

ALNYLAM PHARMACEUTICALS, INC.

Form 10-Q

August 07, 2009

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**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, 2009

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)

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 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 Smaller reporting company

(Do not check if a 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

As of July 31, 2009, the registrant had 41,728,062 shares of Common Stock, \$0.01 par value per share, outstanding.

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<u>Ex-10.3 Amended and Restated Strategic Collaboration and License Agreement effective as of April 28, 2009 between Isis Pharmaceuticals, Inc. and the Registrant</u>	
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<u>Ex-31.1 Section 302 Certification of the Principal Executive Officer</u>	
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<u>Ex-32.2 Section 906 Certification of the Principal Financial Officer</u>	

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(In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 147,870	\$ 191,792
Marketable securities	119,368	238,596
Collaboration receivables	5,857	4,188
Prepaid expenses and other current assets	5,327	4,674
Restricted cash		2,999
Total current assets	278,422	442,249
Marketable securities	206,533	82,321
Property and equipment, net	18,483	19,194
Deferred tax assets	5,606	5,382
Investment in joint venture (Regulus Therapeutics Inc.)	8,901	1,583
Intangible assets, net	708	795
Restricted cash, net of current portion		3,152
Total assets	\$ 518,653	\$ 554,676
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 6,463	\$ 2,588
Accrued expenses	9,908	9,328
Income taxes payable	1,829	6,111
Deferred rent	1,561	1,561
Deferred revenue	82,570	79,864
Total current liabilities	102,331	99,452
Deferred rent, net of current portion	1,951	2,732
Deferred revenue, net of current portion	229,669	250,121
Other long-term liabilities	220	246
Total liabilities	334,171	352,551
Commitments and contingencies (Note 5)		
Stockholders equity:		
Preferred stock, \$0.01 par value, 5,000,000 shares authorized and no shares issued and outstanding at June 30, 2009 and December 31, 2008		
Common stock, \$0.01 par value, 125,000,000 shares authorized; 41,705,344 shares issued and outstanding at June 30, 2009; 41,413,828 shares issued and	417	414

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outstanding at December 31, 2008		
Additional paid-in capital	465,277	452,767
Accumulated other comprehensive income	1,621	1,186
Accumulated deficit	(282,833)	(252,242)
Total stockholders' equity	184,482	202,125
Total liabilities and stockholders' equity	\$ 518,653	\$ 554,676

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

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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		Six Months Ended June	
	30,		30,	
	2009	2008	2009	2008
Net revenues from research collaborators	\$ 24,601	\$ 23,833	\$ 49,658	\$ 46,025
Operating expenses:				
Research and development ⁽¹⁾	38,615	29,558	63,936	49,835
General and administrative ⁽¹⁾	8,398	7,106	16,114	12,978
Total operating expenses	47,013	36,664	80,050	62,813
Loss from operations	(22,412)	(12,831)	(30,392)	(16,788)
Other income (expense):				
Equity in loss of joint venture (Regulus Therapeutics Inc.)	(816)	(1,605)	(2,286)	(3,234)
Interest income	1,458	3,547	3,506	8,249
Interest expense		(208)		(440)
Other (expense) income	(24)	(412)	154	(330)
Total other income (expense)	618	1,322	1,374	4,245
Loss before income taxes	(21,794)	(11,509)	(29,018)	(12,543)
Provision for income taxes	(908)	(1,251)	(1,573)	(1,456)
Net loss	\$ (22,702)	\$ (12,760)	\$ (30,591)	\$ (13,999)
Net loss per common share basic and diluted	\$ (0.55)	\$ (0.31)	\$ (0.74)	\$ (0.34)
Weighted average common shares used to compute basic and diluted net loss per common share	41,520	40,908	41,460	40,821
Comprehensive loss:				
Net loss	\$ (22,702)	\$ (12,760)	\$ (30,591)	\$ (13,999)
Foreign currency translation	(23)	(499)	(113)	(489)
Unrealized gain (loss) on marketable securities	1,021	(1,808)	548	(1,472)
Comprehensive loss	\$ (21,704)	\$ (15,067)	\$ (30,156)	\$ (15,960)

