

ALNYLAM PHARMACEUTICALS, INC.

Form 10-Q

November 07, 2013

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2013

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 000-50743

ALNYLAM PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

77-0602661
(I.R.S. Employer
Identification No.)

300 Third Street, Cambridge, MA
(Address of Principal Executive Offices)
(617) 551-8200

02142
(Zip Code)

(Registrant's Telephone Number, Including Area Code)

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

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

Large accelerated filer Accelerated filer

Non-accelerated filer (do not check if a smaller reporting company) Smaller reporting company

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

At October 31, 2013, the registrant had 63,430,076 shares of Common Stock, \$0.01 par value per share, outstanding.

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ALNYLAM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

(Unaudited)

	September 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,840	\$ 51,405
Marketable securities	181,939	71,407
Billed and unbilled collaboration receivables	609	104
Prepaid expenses and other current assets	4,776	2,641
Total current assets	199,164	125,557
Marketable securities	173,366	103,416
Investment in equity securities of Regulus Therapeutics Inc.	57,999	38,748
Property and equipment, net	16,974	19,799
Total assets	\$ 447,503	\$ 287,520
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 2,728	\$ 4,420
Accrued expenses	15,386	11,558
Accrued intraperiod tax allocation	2,023	
Deferred rent	1,200	950
Deferred revenue	33,558	31,417
Total current liabilities	54,895	48,345
Deferred rent, net of current portion	3,247	4,248
Deferred revenue, net of current portion	91,779	100,874
Total liabilities	149,921	153,467
Commitments and contingencies (Note 3)		
Stockholders equity:		
Preferred stock, \$0.01 par value, 5,000,000 shares authorized and no shares issued and outstanding at September 30, 2013 and December 31, 2012		
Common stock, \$0.01 par value, 125,000,000 shares authorized; 63,236,216 shares issued and outstanding at September 30, 2013; 52,489,936 shares issued and outstanding at December 31, 2012	632	525

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Additional paid-in capital	833,660	624,876
Accumulated other comprehensive income	27,168	15,662
Accumulated deficit	(563,878)	(507,010)
Total stockholders' equity	297,582	134,053
Total liabilities and stockholders' equity	\$ 447,503	\$ 287,520

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

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ALNYLAM PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net revenues from research collaborators	\$ 8,991	\$ 16,759	\$ 36,320	\$ 58,230
Operating expenses:				
Research and development ⁽¹⁾	34,457	22,094	80,851	64,891
General and administrative ⁽¹⁾	6,768	12,812	18,819	34,446
Total operating expenses	41,225	34,906	99,670	99,337
Loss from operations	(32,234)	(18,147)	(63,350)	(41,107)
Other income (expense):				
Equity in loss of joint venture (Regulus Therapeutics Inc.)		(1,613)		(3,641)
Interest income	290	261	784	755
Other (expense) income	(12)	(3)	(18)	167
Total other income (expense)	278	(1,355)	766	(2,719)
Loss before income taxes	(31,956)	(19,502)	(62,584)	(43,826)
Benefit from income taxes	2,270		5,716	
Net loss	\$ (29,686)	\$ (19,502)	\$ (56,868)	\$ (43,826)
Net loss per common share - basic and diluted	\$ (0.48)	\$ (0.38)	\$ (0.93)	\$ (0.88)
Weighted average common shares used to compute basic and diluted net loss per common share	62,416	51,542	61,103	49,772
Comprehensive loss:				
Net loss	\$ (29,686)	\$ (19,502)	\$ (56,868)	\$ (43,826)
Unrealized (loss) gain on marketable securities, net of tax	(962)	170	11,506	273
Comprehensive loss	\$ (30,648)	\$ (19,332)	\$ (45,362)	\$ (43,553)

(1) Non-cash stock-based compensation expenses included in operating expenses are as follows:

Research and development	\$ 6,805	\$ 2,271	\$ 11,092	\$ 6,357
General and administrative	2,040	1,115	4,205	3,281

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

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ALNYLAM PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	\$ (56,868)	\$ (43,826)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,602	7,011
Non-cash stock-based compensation	15,297	9,638
Charge for 401(k) company stock match	351	310
Equity in loss of joint venture (Regulus Therapeutics Inc.)		3,641
Realized gain on sale of marketable securities		(179)
Benefit from intraperiod tax allocation on marketable securities	(5,716)	
Changes in operating assets and liabilities:		
Proceeds from landlord tenant improvements	192	1,214
Billed and unbilled collaboration receivables	(505)	(450)
Prepaid expenses and other assets	(2,222)	(1,359)
Accounts payable	(1,336)	(707)
Accrued expenses and other	3,871	2,678
Deferred revenue	(6,954)	(24,668)
Net cash used in operating activities	(46,288)	(46,697)
Cash flows from investing activities:		
Purchases of property and equipment	(3,128)	(7,662)
Increase in restricted cash		(162)
Purchases of marketable securities	(335,197)	(195,672)
Sales and maturities of marketable securities	151,772	163,357
Net cash used in investing activities	(186,553)	(40,139)
Cash flows from financing activities:		
Proceeds from exercise of stock options and other types of equity	19,819	5,974
Proceeds from issuance of common stock, net of offering costs	173,572	86,800
Payments for repurchase of common stock for employee tax withholding	(115)	(328)
Net cash provided by financing activities	193,276	92,446
Net (decrease) increase in cash and cash equivalents	(39,565)	5,610
Cash and cash equivalents, beginning of period	51,405	70,228

