectual property dispute

If we become involved in intellectual property litigation or other proceedings related to a determination of rights, we cou

Third parties may sue us for infringing their patent rights. For example, in October 2017, Silence sued us in the UK alleging th

Furthermore, third parties may challenge the inventorship of our patents or licensed patents. For example, in March 2011, Th
After several years of court proceedings and discovery, the court granted our motions for summary judgment and dismissed Utah’

We may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of propr
District of Delaware against Pfizer and Moderna seeking damages for infringement of U.S. Patent No. 11,246,933, or the ’933 pat

’979 patent. The court combined the two patents in a single suit for each of Pfizer/BioNTech, or the 2022 Lawsuit, and Moderna
August 9, 2023, a Markman hearing was held in the U.S. District Court for the District of Delaware to consider the meaning of thre
two of our patents, and that judgment was entered by the court on August 30, 2023, and on September 7, 2023, we appealed the
On October 2, 2024, we and Moderna jointly agreed to final judgment of 2025. non-infringement. On October 16, 2024, Moderna f
the trial date from November 2024 to the first half of 2025, with the final schedule to be determined by the court. case. On Januar
for the District of Delaware, seeking a judgment adding certain Acuitas employees as co-inventors on the patents we have asserte

In protecting our intellectual patent rights through litigation or other means, a third party may claim that we have improperly as
above, in April 2018, we and Dicerna settled all claims in the litigation between us.

In addition, in connection with certain license and collaboration agreements, we have agreed to indemnify certain third parties
substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation or legal proceeding cou

If any parties successfully claim that our creation or use of proprietary technologies infringes upon or otherwise violates their
licenses are in many instances non-exclusive and, therefore, our competitors may have access to the same technology that is lic
may be offset by amounts paid by our collaborators to third parties who have competing or superior intellectual property positions

If we fail to comply with our obligations under any licenses or related agreements, we may be required to pay damages a

Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercializati
that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, we could
and AT3 License Terms. Ionis claimed it was owed technology access fees, or TAFs, based on rights granted and amounts paid
which ruled in favor of Ionis’s request for a TAF on certain rights the panel determined we received in the Sanofi restructuring (but

Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be
we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other

In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collabora
assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determi

Risks Related to Competition

The pharmaceutical market is intensely competitive. If we or our collaborators are unable to compete effectively with exi

The pharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology com

- substantially greater financial, technical and human resources than we have;
- more extensive experience in pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufac
- product candidates that are based on previously tested or accepted technologies;
- multiple products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face intense competition from drugs that have already been approved and accepted by the medical community for the

For example, assuming regulatory approval, vutrisiran, our RNAi therapeutic in development for treatment of ATTR amyloido
announced that the

EMA accepted its marketing authorization application with a decision expected in 2025, and that it anticipates additional global re
Novo Nordisk and is in Phase 2 clinical development; and NI006, which is being developed by Neurimmune AG and AstraZeneca

ONPATTRO and AMVUTTRA are approved in certain jurisdictions for the treatment of certain patients with hATTR amyloidosi
ONPATTRO and AMVUTTRA have and will continue to have a competitive product profile for the treatment of patients with hATTF

If we or our collaborators continue to successfully develop product candidates, and obtain approval for them, we and our colla

- the safety and effectiveness of our or our collaborators' products relative to alternative therapies, if any;
- the ease with which our or our collaborators' products can be administered and the extent to which patients accept relativ
- the timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the price of our or our collaborators' products relative to alternative approved therapies;
- reimbursement coverage; and
- patent position.

We are aware of product candidates in various stages of clinical development for the treatment of PH1 which would compete
respective intellectual property related to lumasiran and Dicerna's nedosiran. In addition, several companies have investigational

Our competitors may develop or commercialize products with significant advantages over any products we or our collaborat
prospects, operating results and financial condition. Competitive products may make any products we or our collaborators develo
devices. The development of new medical devices or other treatment methods for the diseases we and our collaborators are targ

We and our collaborators face competition from other companies that are working to develop novel drugs and technolog

In addition to the competition we face from competing drugs in general, we and our collaborators also face competition from c
like molecules within cells.

