Ardea Biosciences, Inc./DE
Form 10-Q
May 11, 2009

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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, 2009

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. (Check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer o Smaller Reporting Company o

(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 o No þ

The number of shares of the registrant s common stock, par value $0.001 per share, outstanding as of April 30, 2009 was 17,856,061.

ARDEA BIOSCIENCES, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2009
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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, 2009 (Unaudited)	December 31, 2008 (See Note)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,625	$ 41,551
Short-term investments, available-for-sale	28,456	16,192
Receivables	179	384
Prepaids and other current assets	219	237
Total current assets	45,479	58,364
Property and equipment, net	2,234	2,310
Other assets	730	801
Total assets	$ 48,443	$ 61,475
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,374	$ 2,260
Accrued clinical liabilities	2,855	2,278
Accrued payroll and employee liabilities	1,481	1,758
Other accrued liabilities	629	545
Current portion of obligations under capital lease	103	102
Current portion of obligations under notes payable	2,641	1,958
Total current liabilities	9,083	8,901
Deferred rent	107	84
Non-current portion of obligations under capital lease	157	175
Non-current portion of obligations under notes payable	5,313	5,957
Other long-term liabilities	400	400
Commitments and contingencies (see Note 4)		
Stockholders equity:		
Convertible preferred stock		
Common stock	17	17
Additional paid-in capital	363,960	362,345
Accumulated other comprehensive income	52	139

Accumulated deficit	(330,646)	(316,543)
Total stockholders equity	33,383	45,958
Total liabilities and stockholders equity	$ 48,443	$ 61,475

Note: The condensed consolidated balance sheet at December 31, 2008 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,	
	2009	2008
Collaboration revenues	$	$ 260
Operating expenses:		
Research and development	10,996	9,969
General and administrative	2,877	3,408
Total operating expenses	13,873	13,377
Loss from operations	(13,873)	(13,117)
Other income (expense):		
Interest income	136	607
Interest expense	(364)	
Other income, net	(2)	135
Total other income (expense)	(230)	742
Net loss	(14,103)	(12,375)
Non-cash dividends on Series A preferred stock		(60)
Net loss applicable to common stockholders	$ (14,103)	$ (12,435)
Basic and diluted net loss per share applicable to common stockholders	$ (0.79)	$ (0.93)
Shares used in computing basic and diluted net loss per share applicable to common stockholders	17,849	13,341

See accompanying notes.

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

	Three Months Ended March 31,	
	2009	2008
Operating activities:		
Net loss	$ (14,103)	$ (12,375)
Adjustments to reconcile net loss to net cash used for operating activities:		
Share-based compensation	1,542	1,110
Depreciation	171	89
Amortization of debt discount and debt issuance costs	117	
Gain on disposal of property and equipment	2	
Deferred rent	23	
Amortization of premium on short-term investments	18	9
Change in operating assets and liabilities:		
Receivables	205	823
Prepaids and other current assets	18	(188)
Other assets		(9)
Accounts payable	(886)	761
Accrued clinical liabilities	577	1,133
Accrued payroll and employee liabilities	(277)	(467)
Other accrued liabilities	84	1
Net cash used for operating activities	(12,509)	(9,113)
Investing activities:		
Purchases of short-term investments	(15,819)	(21,327)
Proceeds from sale or maturity of short-term investments	3,450	2,450
Proceeds from sale of property and equipment	8	
Purchases of property and equipment	(105)	(1,294)
Net cash used for investing activities	(12,466)	(20,171)
Financing activities:		
Payments on notes payable obligations	(7)	
Payments on capital lease obligations	(17)	
Net proceeds from issuance of common stock	73	197
Net cash provided by financing activities	49	197
Net decrease in cash and cash equivalents	(24,926)	(29,087)
Cash and cash equivalents at beginning of period	41,551	46,384
Cash and cash equivalents at end of period	$ 16,625	$ 17,297

Supplemental schedule of non-cash information:		
Net unrealized gain (loss) on short-term investments	$ (87)	$ 169
Issuance of common stock dividend on Series A preferred stock	$	$ (60)

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, 2009 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2009. 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, 2008 included in the Company s Form 10-K filed with the Securities and Exchange Commission.

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 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 2008 financial statements have been reclassified to conform to the 2009 presentation.

Revenue Recognition

The Company recognizes revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*. Amounts received for research funding are recognized as revenues as the research services that are the subject of such funding are performed. Revenue from milestones is recognized when earned, as evidenced by written acknowledgement from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement.