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

Research and development	\$ 3,248	\$ 2,857	\$ 6,282	\$ 5,171
General and administrative	2,164	1,691	4,267	3,197

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

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	Six Months Ended June 30,	
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (30,591)	\$ (13,999)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	3,745	2,297
Deferred income taxes	(250)	32
Non-cash stock-based compensation	10,153	8,886
Charge for 401(k) company stock match	249	192
Equity in loss of joint venture (Regulus Therapeutics Inc.)	2,682	2,717
Changes in operating assets and liabilities:		
Proceeds from landlord for tenant improvements		581
Collaboration receivables	(1,669)	(95)
Prepaid expenses and other assets	(653)	(1,256)
Accounts payable	3,875	2,414
Income taxes payable	(4,282)	1,221
Accrued expenses and other	(201)	(2,998)
Deferred revenue	(17,746)	86,358
Net cash (used in) provided by operating activities	(34,688)	86,350
Cash flows from investing activities:		
Purchases of property and equipment	(2,947)	(7,198)
Decrease in restricted cash	6,151	
Purchases of marketable securities	(267,988)	(283,536)
Sales and maturities of marketable securities	263,552	341,722
Investment in joint venture (Regulus Therapeutics Inc.)	(10,000)	
Net cash (used in) provided by investing activities	(11,232)	50,988
Cash flows from financing activities:		
Proceeds from issuance of common stock	957	1,476
Proceeds from issuance of shares to Novartis	1,154	5,408
Repayments of notes payable		(1,852)
Net cash provided by financing activities	2,111	5,032
Effect of exchange rate on cash	(113)	9
Net (decrease) increase in cash and cash equivalents	(43,922)	142,379
Cash and cash equivalents, beginning of period	191,792	105,157

Cash and cash equivalents, end of period	\$ 147,870	\$ 247,536
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The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**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, 2008, which were included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC) on March 2, 2009. 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., formerly Regulus Therapeutics LLC (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

The Company accounts for and discloses net loss per common share in accordance with Statement of Financial Accounting Standards (SFAS) No. 128, *Earnings per 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,	
	2009	2008
Options to purchase common stock	7,071	5,595
Unvested restricted common stock	29	57
	7,100	5,652

Fair Value Measurements

Effective January 1, 2009, the Company implemented SFAS No. 157, *Fair Value Measurements* (SFAS 157), for all nonfinancial assets and nonfinancial liabilities not recognized or disclosed at fair value in the financial statements on a recurring basis. The implementation of SFAS 157 for those assets and liabilities did not have a material impact on the Company's operating results or

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financial position, however, could have an impact in future periods. The Company did not have any nonfinancial assets or nonfinancial liabilities that would be recognized or disclosed at fair value on a recurring basis as of June 30, 2009.

The following tables present information about the Company's assets that are measured at fair value on a recurring basis as of June 30, 2009 and December 31, 2008, 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	As of June 30, 2009	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 144,415	\$ 143,576	\$ 839	\$
Marketable securities (fixed income)				
Government obligations	177,019		177,019	
Corporate notes	114,844		114,844	
Commercial paper	31,964		31,964	
Marketable securities (equity holdings)	2,074		2,074	
Total	\$ 470,316	\$ 143,576	\$ 326,740	\$

Description	As of December 31, 2008	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 187,057	\$ 167,293	\$ 19,764	\$
Marketable securities (fixed income)	320,269		320,269	
Marketable securities (equity holdings)	648		648	
Total	\$ 507,974	\$ 167,293	\$ 340,681	\$

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.