Companies working on chemically synthesized siRNAs include, but are not limited to, Arrowhead and its collaborators, Takeda Ph
Ltd., Arrowhead, Arbutus, Quark, Sylentis and other companies under which these companies may independently develop RNAi t

We and our collaborators also compete with companies working to develop antisense-based drugs. Similar to RNAi therape
antisense product candidates in clinical trials. Ionis is also developing antisense drugs using ligand-conjugated GalNAc technolog

In addition to competition with respect to RNAi and with respect to specific products, we face substantial competition to disco
types, including both private companies and academic laboratories. Some of our competitors have substantially greater resources

Our stock price has been and may in the future be volatile, and an investment in our common stock could suffer a declin

Our stock price has been and may in the future be volatile. The stock market in general and the market for biotechnology com

- the information contained in our quarterly earnings releases, including updates regarding our or our collaborators' comme
- the success of existing or new competitive products or technologies;
- regulatory actions with respect to our or our collaborators' products or product candidates;
- announcements by us or our competitors of significant acquisitions, collaborations, joint ventures, collaborations or capita
- the timing and results of clinical trials of our or our collaborators' other product candidates;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our or our collaborators' development programs;
- results of clinical trials of our competitors' product candidates;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our or our collaborators' efforts to develop additional product candidates or products;
- actual or anticipated changes in financial results or development timelines;

- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by any of the securities analysts that cover us;

- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, securities class action litigation has often been brought against companies following declines in the market price additional litigation of this type in the future. Securities litigation against us could result in substantial costs and divert our manag underwriters of our securities offerings, in connection with certain litigation, and those obligations may not be covered by insuranc

Sales of a substantial number of shares of our common stock, including by us, our officers or directors, or our significa

A small number of our stockholders beneficially own a substantial amount of our common stock. As of June 30, 2024 Septem raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Anti-takeover provisions in our governing documents and under Delaware law could make an acquisition of us, which m

Provisions in our certificate of incorporation and our bylaws may delay or prevent an acquisition of us or a change in the curre

- establish a classified board of directors such that all members of our board of directors are not elected at one time;
- establish a prohibition on actions by our stockholders by written consent;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “
- allow the authorized number of our directors to be changed only by resolution of our board of directors.
- limit who may call a special meeting of stockholders;
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amen
- limit the manner in which stockholders can remove directors from our board of directors; and
- establish advance notice requirements for election to our board of directors and for proposing matters that can be acted u

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware Ge stockholders.

We expect that results from our and our collaborators’ clinical development activities and the clinical development activ

Any new information regarding our and our collaborators’ products and product candidates or competitive products or potenti our competitors’ expectations regarding regulatory filings and submissions as well as future clinical development of our products competitors’ clinical trials, may be based on interim rather than final data that may involve interpretation difficulties and may in any

We may not have sufficient cash flow from our business to pay our indebtedness.

As of June 30, 2024 September 30, 2024, we had $1.04 billion in total aggregate principal amount of Notes issued and outsta competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficien any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

In addition, our indebtedness, combined with our other financial obligations and contractual commitments, could have other im

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditio
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a disadvantage compared to our competitors who have less debt;
- limit our ability to borrow additional amounts to fund acquisitions, for working capital and for other general corporate purpo
- make an acquisition of our company less attractive or more difficult.

Any of these factors could harm our business, prospects, operating results and financial condition. In addition, if we incur add

We may not have the ability to raise the funds necessary to settle for cash conversions of the Notes or to repurchase the

Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change (as enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered or N indenture. A default under the indenture governing the Notes or the fundamental change itself could also lead to a default under a

The conditional conversion feature of the Notes, if triggered, may adversely affect our liquidity.

In the event the conditional conversion feature of the Notes is triggered, holders of the Notes will be entitled to convert the N convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding princip

Transactions relating to the Notes may affect the value of our common stock.

The conversion of some or all of the Notes would dilute the ownership interests of existing stockholders to the extent we satis

In addition, in connection with the issuance of the Notes, we entered into the Capped Calls with certain financial institutions, c

In connection with establishing their initial hedges of the Capped Calls, the Option Counterparties or their respective affiliates

From time to time, the Option Counterparties or their respective affiliates may modify their hedge positions by entering into c exercise our option to terminate the relevant portion of the Capped Calls). This activity could cause a decrease and/or increased v

We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions

We are subject to counterparty risk with respect to the Capped Calls.