Net Loss Per Share

Basic and diluted net loss per share is calculated in accordance with Statement of Financial Accounting Standard (SFAS) No. 128, *Earnings per Share,* and SAB No. 98. 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

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net 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 both 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

SFAS No. 130*, Reporting Comprehensive Income* (SFAS 130), requires that all components of comprehensive income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. In accordance with SFAS 130, unrealized gains and losses on available-for-sale securities are included in other comprehensive income (loss) and represent the difference between the Company s net loss and comprehensive net loss for both periods presented. The Company s unrealized gain (loss) on short-term investments totaled ($87,000) and $169,000 for the three months ended March 31, 2009 and 2008, respectively. The Company s comprehensive net loss totaled $14,190,000 and $12,206,000 for the three months ended March 31, 2009 and 2008, respectively.

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (the FASB) ratified the consensus reached by the Emerging Issues Task Force (EITF) on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The EITF concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each participating company s financial statements pursuant to the guidance in Issue 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The EITF also concluded that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. Furthermore, the EITF concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities operations; and whether the partners payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2008, and companies will be required to apply the provisions through retrospective application. On January 1, 2009, the Company adopted the provisions of EITF 07-1, which did not have an impact on the Company s unaudited condensed consolidated results of operations and financial condition for the three months ended March 31, 2009.

In February 2008, FASB Staff Position (FSP) FAS 157-2, *Effective Date of FASB Statement No. 157*, was issued. This FSP provided for a one-year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. On January 1, 2009, the Company adopted the provisions of SFAS No. 157, *Fair Value Measurements* (SFAS 157), with respect to non-financial assets and liabilities, which did not have an impact on the Company s unaudited condensed consolidated results of operations and financial condition for the three months ended March 31, 2009. See Note 3 for further details.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for

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selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP. SFAS 162 shall be effective 60 days following the Securities and Exchange Commission s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not currently believe that the adoption of SFAS 162 will have a material impact on its results of operations and financial condition.

3. Fair Value Measurements

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 provides a definition of fair value, establishes a hierarchy for measuring fair value under GAAP, and requires certain disclosures about fair values used in the financial statements. SFAS 157 does not extend the use of fair value beyond what is currently required by other pronouncements, and it does not pertain to share-based compensation under SFAS No. 123R, *Share-Based Payments* (SFAS 123R) or to leases under SFAS No. 13, *Accounting for Leases*.

SFAS 157 defines fair value 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 under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a 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, which are the following:

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, 2009 (in thousands) were as follows:

	Fair Value Measurements at Reporting Date Using			
	Balance at March 31, 2009	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market funds	$13,783	$ 13,783	$	$
United States government and agency obligations	25,460	4,485	20,975	
United States corporate debt securities	5,495		5,495	
Total	$44,738	$ 18,268	$ 26,470	$

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of SFAS No. 115* (SFAS 159). SFAS 159 expands the use of fair-value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS 159, 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

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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. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings.

The Company considers the carrying amount of cash and cash equivalents, prepaid expenses and other current assets, securities available-for-sale, receivables, accounts payable, 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 the long-term obligations approximate their carrying value. Therefore, the Company has elected not to apply the fair value option to these financial assets and liabilities under SFAS 159. However, the Company does apply fair value accounting to its securities available-for-sale in accordance with SFAS No. 115.

Unrealized gains and losses associated with the Company s investments, if any, are reported in stockholders equity in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. For the three months ended March 31, 2009, the Company recognized $87,000 in net unrealized losses associated with its short-term investments.

4. 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 assumable, none of which have occurred as of March 31, 2009.

5. Stockholders Equity

Share-Based Compensation

Share-based compensation expense related to the Company s equity compensation plans recognized under SFAS 123R for the three-month periods ended March 31, 2009 and 2008 was $1,542,000 and $1,110,000, respectively. As of March 31, 2009, there was $13,320,000 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 2.6 years.

The following table summarizes share-based compensation expense related to employee and director stock options and Employee Stock Purchase Plan (ESPP) purchase rights under SFAS 123R by expense category (in thousands):

	Three Months Ended March 31,	
	2009	2008
Research and development	$ 674	$ 452
General and administrative	868	658
Share-based compensation expense included in operating expenses	$ 1,542	$ 1,110

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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,	
	2009	2008
Options:		
Risk-free interest rate	1.8%	4.2%
Dividend yield	0.0%	0.0%
Volatility	78.0%	73.0%
Expected life (years)	5.5	6.3

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, 2009 and 2008, there were no new offering periods or ESPP purchase rights granted.

