Ardea Biosciences, Inc./DE
Form 10-Q
May 07, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2010

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: 1-33734

ARDEA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3200380**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4939 Directors Place **San Diego, CA**	**92121**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(858) 652-6500**

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 o 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.:

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o (Do not check if a 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

The number of shares of the registrant s common stock, par value $0.001 per share, outstanding as of April 30, 2010 was 22,778,274.

ARDEA BIOSCIENCES, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2010
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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS UNAUDITED

ARDEA BIOSCIENCES, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2010 (Unaudited)	December 31, 2009 (See Note)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,727	$ 11,562
Short-term investments available for sale	32,428	39,329
Receivables	1,365	1,433
Prepaids and other current assets	471	215
Total current assets	39,991	52,539
Property and equipment, net	1,950	1,961
Other assets	509	565
Total assets	$ 42,450	$ 55,065
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,607	$ 1,916
Accrued clinical liabilities	2,632	4,072
Accrued payroll and employee liabilities	1,447	2,138
Other accrued liabilities	620	769
Current portion of deferred revenue	9,706	9,706
Current portion of long-term debt	3,084	2,995
Total current liabilities	20,096	21,596
Deferred rent	175	160
Non-current portion of deferred revenue	2,427	4,853
Non-current portion of long-term debt	2,544	3,315
Other long-term liabilities	400	400
Commitments and contingencies (see Note 6)		
Stockholders equity:		
Common stock	18	18
Additional paid-in capital	374,263	372,091
Accumulated other comprehensive income	20	42
Accumulated deficit	(357,493)	(347,410)

Total stockholders equity	16,808	24,741
Total liabilities and stockholders equity	$ 42,450	$ 55,065

Note: The condensed consolidated balance sheet at December 31, 2009 has been derived from the audited financial statements as of that date, but does not include all of the information and disclosures required by accounting principles generally accepted in the United States of America.

See accompanying notes.

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ARDEA BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2010	2009
Revenues:		
License fees	$ 2,426	$
Reimbursable research and development costs	847	
Total revenues	3,273	
Operating expenses:		
Research and development	10,251	10,996
General and administrative	2,926	2,877
Total operating expenses	13,177	13,873
Loss from operations	(9,904)	(13,873)
Other income (expense):		
Interest income	69	136
Interest expense	(261)	(364)
Other income, net	13	(2)
Total other income (expense)	(179)	(230)
Net loss	$ (10,083)	$ (14,103)
Basic and diluted net loss per share	$ (0.54)	$ (0.79)
Shares used in computing basic and diluted net loss per share	18,559	17,849

See accompanying notes.

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ARDEA BIOSCIENCES, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Three Months Ended March 31,,	
	2010	2009
Operating activities:		
Net loss	$ (10,083)	$ (14,103)
Adjustments to reconcile net loss to net cash used for operating activities:		
Share-based compensation	1,613	1,542
Depreciation	136	171
Amortization of debt discount and debt issuance costs	86	117
(Gain)/loss on disposal of property and equipment		2
Deferred rent	15	23
Amortization of premium on short-term investments	108	18
Realized gain on short-term investments	(11)	
Change in operating assets and liabilities:		
Receivables	68	205
Prepaids and other assets	(252)	18
Accounts payable	691	(886)
Accrued clinical liabilities	(1,440)	577
Accrued payroll and employee liabilities	(691)	(277)
Other accrued liabilities	(149)	84
Deferred revenue	(2,426)	
Net cash used for operating activities	(12,335)	(12,509)
Investing activities:		
Purchases of short-term investments	(2,498)	(15,819)
Proceeds from sale or maturity of short-term investments	9,280	3,450
Proceeds from sale of property and equipment		8
Purchases of property and equipment	(125)	(105)
Net cash provided by (used for) investing activities	6,657	(12,466)
Financing activities:		
Payments on long-term debt	(716)	(24)
Net proceeds from issuance of common stock	559	73
Net cash (used for) provided by financing activities	(157)	49
Net decrease in cash and cash equivalents	(5,835)	(24,926)
Cash and cash equivalents at beginning of period	11,562	41,551
Cash and cash equivalents at end of period	$ 5,727	$ 16,625

Supplemental schedule of non-cash information:		
Net unrealized loss on short-term investments	$ (22)	$ (87)

See accompanying notes.