The Option Counterparties are financial institutions, and are subject to the risk that any or all of them might default under the Counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increa

The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a mate

The accounting method for reflecting the Notes on our condensed consolidated balance sheet, accruing interest expense for t

In August 2020, the FASB published an Accounting Standards Update, which we refer to as ASU 2020-06, which simplified c

In accordance with ASU 2020-06, the Notes are reflected as a liability on our condensed consolidated balance sheets, with t reported net income or higher reported net loss, as the case may be.

In addition, the shares of common stock underlying the Notes are reflected in our diluted earnings per share using the "if con future in a manner that may adversely affect our diluted earnings per share.

Furthermore, if any of the conditions to the convertibility of the Notes is satisfied, then we may be required under applicable a

ITEM 5. OTHER INFORMATION

Adoption of 10b5-1 Trading Plans by Our Officers and Directors

During our fiscal quarter ended June 30, 2024 September 30, 2024, certain of our officers (as defined in Rule 16a-1(f) under plan." We describe the material terms of these Rule 10b5-1 trading plans **below.**

Kevin Fitzgerald, Ph.D., Executive Vice President, Chief Scientific Officer

On May 10, 2024, Kevin Fitzgerald, Ph.D., our Executive Vice President, Chief Scientific Officer, entered into a Rule 10b5-1 scheduled to terminate on May 10, 2025, subject to earlier termination upon the sale of all shares subject to the plan, upon termin

Dennis A. Ausiello, M.D., David E.I. Pyott, Director

On May 3, 2024 September 5, 2024, Dennis A. Ausiello, M.D., David E.I. Pyott, a member of our board of directors, entered ir common stock is above specified prices from August 5, 2024 January 1, 2025 to May 20, 2025 December 17, 2025. The plan is sc

Pushkal P. Garg, Chief Medical Officer

On September 11, 2024, Pushkal P. Garg, our Chief Medical Officer, entered into a Rule 10b5-1 trading plan that provides th December 18, 2025, subject to earlier termination upon the sale of all shares subject to the plan, upon termination by Dr. Ausiello

Stockholder Proposals Yvonne L. Greenstreet, MBChB, MBA, Chief Executive Officer and Director

On September 12, 2024, Yvonne L. Greenstreet, MBChB, MBA, our Chief Executive Officer, entered into a Rule 10b5-1 tradir

Our notice stock splits, stock combinations, stock dividends and other similar changes to our common stock. Sales of 2024 ar by Dr. Greenstreet or the broker, or as otherwise provided in the section entitled "Additional Information plan.

Tolga Tanguler, Chief Commercial Officer

On September 12, 2024, Tolga Tanguler, our Chief Commercial Officer, entered into a Rule 10b5-1 trading plan that provide common stock is above specified prices from December 13, 2024 to May 10, 2025. The plan is scheduled to terminate on May 1(intend to include broker, or as otherwise provided in the 2025 Proxy. The corrected section is set forth below:

STOCKHOLDER PROPOSALS

In order to be included in the proxy materials for the 2025 annual meeting of stockholders, stockholders' proposals must be stockholders wish to present for action at an annual meeting of stockholders, other than matters included in our proxy statement. the first anniversary of the 2024 annual meeting of stockholders, notice must be received not earlier than the 120th day prior to su

Our bylaws also specify requirements relating to the content of the notice which stockholders must provide, includir

To comply with the universal proxy rules, stockholders who intend to solicit proxies in support of director nominees other than

ITEM 6. EXHIBITS

10.1#** 10.1#†	Form Amendment No. 3 entered into as of Performance Stock Unit Award August 1,
10.2#**	Form of Restricted Stock Unit Award Agreement for Executive Officers under 2018 S
10.3#**	Form of Nonstatutory Stock Option Agreement for Executive Officers under 2018 St
10.4#**	Form of Nonstatutory Stock Option Agreement for Non-Employee Directors under 2
31.1#	Certification of principal executive officer pursuant to Rule 13a-14(a) promulgated u
31.2#	Certification of principal financial officer pursuant to Rule 13a-14(a) promulgated un
32.1#+	Certification of principal executive officer pursuant to Rule 13a-14(b) promulgated u
32.2#+	Certification of principal financial officer pursuant to Rule 13a-14(b) promulgated un
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonom

#	Filed herewith.
**†	Management contract, compensatory plan or agreement. Portions of this exhibit (inc
+	This certification will not be deemed “filed” for purposes of Section 18 of the Securiti

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be sign

Date: August 1, 2024 October 31, 2024

Date: August 1, 2024 October 31, 2024

ALNYLAM PHARMACEUTIC

Grant Date: []

Pursuant to the Alnylam Pharmaceuticals, Inc. 2018 Stock Incentive Plan, as amended through the d

This Amendment No. 3 ("**Plan**"), Alnylam Pharmaceuticals, Inc. (the "Company") hereby grants an award of term of [_____ (___)] years from the Grant Date.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned o the Plan and this Agreement.

