ALNYLAM PHARMACEUTICALS, INC.
Form 10-Q
August 03, 2011

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2011

OR

o **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)	02142 (Zip Code)

(617) 551-8200

(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 þ No o

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 þ No o

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 o	Accelerated filer þ	Non-accelerated filer o (do not check if smaller reporting company)	Smaller reporting company o

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

At July 29, 2011, the registrant had 42,651,782 shares of Common Stock, $0.01 par value per share, outstanding.

INDEX

Table of Contents

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

	June 30, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 67,110	$ 74,599
Marketable securities	150,839	158,532
Collaboration receivables	1,308	3,450
Income taxes receivable		10,669
Prepaid expenses and other current assets	5,077	6,889
Total current assets	224,334	254,139
Marketable securities	98,080	116,773
Property and equipment, net	16,252	18,289
Investment in joint venture (Regulus Therapeutics Inc.)	1,801	3,616
Intangible assets, net	361	448
Total assets	$ 340,828	$ 393,265
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 7,949	$ 9,312
Accrued expenses	11,380	11,116
Deferred rent	484	484
Deferred revenue	80,721	81,134
Total current liabilities	100,534	102,046
Deferred rent, net of current portion	2,879	2,869
Deferred revenue, net of current portion	100,122	129,974
Other long-term liabilities	742	143
Total liabilities	204,277	235,032
Commitments and contingencies (Notes 4, 5 and 6)		
Stockholders equity:		
Preferred stock, $0.01 par value, 5,000,000 shares authorized and no shares issued and outstanding at June 30, 2011 and December 31, 2010		
Common stock, $0.01 par value, 125,000,000 shares authorized; 42,653,915 shares issued and outstanding at June 30, 2011; 42,343,423 shares issued and outstanding at December 31, 2010	427	423
Additional paid-in capital	509,826	500,443
Accumulated other comprehensive (loss) income	(246)	714
Accumulated deficit	(373,456)	(343,347)

Total stockholders equity	136,551	158,233
Total liabilities and stockholders equity	$ 340,828	$ 393,265

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

Table of Contents

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	**2010**	**2011**	**2010**
Net revenues from research collaborators	$ 20,614	$ 26,617	$ 41,511	$ 51,181
Operating expenses:				
Research and development (1)	25,303	28,136	51,652	52,836
General and administrative (1)	8,429	10,107	18,653	21,277
Total operating expenses	33,732	38,243	70,305	74,113
Loss from operations	(13,118)	(11,626)	(28,794)	(22,932)
Other income (expense):				
Equity in loss of joint venture (Regulus Therapeutics Inc.)	(1,012)	(3,919)	(2,084)	(5,497)
Interest income	322	641	704	1,231
Other (expense) income	(16)	43	65	32
Total other income (expense)	(706)	(3,235)	(1,315)	(4,234)
Loss before income taxes	(13,824)	(14,861)	(30,109)	(27,166)
Benefit from income taxes		229		211
Net loss	$ (13,824)	$ (14,632)	$ (30,109)	$ (26,955)
Net loss per common share basic and diluted	$ (0.33)	$ (0.35)	$ (0.71)	$ (0.64)
Weighted average common shares used to compute basic and diluted net loss per common share	42,379	41,991	42,369	41,920
Comprehensive loss:				
Net loss	$ (13,824)	$ (14,632)	$ (30,109)	$ (26,955)
Foreign currency translation		(29)		(29)
Unrealized (loss) gain on marketable securities	(228)	492	(960)	599
Comprehensive loss	$ (14,052)	$ (14,169)	$ (31,069)	$ (26,385)

(1) Non-cash stock-based compensation expenses included in operating expenses are as follows:				
Research and development	$ 2,830	$ 3,246	$ 5,495	$ 6,475
General and administrative	1,384	1,822	2,841	3,920