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ARDEA BIOSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Ardea Biosciences, Inc. and its wholly owned subsidiary (collectively, the Company) have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2010 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2010. For more complete financial information, these unaudited condensed consolidated financial statements and the notes thereto should be read in conjunction with the audited financial statements for the year ended December 31, 2009 included in the Company s Form 10-K filed with the Securities and Exchange Commission (SEC).

2. Accounting Policies

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of Ardea Biosciences, Inc. and its wholly owned subsidiary, Ardea Biosciences Limited, which was incorporated in England and Wales in February 2008. Ardea Biosciences Limited has no business and no material assets or liabilities and there have been no significant transactions related to Ardea Biosciences Limited since its inception.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and disclosures made in the accompanying notes to the unaudited condensed consolidated financial statements. Actual results could differ materially from those estimates.

Reclassification

Certain amounts in the 2009 condensed consolidated financial statements have been reclassified to conform to the 2010 presentation.

Revenue Recognition

The Company s collaboration arrangements may contain multiple revenue elements and the Company may be eligible for payments made in the form of upfront license fees, research funding, cost reimbursement, milestone payments and royalties.

Revenue from upfront, nonrefundable license fees is recognized over the period that any related services are to be provided by the Company. Amounts received for research funding are recognized as revenue as the research services that are the subject of such funding are performed. Revenue derived from reimbursement of research and development costs in transactions where the Company acts as a principal are recorded as revenue for the gross amount of the reimbursement, and the costs associated with these reimbursements are reflected as a component of research and development expense in the condensed consolidated statements of operations. Revenue from milestones is recognized when earned, as evidenced by written acknowledgement from the collaborator, or other persuasive evidence that the

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milestone has been achieved, provided that the milestone event is substantive and its achievability was not reasonably assured at the inception of the applicable agreement. Revenues recognized for royalty payments, if any, are based upon actual net sales of the licensed compounds, as provided by the collaboration arrangement, in the period the sales occur. Any amounts received prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue on its condensed consolidated balance sheet.

Earnings Per Share

Basic earnings per share (EPS) is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration of common share equivalents. Diluted EPS is computed by dividing the net income or loss by the weighted-average number of common shares and common share equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted EPS when their effect is dilutive.

Because the Company has incurred a net loss for all periods presented in the unaudited condensed consolidated statements of operations, stock options and warrants are not included in the computation of net loss per share because their effect is anti-dilutive. The shares used to compute basic and diluted net loss per share represent the weighted-average common shares outstanding.

Comprehensive Loss

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Unrealized gains and losses on available-for-sale securities are included in other comprehensive net loss and represent the difference between the Company s net loss and comprehensive net loss for both periods presented. The following are the components of the Company s comprehensive net loss (in thousands) for the three months ended March 31:

	Three Months Ended March 31,	
	2010	**2009**
Net loss	$ 10,083	$ 14,103
Net unrealized loss on short-term investments	22	87
Comprehensive net loss	$ 10,105	$ 14,190

Recent Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2010-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements*. ASU No. 2010-06 requires an entity to disclose separately the amounts of significant transfers in and out of Level 1 and 2 fair value measurements, and describe the reasons for the transfers. Also, it requires additional disclosure regarding purchases, sales, issuances and settlements of Level 3 measurements. ASU 2010-06 is effective for interim and annual periods beginning after December 15, 2009, except for the additional disclosure of Level 3 measurements, which is effective for fiscal years beginning after December 15, 2010. The adoption of ASU No. 2010-06 did not have a material impact on the Company s consolidated results of operations or financial condition for the quarter ended March 31, 2010.