Cash and cash equivalents, end of period	\$	11,840	\$	75,838
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The accompanying notes are an integral part of these condensed consolidated financial statements.

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ALNYLAM PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements of Alnylam Pharmaceuticals, Inc. (the Company or Alnylam) are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America (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. The Company's condensed consolidated financial statements have also been prepared on a basis substantially consistent with, and should be read in conjunction with, the Company's audited consolidated financial statements for the year ended December 31, 2012, which were included in the Company's Annual Report on Form 10-K that was filed with the Securities and Exchange Commission (the SEC) on February 19, 2013. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year.

The accompanying condensed consolidated financial statements reflect the operations of the Company and Alnylam U.S., Inc., Alnylam Europe AG, Alnylam (Bermuda) Ltd. and Alnylam Securities Corporation, which are wholly-owned subsidiaries of the Company. All significant intercompany accounts and transactions have been eliminated.

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 at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Net Loss Per Common Share

The Company computes basic net loss per common share by dividing net loss by the weighted average number of common shares outstanding. The Company computes diluted net loss per common share by dividing net loss by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. Potential common shares consist of shares issuable upon the exercise of stock options (using the treasury stock method) and unvested restricted stock awards. Because the inclusion of potential common shares would be anti-dilutive for all periods presented, diluted net loss per common share is the same as basic net loss per common share.

The following table sets forth for the periods presented the potential common shares (prior to consideration of the treasury stock method) excluded from the calculation of net loss per common share because their inclusion would be anti-dilutive, in thousands:

	Three and Nine Months Ended September 30,	
	2013	2012
Options to purchase common stock	8,021	8,156
Unvested restricted common stock	593	638
	8,614	8,794

Restricted Stock Awards

In January 2012, as part of its post-restructuring retention program, the Company granted an aggregate of 508,928 shares of restricted stock to its retained employees, excluding the Company's chief executive officer and president and chief operating officer. These restricted stock awards were valued at \$5.3 million on the grant date and vest in full on the second anniversary of the grant date.

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The Company recognized an aggregate of \$1.3 million and \$0.7 million of stock-based compensation expense related to all outstanding restricted stock awards for the three months ended September 30, 2013 and 2012, respectively. The Company recognized an aggregate of \$2.6 million and \$1.9 million of stock-based compensation expense related to all outstanding restricted stock awards for the nine months ended September 30, 2013 and 2012, respectively.

Public Offering

In February 2012, the Company sold an aggregate of 8,625,000 shares of its common stock through an underwritten public offering at a price to the public of \$10.75 per share. As a result of the offering, the Company received aggregate net proceeds of approximately \$86.8 million, after deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$5.9 million.

In January 2013, the Company sold an aggregate of 9,200,000 shares of its common stock through an underwritten public offering at a price to the public of \$20.13 per share. As a result of this offering, the Company received aggregate net proceeds of approximately \$173.6 million, after deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$11.6 million.

Fair Value Measurements

The following tables present information about the Company's assets that are measured at fair value on a recurring basis at September 30, 2013 and December 31, 2012, and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices (adjusted), interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. The fair value hierarchy level is determined by the lowest level of significant input. Financial assets measured at fair value on a recurring basis are summarized as follows, in thousands:

Description	At September 30, 2013	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 10,515	\$ 10,515	\$	\$
Marketable securities (fixed income)				
Corporate notes	266,418		266,418	
U.S. Government obligations	69,901		69,901	
Commercial paper	18,986		18,986	
Marketable securities (Regulus equity holdings)	57,999		57,999	
Total	\$ 423,819	\$ 10,515	\$ 413,304	\$

Description	At December 31,	Quoted Prices in Active	Significant Observable	Significant Unobservable
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	2012	Markets (Level 1)	Inputs (Level 2)	Inputs (Level 3)
Cash equivalents	\$ 50,213	\$ 50,213	\$	\$
Marketable securities (fixed income)				
Corporate notes	91,523		91,523	
U.S. Government obligations	60,661		60,661	
Commercial paper	22,639			