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

Table of Contents

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

	Six Months Ended June 30,	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (30,109)	$ (26,955)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,626	2,384
Deferred income taxes		(144)
Non-cash income tax benefit		(216)
Non-cash stock-based compensation	8,336	10,395
Charge for 401(k) company stock match	274	271
Equity in loss of joint venture (Regulus Therapeutics Inc.)	2,084	5,497
Changes in operating assets and liabilities:		
Collaboration receivables	2,142	(314)
Income taxes receivable	10,669	
Prepaid expenses and other assets	1,812	(1,870)
Accounts payable	(1,363)	(2,091)
Income taxes payable		(5,547)
Accrued expenses and other	910	(2,570)
Deferred revenue	(30,265)	(18,755)
Net cash used in operating activities	(32,884)	(39,915)
Cash flows from investing activities:		
Purchases of property and equipment	(502)	(2,527)
Purchases of marketable securities	(163,759)	(182,076)
Sales and maturities of marketable securities	189,185	150,178
Net cash provided by (used in) investing activities	24,924	(34,425)
Cash flows from financing activities:		
Proceeds from issuance of common stock	471	2,090
Proceeds from issuance of shares to Novartis		993
Net cash provided by financing activities	471	3,083
Effect of exchange rate on cash		(29)
Net decrease in cash and cash equivalents	(7,489)	(71,286)
Cash and cash equivalents, beginning of period	74,599	137,468
Cash and cash equivalents, end of period	$ 67,110	$ 66,182

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

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 present 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, 2010, 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 18, 2011. 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 its wholly-owned subsidiaries, Alnylam U.S., Inc., Alnylam Europe AG (Alnylam Europe) and Alnylam Securities Corporation. All significant intercompany accounts and transactions have been eliminated. The Company uses the equity method of accounting to account for its investment in Regulus Therapeutics Inc. (Regulus).

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

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders 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 Six Months Ended June 30,	
	2011	**2010**
Options to purchase common stock	8,925	7,872
Unvested restricted common stock	341	
	9,266	7,872

Restricted Stock Awards

The fair value of restricted stock awards granted to employees is based upon the quoted closing market price per share on the date of grant, adjusted for assumed forfeitures. For performance-based restricted stock awards, the value of the awards is measured when the Company determines the achievement of such performance conditions are deemed probable. Expense is recognized over the vesting period, commencing when the Company determines that it is probable that the awards will vest. In May 2011, the Company granted an aggregate of 229,806 shares of performance-based restricted stock awards to all employees, excluding the Company s leadership team. These restricted stock awards were valued

Table of Contents

at $2.3 million on the grant date and have a term of five years. The vesting of these awards is predicated on the Company s achievement of certain clinical development goals. For the six months ended June 30, 2011, the Company recorded $0.3 million of stock-based compensation expense related to these restricted stock awards.

Fair Value Measurements

The following tables present information about the Company s assets that are measured at fair value on a recurring basis at June 30, 2011 and December 31, 2010, 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. Financial assets measured at fair value on a recurring basis are summarized as follows, in thousands:

Description	At June 30, 2011	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 63,962	$ 46,462	$ 17,500	$
Marketable securities (fixed income)				
Corporate notes	119,353		119,353	
U.S. Government obligations	102,036		102,036	
Commercial paper	26,484		26,484	
Marketable securities (equity holdings)	1,046		1,046	
Total	$ 312,881	$ 46,462	$ 266,419	$

Description	At December 31, 2010	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 59,702	$ 40,686	$ 19,016	$
Marketable securities (fixed income)				
Corporate notes	133,341		133,341	
U.S. Government obligations	122,273		122,273	
Commercial paper	17,733		17,733	
Marketable securities (equity holdings)	1,958		1,958	
Total	$ 335,007	$ 40,686	$ 294,321	$

The carrying amounts reflected in the Company s condensed consolidated balance sheets for cash, collaboration receivables, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