In April 2010, FASB issued ASU No. 2010-17, *Revenue Recognition Milestone Method (Topic 605): Milestone Method of Revenue Recognition*. ASU No. 2010-17 codifies the consensus reached in Emerging Issues Task Force Issue No. 08-9, Milestone Method of Revenue Recognition. ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply

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the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and non-substantive milestones, and each milestone should be evaluated individually to determine if it is substantive. ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. The Company does not expect the adoption of this ASU to have a material impact on its consolidated results of operations or financial condition.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy, based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, is as follows:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company measures the following financial assets at fair value on a recurring basis. The fair values of these financial assets at March 31, 2010 (in thousands) were as follows:

		Fair Value Measurements at Reporting Date Using		
	Balance at March 31, 2010	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market funds	$ 4,743	$ 4,743	$	$
United States government agency obligations	16,745		16,745	
United States corporate debt securities	3,585		3,585	
United States commercial paper	7,295		7,295	
United States certificates of deposits	3,203		3,203	
Foreign commercial paper	1,600		1,600	
Total	$ 37,171	$ 4,743	$ 32,428	$

As of March 31, 2010, the Company s short-term investments consisted of approximately $28,228,000 of available-for-sale securities with contractual maturities of one year or less and approximately $4,200,000 with contractual maturities not to exceed 15 months.

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A company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item such as debt issuance costs must be recognized in earnings and cannot be deferred. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. Unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings and any changes in fair value are recognized in earnings. The Company has elected not to apply the fair value option to its financial assets and liabilities.

The Company considers the carrying amount of cash and cash equivalents, prepaid expenses and other current assets, receivables, accounts payable and accrued liabilities to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of these long-term obligations approximate their carrying value. The Company does apply fair value accounting to its securities available for sale.

Unrealized gains and losses associated with the Company s investments, if any, are reported in stockholders equity. For the three months ended March 31, 2010, the Company recognized approximately $22,000 in net unrealized losses on its short-term investments.

4. Bayer Relationship

In April 2009, the Company entered into a Development and Commercialization License Agreement (the License Agreement) with Bayer Health Care AG (Bayer). Under the terms of the License Agreement, the Company granted to Bayer a worldwide, exclusive license to develop and commercialize the Company s mitogen-activated ERK kinase (MEK) inhibitors for all indications. In partial consideration for the license, Bayer paid the Company an upfront cash fee of $35 million. The Company is eligible to receive additional cash payments totaling up to $372 million upon achievement of certain development-, regulatory- and sales-based milestones, as well as low double-digit royalties on worldwide sales of products covered under the License Agreement. The Company is responsible for the completion of the Phase 1 and Phase 1/2 studies currently being conducted for RDEA119. The upfront fee, reimbursement of third-party development costs, payments associated with the achieving specific milestones and royalties based on product sales, if any, will be accounted for as separate units of accounting. In addition, the $35 million upfront payment had been recognized on a straight-line basis over a period of approximately 13 months, which was the original period that the Company expected to complete all of its obligations under the License Agreement. In December 2009, the Company revised its estimate of this period extending it to 26 months. The unamortized balance of the license fee as of the date of the change in estimate of approximately $14,559,000 is being recognized over the revised timeline. For the quarter ended March 31, 2010, the Company recognized revenue of approximately $2,426,000 as licenses fees in the condensed consolidated statement of operations.

Participants in a collaborative arrangement are required to report costs incurred and revenues generated from transactions with third parties in each entity s respective income statement based on whether the participant is considered a principal or an agent. Under the terms of the License Agreement with Bayer and as it pertains to the completion of the ongoing Phase 1 and Phase 1/2 studies, the Company would be considered the principal as the Company is the primary obligor with respect to the third parties, has latitude in establishing price, has discretion in supplier selection and is involved in the determination of product or service specifications. As such, the Company records the gross amount of the reimbursement of third-party development costs for the ongoing clinical trials as revenue and the costs associated with these reimbursements are reflected as a component of research and development expense in the Company s consolidated statement of operations. For the quarter ended March 31, 2010, the Company recognized revenue of approximately $847,000 as reimbursable research and development costs in the condensed consolidated statement of operations.

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Revenue from milestone payments, if any, will be recognized upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, the Company will defer recognition of the milestone payment and recognize it as revenue over the estimated period of performance under the License Agreement as the related performance obligations are completed.

The License Agreement provides that revenues recognized for royalty payments, if any, will be based upon actual net sales of licensed products in the period the sales occur.