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (FASB) reached a consensus on Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. Further, EITF 07-1 clarifies that the determination of whether transactions within a

collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)* (EITF 01-9). EITF 07-1 became effective on January 1, 2009. The adoption of EITF 07-1 did not have a material impact on the Company's condensed consolidated financial statements, however, it resulted in enhanced disclosures for the Company's collaboration activities.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* (SFAS 165). SFAS 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. The adoption of SFAS 165 did not impact the Company's condensed consolidated financial statements. The Company evaluated all events or transactions that occurred after June 30, 2009 up through August 6, 2009, the date these condensed consolidated financial statements were issued. During this period, the Company did not have any material recognizable or unrecognizable subsequent events.

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In June 2009, the FASB issued SFAS No. 166, *Accounting for Transfers of Financial Statements an amendment of FASB Statement No. 140* (SFAS 166). SFAS 166 prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement in transferred financial assets. Specifically, among other aspects, SFAS 166 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities* (SFAS 140), by removing the concept of a qualifying special-purpose entity from SFAS 140 and removing the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised December 2003) an interpretation of ARB No. 51* (FIN 46R) to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS 140. SFAS 166 is effective for transfer of financial assets occurring on or after January 1, 2010. The Company has not determined the effect that the adoption of SFAS 166 will have on its condensed consolidated financial statements but the effect will generally be limited to future transactions.

In June 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)* (SFAS 167). SFAS 167 amends FIN 46R, to require an enterprise to determine whether its variable interest or interests give it a controlling financial interest in a variable interest entity. The primary beneficiary of a variable interest entity is the enterprise that has both (1) the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and (2) the obligation to absorb losses of the entity that could potentially be significant to the variable interest entity or the right to receive benefits from the entity that could potentially be significant to the variable interest entity. SFAS 167 also amends FIN 46R to require ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. SFAS 167 is effective for all variable interest entities and relationships with variable interest entities existing as of January 1, 2010. The Company has not determined the effect that the adoption of SFAS 167 will have on its condensed consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162* (SFAS 168). SFAS 168 replaces SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, to establish the *FASB Accounting Standards Codification* as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with GAAP. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. The adoption of this standard will not impact the Company's condensed consolidated financial statements.

2. SIGNIFICANT AGREEMENTS***Platform Alliances******Roche Alliance***

In July 2007, the Company and, for limited purposes, Alnylam Europe, entered into a license and collaboration agreement (the LCA) with F. Hoffmann-La Roche Ltd (Roche Basel) and Hoffman-La Roche Inc. (together with Roche Basel, Roche). Under the LCA, which became effective in August 2007, the Company granted Roche a non-exclusive license to the Company's intellectual property to develop and commercialize therapeutic products that function through RNA interference (RNAi), subject to the Company's existing contractual obligations to third parties. The license is initially limited to the therapeutic areas of oncology, respiratory diseases, metabolic diseases and certain liver diseases, and may be expanded to include up to 18 additional therapeutic areas, comprising substantially all other fields of human disease, as identified and agreed upon by the parties, upon payment to the Company by Roche of an additional \$50.0 million for each additional therapeutic area, if any.

In consideration for the rights granted to Roche under the LCA, Roche paid the Company \$273.5 million in upfront cash payments. In addition, in exchange for the Company's contributions under the LCA, for each RNAi therapeutic product successfully developed by Roche, its affiliates or sublicensees under the LCA, if any, the Company is entitled to receive milestone payments upon achievement of specified development and sales events, totaling up to an aggregate of \$100.0 million per therapeutic target, together with royalty payments based on worldwide annual net sales, if any.

Under the LCA, the Company and Roche also agreed to collaborate on the discovery of RNAi therapeutic products directed to one or more disease targets (Discovery Collaboration), subject to the Company's existing

contractual obligations to third parties. The collaboration between Roche and the Company will be governed by a joint steering committee for a period of five years that is comprised of an equal number of representatives from each party. In exchange for the Company's contributions to the collaboration, Roche will be required to make additional milestone and royalty payments to the Company.