2. Vesting of Performance Stock Units. So long as the Grantee remains an Eligible Participant, the the one-year anniversary laws of the Grant Date and (ii) the date on which the Board or Committee determin Appendix A, and if Appendix A allocates the Award to multiple different Performance Measures, then the res such Performance Measure cannot be attained, or could All capitalized terms not reasonably be expected to

Notwithstanding the foregoing, the Award will become fully vested in the event the Grantee, while an death of the Grantee, all Performance Measures will be deemed satisfied at target. In the case of any of the

---

Determination Date, or in the case of the death of the Grantee, the date of death, shall be deemed a Vesting

- "Triggering Event" shall mean a termination of the Grantee's employment or service (i) by the
- "Cause," "Change in Control" and "Good Reason" shall have the respective meanings ascribe

WHEREAS, Regeneron and Alnylam are parties to that certain Master Agreement dated April 8, 2019 ("**Mas**

WHEREAS, the Parties now wish to further amend the Agreement to enable the conduct of change certain t

NOW THEREFORE, in control agreement on file consideration of the foregoing and the agreements below, a

1. **Defined Terms:** The following new defined term is hereby added to Article 1 of the Agreement, effective

1.278. "[**] **Research Plan**"has the meaning set forth in Section 3.2.3(f)(iii).

2. The Parties hereby agree that Sections 3.2.3(f)(ii) and (iii) of the Agreement are hereby restated and

3.2.3(f) (ii) The Parties agree to conduct certain technology development activities related to form time. In the event of any dispute between the Parties related to an update or

- "Retirement" shall mean the Grantee's attainment of age sixty (60) and the completion of ten (10) years o

The Committee may at any time accelerate the vesting schedule specified in this Section 2, subject

amendment to the requirements of Section 409A of the Code.

3. Termination of Relationship with the Company. The Grantee shall remain an "Eligible Participant" result of the occurrence of a Vesting Date set forth in Section 2 above shall automatically Deadlocked Dispu

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event

the Company with respect to such shares.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be su

6. Tax Withholding. As a condition to this Award, the Grantee hereby agrees that any required tax w

---

way transactions within the previous six (6) months that were not exempt from Section 16(b) of the Exchang

thereof are satisfied by the Grantee resolved in accordance with this provision, Section 2.2.3(a)(ii). Under the

(iii) The Parties agree to issue any shares of Stock on the Grantee's behalf pursuant conduct certain

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisio

8. No Obligation to Continue Service Relationship. Neither the Company nor any subsidiary is oblig

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to

10. Data Privacy.

(a) Data Collection and Usage. The Company collects, processes and transfers personal data abo

or any other entitlement to shares of Common Stock awarded, canceled, exercised, vested, unvested or out

respective legitimate interests not outweighed by the Grantee's interests, rights or freedoms as needed to pr

(b) mutually agreed research plan attached hereto as Schedule 1.278 (the "[**Stock **] Research Plan

Plan. Such vendor(s) may open an account for the Grantee to receive and trade shares of Common Stock u

---

An updated list with the details of all recipients of the Grantee's Data can be made available upon a r

(c) Data Retention. The Company will hold and use the Data only as long as is necessary to imple

Company of respective legitimate interests not outweighed by the Grantee's interests, rights or freedoms. W

(d) Data Subject Rights. The Grantee understands that the Grantee may have a number of rights

the purposes underlying the processing, (iii) anonymize or delete Data, (iv) restrict or object to the processin

rights or to exercise these rights, the Grantee can contact privacy@alnylam.com.

(e) Voluntariness and Consequences of Consent Denial or Withdrawal. Participation in the Plan is

ability to participate to the JSC. The [**] Research Plan may be affected, updated or amended by mutual writ

or more antibody ligand(s) and Alnylam will provide siRNAs for the activities under the workplan. For clarity,

(iv) The technology development activities described in clauses (i), (ii) and (iii) above may be refer

such withdrawal.