Any amounts received by the Company pursuant to the License Agreement prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue on the consolidated balance sheet.

5. Restructuring

In May 2009, the Company committed to a restructuring plan (the Restructuring Plan) intended to conserve the financial resources of the Company by focusing on its clinical-stage programs. Employees directly affected by the Restructuring Plan received notification and were provided with severance payments upon termination, continued benefits for a specified period of time and outplacement assistance.

The Company expects to incur total restructuring charges of approximately $820,000, primarily for severance-related costs in connection with the Restructuring Plan. The Company did not incur any expense related to contractual or lease obligations or other exit costs. Total restructuring charges of approximately $793,000 were included in research and development expense and approximately $27,000 in general and administrative expense in 2009. The restructuring charges were primarily recognized during the second and third quarters of 2009. The Company made the final payment under the Restructuring Plan in April 2010.

As of March 31, 2010, the Company has paid $664,000 of the total $669,000 cash restructuring charges. The total non-cash charges of approximately $151,000 are primarily for share-based compensation expense resulting from stock option modifications which were included in research and development expense in the second quarter of 2009.

6. Commitments and Contingencies

Under the Asset Purchase Agreement between Valeant Research and Development, Inc. (Valeant) and the Company, dated December 21, 2006, the Company is obligated to make development-based milestone payments and sales-based royalty payments to Valeant upon subsequent development of certain products. The aggregate contingent liability of up to $42,000,000 in milestone payments for the programs covered under the Asset Purchase Agreement is considered a liability in the ordinary course of business. Each milestone payment will be recorded when the related contingency is resolved and consideration is issued or becomes issuable, none of which have occurred as of March 31, 2010.

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7. Long-term Debt

During the first quarter of 2010, the Company did not enter into any new long-term debt obligations. The following is a summary of the Company s long-term debt obligations as of March 31, 2010:

Years ended December 31,	Notes Payable	Capital Lease
2010 (remaining nine months of the year)	$ 2,606	$ 87
2011	3,875	78
2012	46	
2013	45	
2014	45	
Thereafter	19	
Total	6,636	165
Less unamortized discount	(115)	
Less amount representing interest	(1,051)	(7)
Total balance	5,470	158
Less current portion	(2,974)	(110)
Noncurrent portion of long-term debt	$ 2,496	$ 48

8. Stockholders Equity

Share-Based Compensation

Share-based compensation expense related to the Company s equity compensation plans recognized for the three-month periods ended March 31, 2010 and 2009 was approximately $1,613,000 and $1,542,000, respectively. As of March 31, 2010, there was $11,977,000 of total unrecognized compensation cost related to non-vested, share-based payment awards granted under all of the Company s equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize this compensation cost over a weighted-average period of 2.3 years.

The following table summarizes share-based compensation expense for the three months ended March 31, 2010 and 2009 related to employee and director stock options and Employee Stock Purchase Plan (ESPP) purchase rights by expense category (in thousands):

	Three Months Ended March 31,	
	2010	2009
Research and development	$ 684	$ 674
General and administrative	929	868
Share-based compensation expense included in operating expenses	$ 1,613	$ 1,542

The Company estimated the fair value of each option grant on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	March 31,	
	2010	2009
Options:		

Risk-free interest rate	2.8%	1.8%
Dividend yield	0.0%	0.0%
Volatility	78.3%	78.0%
Expected life (years)	5.5-6.1	5.5

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The Company estimates the fair value of each purchase right granted under the ESPP at the beginning of each new offering period using the Black-Scholes option valuation model. A new offering period begins every six months in May and November of each year. For the three months ended March 31, 2010 and 2009, there were no new offering periods or ESPP purchase rights granted.

9. Income Taxes

Deferred income tax assets and liabilities are recognized for temporary differences between financial statements and income tax carrying values using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding the Company s ability to generate future taxable income and consequently realize such deferred income tax assets, a full valuation allowance has been established. The Company continues to maintain a full valuation allowance against its deferred tax assets as of March 31, 2010.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant tax authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There have been no material changes in the Company s unrecognized tax benefits since December 31, 2009 and as such, disclosures included in the Company s 2009 Annual Report on Form 10-K continue to be relevant for the period ended March 31, 2010.