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In July 2007, the Company executed a common stock purchase agreement (the Common Stock Purchase Agreement) with Roche Finance Ltd, an affiliate of Roche (Roche Finance). Under the terms of the Common Stock Purchase Agreement, on August 9, 2007, Roche Finance purchased 1,975,000 shares of the Company's common stock at \$21.50 per share, for an aggregate purchase price of \$42.5 million. The Company recorded this issuance using the closing price of the Company's common stock on August 9, 2007, the date the shares were issued to Roche. Based on the closing price of \$25.98, the fair value of the shares issued was \$51.3 million, which was \$8.8 million in excess of the proceeds received from Roche for the issuance of the Company's common stock. As a result, the Company allocated \$8.8 million of the upfront payment from the LCA to the common stock issuance.

Under the terms of the Common Stock Purchase Agreement, in the event the Company proposes to sell or issue any of its equity securities, subject to specified exceptions, it has agreed to grant to Roche Finance the right to acquire, at fair value, additional securities, such that Roche Finance would be able to maintain its ownership percentage in the Company.

In connection with the execution of the LCA and the Common Stock Purchase Agreement, the Company also executed a Share Purchase Agreement (the Alnylam Europe Purchase Agreement) with Alnylam Europe and Roche Beteiligungs GmbH, an affiliate of Roche (Roche Germany). Under the terms of the Alnylam Europe Purchase Agreement, which became effective in August 2007, the Company created a new, wholly-owned German limited liability company (Roche Kulmbach) into which substantially all of the non-intellectual property assets of Alnylam Europe were transferred, and Roche Germany purchased from the Company all of the issued and outstanding shares of Roche Kulmbach for an aggregate purchase price of \$15.0 million. The Alnylam Europe Purchase Agreement also included transition services that were performed by Roche Kulmbach employees at various levels through August 2008. The Company reimbursed Roche for these services at an agreed-upon rate. The Company recorded contra revenue (a reduction of revenues) of \$0.5 million and \$0.8 million for these services for the three and six months ended June 30, 2008, respectively.

In addition, in connection with the closing of the Alnylam Europe Purchase Agreement, the Company granted restricted stock of the Company to certain employees of Roche Kulmbach. In connection with the closing, the Company also accelerated the unvested portion of the outstanding stock options of certain Alnylam Europe employees.

In summary, the Company received upfront payments totaling \$331.0 million under the Roche alliance, which included an upfront payment under the LCA of \$273.5 million, \$42.5 million under the Common Stock Purchase Agreement and \$15.0 million for the Roche Kulmbach shares under the Alnylam Europe Purchase Agreement.

The Company recorded \$278.2 million as deferred revenue in connection with the Roche alliance. This amount represents the aggregate proceeds received from Roche of \$331.0 million, net of the amount allocated to the common stock issuance of \$51.3 million, and the net book value of Alnylam Europe of \$1.5 million.

When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting as defined in EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Application of this standard requires subjective determinations and requires management to make judgments about the value of each individual element and whether it is separable from the other aspects of the contractual relationship. The Company has determined that the deliverables under the Roche alliance include the license, the Alnylam Europe assets and employees, the steering committees (joint steering committee and future technology committee) and the services that the Company will be obligated to perform under the Discovery Collaboration. The Company has concluded that, pursuant to paragraph 9 of EITF 00-21, the license and assets of Alnylam Europe are not separable from the undelivered services (i.e., the steering committees and Discovery Collaboration) and, accordingly, the license and the services are being treated as a single unit of accounting. When multiple deliverables are accounted for as a single unit of accounting, the Company bases its revenue recognition pattern on the final deliverable. Under the Roche alliance, the steering committee services and the Discovery Collaboration services are the final deliverables and all such services will end, contractually, five years from the effective date of the LCA. The Company is recognizing the Roche-related revenue on a straight-line basis over five years because the Company cannot reasonably estimate the total level of effort required to complete its service obligations under the LCA. The Company will continue to reassess whether it can reasonably estimate the level of