6. Subsequent Events

In April 2009, the Company entered into a Development and Commercialization License Agreement (the License Agreement) with Bayer HealthCare 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 consideration for the license, Bayer will pay the Company a committed upfront cash fee of $35 million for the development and commercialization rights to the Company s MEK inhibitors. 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 for worldwide sales of products covered under the License Agreement.

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. The Restructuring Plan will result in a reduction of approximately 47% of the Company s workforce with the majority of the reductions coming from discovery research and associated general and administrative personnel. Employees directly affected by the Restructuring Plan have received notification and will be provided with severance payments upon termination, continued benefits for a specified period of time and outplacement assistance.

The Company anticipates charges related to the Restructuring Plan of approximately $0.9 million, primarily associated with personnel-related termination costs in 2009. Of this amount, $0.8 million is expected to be paid in cash and the remainder will result from non-cash, share-based compensation expense. The majority of these costs will be recognized during the second quarter of 2009.

The severance-related charges that the Company expects to incur in connection with the Restructuring Plan are subject to a number of assumptions, and actual results may materially differ. The Company may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the Restructuring Plan.

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, 2008 included in our Annual Report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission, or SEC, on March 13, 2009.

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

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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.

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, human immunodeficiency virus (HIV), cancer and inflammatory diseases. We are currently pursuing multiple development programs, including the following:

Product Portfolio

Product Candidate	Target Indication	Development Status
RDEA594	Gout	Phase 2 initiating
RDEA806	HIV	Phase 2a completed
RDEA427	HIV	Phase 0* completed
RDEA119	Cancer	Phase 1 and Phase 1/2 ongoing
RDEA119	Inflammation	Phase 1 completed
RDEA436	Inflammation	Phase 0* completed

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

GOUT

RDEA594

RDEA594 is an inhibitor of URAT1, a transporter in the kidney that regulates uric acid excretion from the body. RDEA594 was well tolerated in Phase 1 studies in normal healthy volunteers and demonstrated significant dose-related decreases in serum uric acid of up to 30% over the first 24 hours after administration of single-ascending doses and up to 45% after 10 days administration of multiple doses. We plan to complete a number of additional studies by the end of 2009, including a Phase 2 dose-ranging study of RDEA594 in gout patients. The uric acid-lowering activity of RDEA594, when administered as its prodrug, RDEA806, has also been demonstrated in a recently completed Phase 2a proof-of-concept study of RDEA806 in gout patients. All of our future studies in gout will be conducted directly with RDEA594.

HIV

RDEA806

RDEA806 is our lead non-nucleoside reverse transcriptase inhibitor, or NNRTI, for the treatment of HIV. *In vitro* preclinical tests have shown RDEA806 to be a potent inhibitor of a wide range of HIV viral isolates, including isolates that are resistant to efavirenz (SUSTIVA®/Stocrin® from Bristol-Myers Squibb Company and Merck & Co., Inc.), the most widely prescribed NNRTI, in addition to other currently available NNRTIs. *In vitro* preclinical tests have also shown RDEA806 to have a high genetic barrier to resistance. *In vivo* preclinical tests suggest that RDEA806 does not pose a risk of reproductive toxicity. Based on both preclinical and clinical data, we anticipate that RDEA806 could be amenable to a once-daily oral dosing regimen, may have limited pharmacokinetic interactions with other drugs and may be readily co-formulated in a single pill with other HIV antiviral drugs, such as Truvada® (emtricitabine and tenofovir from Gilead Sciences, Inc.), which is important for patient compliance and efficacy.

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RDEA806 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. In addition, all dosing regimens tested were well tolerated. We have continued preparing RDEA806 for further clinical development by obtaining additional regulatory approvals to conduct an international Phase 2b HIV trial and by completing a number of important preparatory safety and supportive toxicology studies, including a Thorough QT study. Results from the Thorough QT study demonstrated that QTc intervals were not increased by any dose of RDEA806 tested. In addition, the study provided information on the lack of pharmacokinetic differences between Caucasians and African-Americans. These results provide further support for RDEA806 s cardiac safety profile, as well as its potential to improve current standard-of-care therapy by decreasing the documented increased side effects of efavirenz (Sustiva®, Bristol-Myers Squibb) in African-Americans believed to result from ethnicity-based differences in metabolism. We anticipate that the timing of future studies of RDEA806 will be determined in part by the results of our partnering efforts.