Provisions in the recently enacted Patient Protection and Affordable Care Act (the Act) established funding to provide for a 50% refundable investment tax credit to eligible taxpayers for qualified investments made previously by them in qualifying therapeutic discovery projects under section 48D of the Internal Revenue Code. The Company intends to apply for a tax credit under the Act. However, due to the uncertain nature of the tax credit approval process, the limited funds allocated to the tax credit program and the likely significant number of competing applicants, there can be no assurance that the Company s application will be approved or what amount of funding, if any, will be awarded. Consequently, the Company will not record a related tax benefit in the financial statements until its application is approved by the Treasury Department.

10. Subsequent Events

In April 2010, the Company completed a public offering of 4,025,000 shares of its common stock, including 525,000 shares sold pursuant to the full exercise of an overallotment option granted to the underwriters. The net proceeds to the Company from the sale of shares in the offering, before expenses and after deducting underwriting discounts and commissions, were approximately $77.1 million.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and related notes included in this quarterly report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2009 included in our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the Securities and Exchange Commission, or SEC, on March 12, 2010.

This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those set forth under Risk Factors and elsewhere in this quarterly report on Form 10-Q. All forward-looking statements included in this document are based on information available to us on the date of this document and we assume no obligation to update any forward-looking statements contained in this Form 10-Q.

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Overview and Business Strategy

Ardea Biosciences, Inc., of San Diego, California, is a biotechnology company focused on the development of small-molecule therapeutics for the treatment of gout, cancer and human immunodeficiency virus (HIV). The current status of our development programs is as follows:

Product Portfolio

Product Candidate	Target Indication	Development Status
RDEA594	Gout	Phase 2b ongoing
Next-generation	Gout	Preclinical development ongoing
RDEA119	Cancer	Phase 1 and Phase 1/2 ongoing
RDEA806	HIV	Phase 2a completed
RDEA427	HIV	Phase 0* completed

* First-in-human micro-dose pharmacokinetic study in normal healthy volunteers.

GOUT

Gout is a painful and debilitating disease caused by abnormally elevated levels of uric acid in the blood stream. While gout is a treatable condition, there are limited treatment options, and a number of adverse effects are associated with most current therapies.

Approximately 90 percent of gout patients are considered to have a defect in their ability to excrete sufficient amounts of uric acid and are classified as under-excreters of uric acid, which leads to excessive levels of uric acid in the blood (Rheumatology 2007; 46:215 219). Our most advanced product candidate, RDEA594, is a selective inhibitor of URAT1, a transporter in the kidney that regulates uric acid excretion from the body. RDEA594 has been shown to normalize the amount of uric acid excreted by gout patients. Since the majority of gout patients are under-excreters , normalizing uric acid excretion by moderating URAT1 transporter activity with RDEA594 may provide the most physiologically appropriate and effective means of reducing blood or serum uric acid (sUA) levels when used alone or in combination with other sUA lowering agents, such as allopurinol or febuxostat (Uloric®, Takeda Pharmaceutical Company Limited; Adenuric®, Ipsen and Menarini), which act by reducing the production of uric acid in the body.

The RDEA594 Phase 2 development program is nearing completion. To date, results from this program have indicated RDEA594 s broad clinical utility, as follows:

When administered as a single agent in a recently completed Phase 2b study, RDEA594 was well tolerated and produced significant sUA reductions. In this randomized, double-blind, placebo-controlled, dose-escalation study of 123 gout patients with hyperuricemia (sUA levels greater than or equal to 8 mg/dL) the primary endpoint was a significant increase in the proportion of patients who achieved a response, defined as a reduction of sUA to < 6 mg/dL after four weeks of treatment, compared to placebo. The primary endpoint was achieved. Reductions in sUA and increased response rates occurred in a dose-related manner and were highly clinically and statistically significant at the two highest doses tested. At the highest dose, there was a 38 percent median reduction in sUA levels after four weeks compared to a 1 percent increase on placebo ($p < 0.0001$). This translated into a response rate of 45 percent, compared to 0 percent for placebo ($p < 0.0001$). The response rate at the highest dose in patients with baseline sUA levels of <10 mg/dL (9.2 mg/dL on average) was 58 percent ($p = 0.0012$). Industry sources indicate that patients with serum urate levels less than 10 mg/dL represent a large majority of the gout patient population. RDEA594 was also well tolerated with a profile of possibly drug-related adverse events comparable to placebo and only two patients (2 percent)

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randomized to RDEA594 discontinuing treatment due to an adverse event.