By accepting this Award and indicating consent via the Company's acceptance procedure, the Grante privacy and data protection law and regulation perspective, for the purposes described above.

Finally, the Grantee understands that the Company as the Data Controller of the Data may rely on a c other acknowledgements,

---

agreements or consents as may be required by the Company) that the Company may deem necessary to ob consent requested Materials provided by the Company.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of

ALNYLAM PHARMACEUTICALS, INC

By: _____

Title:

The foregoing Agreement is hereby accepted connection with the Technology Development Activities shall b process) is acceptable.

GRANTEE:

ADDRESS:

[VESTING SCHEDULE]

Name of Grantee: []

No. of Restricted Stock Units: []

Grant Date: []

Pursuant to other Party's reasonable request, each Party will provide the Alnylam Pharmaceuticals, Ir par value $0.01 per share (the "Stock") of the Company. Technology Development Activities.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned o the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Section 1 of this Agreement of Restricted Stock Units specified as vested on such date.

[VESTING SCHEDULE]

Notwithstanding the foregoing, this Award will become fully vested in the event the Grantee, while an shall be deemed a Vesting Date for purposes of Section 4 of this Agreement).

For purposes of this Agreement, the following terms shall have the following meanings:

- "Triggering Event" shall mean a termination of the Grantee's employment or service (i) by the

---

- "Cause," "Change in Control" and "Good Reason" shall have the respective meanings ascribe
- "Retirement" shall mean the Grantee's attainment of age sixty (60) and the completion of ten (

The Committee may at any time accelerate the vesting schedule specified in this Section 2, subject to

3. Termination of Relationship with the Company. If the Grantee ceases to be an Eligible Participan personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be su

6. Tax Withholding. As a condition to this Award, the Grantee hereby agrees that any required tax w
16(b) of the Exchange Act of 1934, as amended, any required tax withholding obligation associated with this
have no obligation to issue any shares of Stock on the Grantee's behalf pursuant to the vesting of this Awar

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisio

---

exemption from, other otherwise comply with, the requirements of Section 409A of the Code. (v) Notwithst
termination, shall instead be paid on the next business day following the expiration of such six (6) month per
"cessation of being an Eligible Participant" and correlative phrases shall be construed to require a "separatio

8. No Obligation to Continue Service Relationship. Neither the Company nor any subsidiary is oblig

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to
individuals who are employees, agents or consultants of Alnylam or its Affiliates or its or their Sublicensees,

10. Data Privacy.

(a) Data Collection and Usage. The Company collects, processes and transfers personal data abo
or any other entitlement to shares of Common Stock awarded, canceled, exercised, vested, unvested or out
respective legitimate interests not outweighed by the Grantee's interests, rights or freedoms as needed to pr

(b) Stock Plan Administration Vendors. The Company may transfer Data to a designated third-par

---

to acknowledge, or agree to, separate terms and data processing practices with the vendor(s) with such agr

An updated list with the details of all recipients of the Grantee's Data can be made available upon a r

(c) Data Retention. The Company will hold and use the Data only as long as is necessary to imple
Company of respective legitimate interests not outweighed by the Grantee's interests, rights or freedoms. W

(d) Data Subject Rights. The Grantee understands that the Grantee may have a number of rights
the purposes underlying the processing, (iii) anonymize or delete Data, (iv) restrict or object to the processin
rights or to exercise these rights, the Grantee can contact privacy@alnylam.com.

(e) Voluntariness and Consequences of Consent Denial or Withdrawal. Participation in the Plan is
ability to participate to the Plan may be affected, as the Company would not (or no longer) be able to grant t

By accepting this Award and indicating consent via the Company's acceptance procedure, the Grante
regulation perspective, for the purposes described above.

Finally, the Grantee understands that the Company as the Data Controller of the Data may rely on a c

---

request that the Grantee provide supplementary consents or provide the Grantee with additional privacy rela
jurisdiction, either now or in the future. The Grantee understands course of such Technology Development A

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of

ALNYLAM PHARMACEUTICALS, INC

By: _____

Title:

The foregoing Agreement is hereby accepted Joint Collaboration IP, and the terms Patent Rights in clause (E
3. The Parties hereby agree that Sections 5.1.5 and conditions thereof 5.2.3 of the Agreement are hereby

GRANTEE:

ADDRESS:

Agreement:

Participant:

ID:

Award Number:

Exercise Price Per Share:

Grant Date:

Vesting Commencement Date:

Expiration Date:

Number of Shares/Units:

1. Grant of Option.

This Nonstatutory Stock Option Agreement ("Agreement") evidences 5.1.5 during the Research Te
sublicenses (other than to subcontractors permitted under Section 3.4.5), under any Alnylam Pharmaceutic
5.2.3 during the Research Term, a non-exclusive, non-transferable (except as permitted by Sectior
which license shall be fully paid-up;

4. Except as specifically amended herein, all other terms of the Company, on the Grant Date, of an option

purchase, in whole or in part, on the terms provided herein and in the Company's 2018 Stock Incentive Pla
common stock, $.01 par value per share, of the Company ("Common Stock") set forth above (the "Shares")

It is intended that the option evidenced by this Agreement shall not be an incentive stock option as d
context, the term "Participant", as used in this Agreement, shall be deemed to include any person who acqu

2. Vesting Schedule.

This option will become exercisable ("vest") as to 25% of the original number of Shares on the first a
exercisable in the event the Participant, while an Eligible Participant, dies, becomes
144558762_4

---

disabled (within the meaning of Section 22(e)(3) of the Code), experiences a Triggering Event or terminates

- "Triggering Event" shall mean a termination of the Participant's employment or service (i) by th
- "Change in Control" and "Good Reason" shall have the respective meanings ascribed to such
  shall be replaced with the words "employees of the Company at the same seniority level as th
- "Retirement" shall mean the Participant's attainment of age sixty (60) and the completion of te

The right of exercise shall be cumulative so that to the extent this option is not exercised in any perio

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, signed by the Partici
purchase less than the number of Shares covered hereby, provided that no partial exercise of this option m

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Se
the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Partic
the Company determines that the Participant, prior to the Expiration Date, violates the non-competition or c

(d) Exercise Period Upon Death, Disability, Triggering Event or Terminationdue to Retirement. If th
this option shall be exercisable, within the period of one year following the date of the Participant's death or
termination of employment due to Retirement (after taking into account any acceleration), and further provi

(e) Termination for Cause. If, prior to the Expiration Date, the Participant's employment or other re
date of such termination of employment or other relationship. "Cause" shall mean willful misconduct by the
conclusive. The Participant's employment or other relationship shall be considered to have been terminated

4. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays

5. Transfer Restrictions.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Particip

---

and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Partic
proposed transferee, the Company would be eligible to use a Form S-8 for the registration of the sale of the
bound by all of the terms and conditions of this Agreement and the Plan. References to the Participant, to t

6. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments t

7. Data Privacy Consent.

(a) Data Collection same agreement. This Amendment No. 3 may be executed or delivered electro
security number, passport number or other national identification number, salary, nationality, job title, any sh
basis, where required, for the processing of Data is the Participant's consent, compliance with relevant laws
(b) [*Stock Plan Administration Vendors signatures follow*. The Company may transfer Data to a designated

An updated list with the details of all recipients of the Participant's Data can be made available upon

(c) Data Retention. The Company will hold and use the Data only as long as is necessary to imple

---

required to comply with legal or regulatory obligations, including under tax and security laws. In the latter ca
Participant understands the Company will isolate it from active systems, remove it from its systems, or anon

(d) Data Subject Rights. The Participant understands that the Participant may have a number of ri
in light of the purposes underlying the processing, (iii) anonymize or delete Data, (iv) restrict or object to the
complaints with competent authorities in the Participant's jurisdiction, (vii) receive a list with the names and

(e) Voluntariness and Consequences of Consent Denial or Withdrawal. Participation in the Plan is
that the Participant's ability to participate to the Plan may be affected, as the Company would not (or no long

By accepting this award and indicating consent via the Company's acceptance procedure, the Partic
and regulation perspective, for the purposes described above.

Finally, the Participant understands that the Company as the Data Controller of the Data may rely on
Company (or any other acknowledgements, agreements or consents as may be required by the Company)

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate s

of the Amendment No. 3 Effective Date.

ALNYLAM PHARMACEUTICALS, INC.

By: REGENERON PHARMACEUTICALS, INC.