effort required to fulfill its obligations under the Roche alliance. In particular, when the Discovery Collaboration commences, the Company may be able to make such an estimate. When, and if, the Company can make a reasonable estimate of its remaining efforts under the collaboration, the Company would modify its method of recognition and utilize a proportional performance method. As future substantive milestones are achieved, a portion of the milestone payment, equal to the percentage of the performance period completed when the milestone is achieved, multiplied by the amount of the milestone payment, will be recognized as revenue upon achievement of such milestone. The remaining portion of the milestone will be recognized over the remaining performance period on a straight-line basis. The Company recognized \$14.0 million and \$27.8 million in revenues in its condensed consolidated statements of operations for the three and six months ended June 30, 2009, respectively, and \$13.4 million and \$26.8 million in revenues for the three and six months ended June 30, 2008, respectively, under the Roche alliance.

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In May 2008, the Company entered into a license and collaboration agreement (the Takeda Collaboration Agreement) with Takeda Pharmaceutical Company Limited (Takeda) to pursue the development and commercialization of RNAi therapeutics. Under the Takeda Collaboration Agreement, the Company granted Takeda a non-exclusive, worldwide, royalty-bearing license to the Company s intellectual property to develop, manufacture, use and commercialize RNAi therapeutics, subject to the Company s existing contractual obligations to third parties. The license initially is limited to the fields of oncology and metabolic disease and may be expanded at Takeda s option to include other therapeutic areas, subject to specified conditions. Under the Takeda Collaboration Agreement, Takeda will be the Company s exclusive platform partner in the Asian territory, as defined in the Takeda Collaboration Agreement, for a period of five years.

In consideration for the rights granted to Takeda under the Takeda Collaboration Agreement, Takeda agreed to pay the Company \$150.0 million in upfront and near-term technology transfer payments. In addition, the Company has the option, exercisable until the start of Phase III development, to opt-in under a 50-50 profit sharing agreement to the development and commercialization in the United States of up to four Takeda licensed products, and would be entitled to opt-in rights for two additional products for each additional field expansion, if any, elected by Takeda under the Takeda Collaboration Agreement. In June 2008, Takeda paid the Company an upfront payment of \$100.0 million. Takeda is also required to make the additional \$50.0 million in payments to the Company upon achievement of specified technology transfer milestones, \$20.0 million of which was achieved in September 2008 and paid in October 2008, \$20.0 million of which is required to be paid upon achievement of specified technology transfer activities, but no later than 24 months after execution of the Takeda Collaboration Agreement, and \$10.0 million of which is required to be paid upon achievement of specified technology transfer activities within 24 to 36 months after execution of the Takeda Collaboration Agreement (collectively, the Technology Transfer Milestones). If Takeda elects to expand its license to additional therapeutic areas, Takeda will be required to pay the Company \$50.0 million for each of up to approximately 20 total additional fields selected, comprising substantially all other fields of human disease, as identified and agreed upon by the parties. In addition, for each RNAi therapeutic product developed by Takeda, its affiliates and sublicensees, if any, the Company is entitled to receive specified development and commercialization milestones, totaling up to \$171.0 million per product, together with royalty payments based on worldwide annual net sales, if any.

Pursuant to the Takeda Collaboration Agreement, the Company and Takeda have also agreed to collaborate on the research of RNAi therapeutics directed to one or two disease targets agreed to by the parties (the Research Collaboration), subject to the Company s existing contractual obligations with third parties. Takeda also has the option, subject to certain conditions, to collaborate with the Company on the research and development of RNAi drug delivery technology for targets agreed to by the parties. In addition, Takeda has a right of first negotiation for the development and commercialization of the Company s RNAi therapeutic products in the Asian territory, excluding the Company s ALN-RSV program. In addition to the 50-50 profit sharing option, the Company has a similar right of first negotiation to participate with Takeda in the development and commercialization in the United States of licensed products. The collaboration between the Company and Takeda is governed by a joint technology transfer committee (the JTTC), a joint research collaboration committee (the JRCC) and a joint delivery collaboration committee (the JDCC), each of which is comprised of an equal number of representatives from each party.