Investments in Marketable Securities

The Company invests its excess cash balances in short-term and long-term marketable debt and equity securities. The Company classifies its investments in marketable debt securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time it purchased the securities. At each balance sheet date presented, the Company classified all of its investments in debt and equity securities as available-for-sale. The Company reports available-for-sale investments at fair value at each balance sheet date and includes any unrealized holding gains and losses (the adjustment to fair value) in stockholders equity. Realized gains and losses are determined using the specific identification method and are included in other income. If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is other than temporary and, if so, marks the investment to market through a charge to its condensed consolidated statements of operations. The Company did not record any impairment charges related to its fixed income marketable securities during the current period. The Company s marketable securities are classified as cash equivalents if the original maturity, from the date of purchase, is 90 days or less, and as marketable securities if the original maturity, from the date of purchase, is in excess of 90 days. The Company s cash equivalents are composed of money market funds, U.S. government obligations and commercial paper.

The following tables summarize the Company s marketable securities at June 30, 2011 and December 31, 2010, in thousands:

Table of Contents

	June 30, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper (Due within 1 year)	$ 26,488	$	$ (4)	$ 26,484
Corporate notes (Due within 1 year)	87,255	92	(13)	87,334
Corporate notes (Due after 1 year through 2 years)	32,033	10	(24)	32,019
U.S. Government obligations (Due within 1 year)	37,013	10	(2)	37,021
U.S. Government obligations (Due after 1 year through 2 years)	65,031	13	(29)	65,015
Equity securities	1,345		(299)	1,046
Total	$ 249,165	$ 125	$ (371)	$ 248,919

	December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper (Due within 1 year)	$ 17,734	$ 2	$ (3)	$ 17,733
Corporate notes (Due within 1 year)	116,385	204	(23)	116,566
Corporate notes (Due after 1 year through 2 years)	16,767	33	(25)	16,775
U.S. Government obligations (Due within 1 year)	24,246	1	(14)	24,233
U.S. Government obligations (Due after 1 year through 2 years)	98,111	22	(93)	98,040
Equity securities	1,345	613		1,958
Total	$ 274,588	$ 875	$ (158)	$ 275,305

Subsequent Events

The Company evaluated all events or transactions that occurred after June 30, 2011 up through the date these condensed consolidated financial statements were issued. During this period, the Company did not have any material recognizable or nonrecognizable subsequent events.

Recent Accounting Pronouncements

In January 2011, the Company adopted new authoritative guidance on revenue recognition for multiple element arrangements. The guidance, which applies to multiple element arrangements entered into or materially modified on or after January 1, 2011, amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual method. The fair value of deliverables under the arrangement may be derived using a best estimate of selling price if vendor specific objective evidence and third-party evidence is not available. Deliverables under the arrangement will be separate units of accounting provided (i) a delivered item has value to the customer on a standalone basis; and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. The Company did not enter into any significant multiple element arrangements or materially modify any existing multiple element arrangements during the six months ended June 30, 2011. The Company s existing license and collaboration agreements continue to be accounted for under previously issued revenue recognition guidance for multiple element arrangements.

In May 2011, the Financial Accounting Standards Board (FASB) issued a new accounting standard that clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This new standard is effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The Company does not expect that adoption of this new standard will have a material impact on its condensed consolidated financial statements.

In June 2011, the FASB issued a new accounting standard that eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity, requires the consecutive presentation of the statement of net income and other comprehensive income and requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this new standard do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor do the amendments affect how earnings per share is calculated or presented. This new standard is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011. As this new standard only requires enhanced disclosure, the adoption of this standard will not impact the Company s condensed consolidated financial statements.

Table of Contents

2. SIGNIFICANT AGREEMENTS

The following table summarizes the Company s total consolidated net revenues from research collaborators, for the periods indicated, in thousands:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Roche	$ 13,994	$ 13,994	$ 27,988	$ 27,988
Takeda	5,493	5,489	11,261	10,923
Novartis	59	2,614	118	4,973
Other	1,068	4,520	2,144	7,297

Total net r