RDEA427

The lead compound in our next generation NNRTI program, RDEA427, is from a chemical class that is distinct from the RDEA806 chemical class. Based on early preclinical data, we believe that RDEA427 may share certain of the positive attributes of RDEA806, but may also have even greater activity against a wide range of drug-resistant viral isolates. We have evaluated RDEA427, in a human micro-dose pharmacokinetic study. We anticipate that the timing of future studies of RDEA427 will be determined in part by the results of our partnering efforts.

CANCER

RDEA119

RDEA119, our lead mitogen-activated ERK kinase, or MEK, inhibitor for the treatment of cancer, is a potent and selective inhibitor of MEK, which is believed to play an important role in cancer cell proliferation, apoptosis and metastasis. *In vivo* preclinical tests have shown RDEA119 to have potent anti-tumor activity.

Data from an ongoing Phase 1 study of RDEA119 in advanced cancer patients suggests that RDEA119 has a pharmacokinetic profile allowing for convenient once-daily oral dosing. Once the maximum tolerated dose is determined, we plan to evaluate the activity of RDEA119 in advanced cancer patients with selected tumor types, such as hepatocellular, sarcoma, glioma, non-small cell lung, colon, pancreatic or thyroid cancer or melanoma.

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® from Bayer HealthCare AG (Bayer) and Onyx Pharmaceuticals, Inc.). We are currently conducting a Phase 1/2 study of RDEA119 in combination with sorafenib in advanced cancer patients to evaluate the safety, tolerability, pharmacokinetics and anti-tumor activity of this combination therapy. Under our Development and License Agreement (the License Agreement) with Bayer we are responsible for the completion of the Phase 1 and Phase 1/2 studies currently being conducted for RDEA119. Thereafter, Bayer will be responsible for the further development and commercialization of RDEA119 and any of our other MEK inhibitors.

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INFLAMMATION

RDEA119

In vivo preclinical tests have also shown RDEA119 to significantly inhibit production of inflammatory cytokines. Results from a completed Phase 1 study in normal healthy volunteers demonstrated that RDEA119 was well tolerated with a pharmacokinetic profile allowing for convenient once-daily oral dosing. The timing of future studies of RDEA119 for inflammatory diseases, if any, will be determined by Bayer pursuant to the License Agreement.

RDEA436

The lead compound in our next generation MEK inhibitor program, RDEA436, is from a chemical class that is distinct from the RDEA119 chemical class. Based on early preclinical data, we believe that RDEA436 may potentially share certain of the positive attributes of RDEA119, and may have even greater potency than RDEA119. We have evaluated RDEA436 in a human micro-dose pharmacokinetic study. We received regulatory approval in December 2008 to initiate a Phase 1 study of RDEA436 evaluating safety, pharmacokinetics and inflammatory disease biomarkers in normal healthy volunteers. The timing of future studies of RDEA436 for inflammatory diseases, if any, will be determined by Bayer pursuant to the License Agreement.

Valeant Relationship

On December 21, 2006, we acquired intellectual property and other assets from Valeant Research & Development, Inc. related to RDEA806 and our next generation NNRTI program, and RDEA119 and our next generation MEK inhibitor program. Concurrent with the closing of the acquisition from Valeant, we hired a new senior management team and changed our name from IntraBiotics Pharmaceuticals, Inc. to Ardea Biosciences, Inc.

In consideration for the assets purchased from Valeant and subject to the satisfaction of certain conditions, Valeant has the right to receive development-based milestone payments and sales-based royalty payments from us. There is one set of milestones for RDEA806 and the next generation NNRTI program and a separate set of milestones for RDEA119 and the next generation MEK inhibitor program. In the event of the successful commercialization of a product incorporating RDEA806 or a compound from the next generation NNRTI program, resulting milestone payments could total up to $25.0 million. In the event of the successful commercialization of a product incorporating RDEA119 or a compound from the next generation MEK inhibitor program, resulting milestone payments could total up to $17.0 million. Milestones are paid only once for each program, regardless of how many compounds are developed or commercialized. The first milestone payments of $2.0 million and $1.0 million in the NNRTI program and the MEK inhibitor program, respectively, would be due after the first patient is dosed in the first Phase 2b study, and approximately 80% of the total milestone payments in each program would be due upon United States Food and Drug Administration acceptance and approval of a New Drug Application, or NDA. The royalty rates on all products are in the mid-single digits. We agreed to further develop these compounds with the objective of obtaining marketing approval in the United States, the United Kingdom, France, Spain, Italy and Germany.