In a Phase 2a study, RDEA594 was well tolerated and produced significant reductions in sUA levels when administered as a single agent and when combined with allopurinol in gout patients with hyperuricemia. Significant reductions in sUA were also demonstrated when RDEA594 was administered as a single agent in gout patients with mild to moderate renal impairment. The single-agent reductions and response rates observed with RDEA594 were comparable to those achieved with approved doses of allopurinol and febuxostat. The combination of RDEA594 and allopurinol in gout patients was well tolerated and reduced sUA levels an additional 24 percent compared to allopurinol alone.

The combination of RDEA594 and febuxostat in a Phase 1 study in healthy volunteers was well tolerated and resulted in sUA reductions of approximately 70 to 80 percent from baseline.

Additional data from our Phase 2 development program will include results from a Phase 2b study evaluating 200 mg, 400 mg and 600 mg of RDEA594 as an add-on to allopurinol in patients that do not respond adequately to allopurinol alone, and studies of RDEA594 in subjects with renal impairment.

Based on preclinical results, our next-generation inhibitors of the URAT1 transporter for the treatment of gout patients with hyperuricemia demonstrate many of the same positive attributes as RDEA594, but with significantly greater potency against the URAT1 transporter. Preclinical development activities with respect to these next-generation product candidates are ongoing.

CANCER

Mitogen-activated ERK kinase (MEK) is believed to play an important role in cancer cell proliferation, apoptosis and metastasis. RDEA119 is a potent and selective inhibitor of MEK in development for the treatment of cancer. *In vivo* preclinical tests have shown RDEA119 to have potent anti-tumor activity. In addition, preclinical *in vitro* and *in vivo* studies of RDEA119 have demonstrated synergistic activity across multiple tumor types when RDEA119 is used in combination with other anti-cancer agents, including sorafenib (Nexavar®, Bayer HealthCare AG (Bayer) and Onyx Pharmaceuticals, Inc.).

RDEA119 is currently being evaluated in advanced cancer patients with different tumor types as a single agent in a Phase 1 study, as well as in combination with sorafenib in a Phase 1/2 study.

In April 2009, we entered into a global license agreement with Bayer to develop and commercialize MEK inhibitors for the treatment of cancer. Under the license agreement, we are responsible for the completion of the ongoing Phase 1 and Phase 1/2 studies. Thereafter, Bayer will be responsible for the further development and commercialization of RDEA119 and any of our other MEK inhibitors.

HIV

RDEA806, a non-nucleoside reverse transcriptase inhibitor, or NNRTI, for the treatment of HIV, has successfully completed Phase 1 and Phase 2a studies and has been evaluated in over 250 subjects. Results from a Phase 2a monotherapy proof-of-concept study of RDEA806 demonstrated placebo-adjusted plasma viral load reductions of up to 2.0 $\log_{10}$ on day 8 with once-daily dosing of RDEA806. All dosing regimens tested were well tolerated in this study.

RDEA427, a next generation NNRTI, is from a chemical class that is distinct from the RDEA806 chemical class. Based on preclinical results, RDEA427 demonstrates many of the same positive attributes as RDEA806, but is more potent, has superior pharmacokinetic properties, and has even greater activity against a wide range of drug-resistant viral isolates, than RDEA806. We have evaluated RDEA427 in a human micro-dose pharmacokinetic study.

The timing of future studies of RDEA806 and RDEA427 will be dependent on the results of our partnering efforts.

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Bayer Relationship

Under the terms of our license agreement with Bayer, we granted to Bayer a worldwide, exclusive license to develop and commercialize our MEK inhibitors for all indications. In June 2009, Bayer paid us a non-refundable, upfront cash payment of $35 million in partial consideration for