The Company has determined that the deliverables under the Takeda agreement include the license, the joint committees (the JTTC, JRCC and JDCC), the technology transfer activities and the services that the Company will be obligated to perform under the Research Collaboration. The Company has determined that, pursuant to EITF 00-21, the license and undelivered services (i.e., the joint committees and the Research Collaboration) are not separable and, accordingly, the license and services are being treated as a single unit of accounting.

When multiple deliverables are accounted for as a single unit of accounting, the Company bases its revenue recognition pattern on the final deliverable. Under the Takeda Collaboration Agreement, the last elements to be delivered are the JDCC and JTTC services, each of which has a life of no more than seven years. The Company is recognizing the upfront payment of \$100.0 million, the first Technology Transfer Milestone of \$20.0 million and the \$30.0 million of remaining Technology Transfer Milestones, the receipt of which the Company believes is probable,

on a straight-line basis over seven years because the Company is unable to reasonably estimate the level of effort to fulfill these obligations, primarily because the effort required under the Research Collaboration is largely unknown. As future substantive milestones are achieved, a portion of the milestone payment, equal to the percentage of the performance period completed when the milestone is achieved, multiplied by the amount of the milestone payment, will be recognized as revenue upon achievement of such milestone. The remaining portion of the milestone will be recognized over the remaining performance period on a straight-line basis. The Company will continue to reassess whether it can reasonably estimate

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the level of effort required to fulfill its obligations under the Takeda Collaboration Agreement. When, and if, the Company can make a reasonable estimate of its remaining efforts under the collaboration, the Company would modify its method of recognition and utilize a proportional performance method. The Company recognized \$5.4 million and \$10.8 million in revenues in its condensed consolidated statements of operations for the three and six months ended June 30, 2009, respectively, and \$2.1 million in revenues for each of the three and six months ended June 30, 2008, under the Takeda Collaboration Agreement.

In connection with the Takeda Collaboration Agreement, the Company paid \$5.0 million of license fees to the Company's licensors, primarily Isis Pharmaceuticals, Inc. (Isis), during 2008, in accordance with the applicable license agreements with those parties. These fees were charged to research and development expense.

Discovery and Development Alliances

Isis Collaboration and License Agreement

In April 2009, the Company and Isis amended and restated their existing strategic collaboration and license agreement (as amended and restated, the Amended and Restated Isis Agreement), originally entered into in March 2004. Under this agreement, the Company and Isis agreed to extend the broad cross-licensing arrangement regarding double-stranded RNAi that was established in 2004, pursuant to which Isis granted the Company licenses to its current and future patents and patent applications relating to chemistry and to RNA-targeting mechanisms for the research, development and commercialization of double-stranded RNA products. The Company has the right to use Isis technologies in its development programs or in collaborations and Isis has agreed not to grant licenses under these patents to any other organization for the discovery, development and commercialization of double-stranded RNA products designed to work through an RNAi mechanism, except in the context of a collaboration in which Isis plays an active role. The Company granted Isis non-exclusive licenses to its current and future patents and patent applications relating to RNA-targeting mechanisms and to chemistry for research use. The Company also granted Isis the non-exclusive right to develop and commercialize double-stranded RNA products developed using RNAi technology against a limited number of targets. In addition, the Company granted Isis non-exclusive rights to research, develop and commercialize single-stranded RNA products.

The Company agreed to pay Isis milestone payments, totaling up to approximately \$3.4 million, upon the occurrence of specified development and regulatory events, and royalties on sales, if any, for each product that the Company or a collaborator develops using Isis intellectual prop