Name:

Title:

The undersigned hereby accepts the foregoing option and agrees to the terms and conditions thereo

By: /s/ Jeff Poulton

Name: Jeff Poulton

Title: Chief Financial Officer

PARTICIPANT:

Address:

By: /s/ Kerry Reinertsen

Name: Kerry Reinertsen

Title: SVP Strategic Alliances

Participant:

ID:

Award Number:

Exercise Price Per Share:

Grant Date:

Vesting Commencement Date:

Expiration Date:

Number of Shares/Units:

1. Grant of Option.

This Nonstatutory Stock Option Agreement ("Agreement") evidences the grant by Alnylam Pharmace Company ("Common Stock") set forth above (the "Shares") at the Exercise Price Per Share set forth above. continuous service on the Board (such earlier date, the "Final Exercise Date").

It is intended that the option evidenced by this Agreement shall not be an incentive stock option as de

---

Schedule 1.278

[This option will become exercisable ("vest") as to 100% of the original number of Shares upon the ea disabled (within the meaning of Section 22(e)(3) of the Code), or there is a Change in Control, in each case that the Participant is, and has been at all times since the Grant Date, an employee, officer or director of, or

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, signed by the Partici no partial exercise of this option may be for any fractional share or for fewer than ten whole shares. This opt

(b) Termination of Relationship with the Company. If the Participant ceases to provide services to

1 For participants who receive a stock option award in connection with their initial election or appointment to the Board, the brac

4. Transfer Restrictions.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Particip the Participant and/or an immediate family member thereof if, with respect to such proposed transferee, the substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms an

5. Provisions of the Research Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to

6. Data Privacy Consent.

(a) Data Collection and Usage. The Company collects, processes and transfers personal data abo or any other entitlement to shares of Common Stock awarded, canceled, exercised, vested, unvested or out its respective legitimate interests not outweighed by the Participant's interests, rights or freedoms as needed

(b) Stock Plan Administration Vendors. The Company may transfer Data to a designated third-par separate terms and data processing practices with the vendor(s) with such agreement being a condition of p

An updated list with the details of all recipients of the Participant's Data can be made available upon a

(c) Data Retention. The Company will hold and use the Data only as long as is necessary to imple Company of respective legitimate interests not outweighed by the Participant's interests, rights or freedoms.

(d) Data Subject Rights. The Participant understands that the Participant may have a number of ri in light of the purposes underlying the processing, (iii) anonymize or delete Data, (iv) restrict or object to the regarding these rights or to exercise these rights, the Participant can contact privacy@alnylam.com.

(e) Voluntariness and Consequences of Consent Denial or Withdrawal. Participation in the Plan is Participant's ability to participate to the Plan may be affected, as the Company would not (or no longer) be a

By accepting this award and indicating consent via the Company's acceptance procedure, the Partici regulation perspective, for the purposes described above.

Finally, the Participant understands that the Company as the Data Controller of the Data may rely on

additional privacy related information as the case may be. If applicable and upon request of the Company, th
Participant will not be able to participate in the Plan if the Participant fails to execute any such acknowledge

---

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate se

ALNYLAM PHARMACEUTICALS, INC.
By:
Name:
Title:

The undersigned hereby accepts the foregoing option and agrees to the terms and conditions thereof

PARTICIPANT:

Name:

Address:

I, Yvonne L. Greenstreet, MBChB, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Alnylam Pharmaceuticals, Inc.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly p

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedur

   b) Designed such internal control over financial reporting, or caused such internal control over financial

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in th

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occ

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal co

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over

   b) Any fraud, whether or not material, that involves management or other employees who have a signifi

Dated: August 1, 2024 October 31, 2024

I, Jeffrey V. Poulton, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Alnylam Pharmaceuticals, Inc.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly p

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedur

   b) Designed such internal control over financial reporting, or caused such internal control over financial

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in th

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occ

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal co

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over

   b) Any fraud, whether or not material, that involves management or other employees who have a signifi

Dated: August 1, 2024 October 31, 2024

In connection with the Quarterly Report on Form 10-Q of Alnylam Pharmaceuticals, Inc. (the “Compa

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Excha

(2) the information contained in the Report fairly presents, in all material respects, the financial cond

Dated: August 1, 2024 October 31, 2024

A signed original of this written statement required by Section 906 has been provided to the Company

In connection with the Quarterly Report on Form 10-Q of Alnylam Pharmaceuticals, Inc. (the “Compa

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Excha

(2) the information contained in the Report fairly presents, in all material respects, the financial cond

Dated: August 1, 2024 October 31, 2024

A signed original of this written statement required by Section 906 has been provided to the Company

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPO
DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARI

REFINITIV