Valeant also has the right to exercise a one-time option to repurchase commercialization rights in territories outside the United States and Canada (the Valeant Territories) to the first NNRTI compound derived from the acquired intellectual property to complete a Phase 2b study in HIV. If Valeant exercises this option, which it can do following the completion of a Phase 2b HIV study, but prior to the initiation of a Phase 3 study, we would be responsible for completing Phase 3 studies and for registration of the product in the United States and the European Union. Valeant would pay us a $10.0 million option fee, up to $21.0 million in milestone payments based on regulatory approvals, and a mid-single-digit royalty on product sales in the Valeant Territories.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our

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unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to accrued clinical liabilities and share-based compensation. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following critical accounting policies involve significant judgments and estimates used in the preparation of our condensed consolidated financial statements.

Accrued Clinical Liabilities

We review and accrue clinical costs based on work performed, which relies on estimates of the services received and related expenses incurred. Clinical trial-related contracts vary significantly in length, and may be for a fixed amount, based on milestones or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development costs; however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

Share-Based Compensation

We grant equity based awards under three share-based compensation plans. We have granted, and may in the future grant, options and restricted stock awards to employees, directors, consultants and advisors under either our 2002 Non-Officer Equity Incentive Plan or our 2004 Stock Incentive Plan. In addition, all of our employees are eligible to participate in our 2000 Employee Stock Purchase Plan which enables employees to purchase common stock at a discount through payroll deductions. The benefits provided under all of these plans are subject to the provisions of Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment* (SFAS 123R), which we adopted effective January 1, 2006 under the modified prospective application method. The valuation provisions of SFAS 123R apply to new awards and to awards that are outstanding on the adoption date and are subsequently modified or cancelled.

We estimate the fair value of stock options granted using the Black-Scholes-Merton, or Black-Scholes, option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including each option s expected life and price volatility of the underlying stock. Expected volatility is based on the weighted-average volatility of our stock factoring in daily share price observations and the historical price volatility of certain peers within our industry sector. In computing expected volatility, the length of the historical period used is equal to the length of the expected term of the option and the share purchase right. The expected life of employee stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method, under Staff Accounting Bulletin No. 107, *Share-Based Payments* and SAB No. 110.

As share-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (the FASB) ratified the consensus reached by the Emerging Issues Task Force (EITF) on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The scope of EITF 07-1 is limited to collaborative

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arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The EITF concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each participating company s financial statements pursuant to the guidance in Issue 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The EITF also concluded that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. Furthermore, the EITF concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities respective operations; and whether the partners payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2008, and companies will be required to apply the provisions through retrospective application. On January 1, 2009, we adopted the provisions of EITF 07-1, which did not have an impact on our unaudited condensed consolidated results of operations and financial condition for the three months ended March 31, 2009.

In February 2008, FASB Staff Position (FSP) FAS 157-2, *Effective Date of FASB Statement No. 157*, was issued. This FSP provided for a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. On January 1, 2009, we adopted the provisions of SFAS No. 157, *Fair Value Measurements* (SFAS 157), with respect to non-financial assets and liabilities, which did not have an impact on our unaudited condensed consolidated results of operations and financial condition for the three months ended March 31, 2009. See Note 3 to the unaudited condensed consolidated financial statements for further details.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP. SFAS 162 shall be effective 60 days following the Securities and Exchange Commission s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not currently believe that the adoption of SFAS 162 will have a material impact on our results of operations and financial condition.

Results of Operations

Three Months Ended March 31, 2009 and 2008

Revenues

There were no revenues for the three months ended March 31, 2009. Revenues for the three months ended March 31, 2008 totaled $0.3 million. Historically, our revenues have resulted from the research services we have provided under our master services agreement with Valeant for its preclinical neuropharmacology program. The decrease in revenues from 2008 was due to the earlier than anticipated identification of a clinical development candidate from that program and Valeant s subsequent reduction in the utilization of our research and development services.

Research and Development Expense

For the three months ended March 31, 2009, research and development expense increased to $11.0 million from $10.0 million for the same period in 2008. The increase in research and development expense was primarily due to continued development and progression of our clinical stage programs, which included increased spending of approximately $0.7 million on contract manufacturing organizations, investigator grants and consultants for the three months ended March 31, 2009. In addition, the increase in research and development expense was a result of additional personnel and related costs of approximately $0.5 million and an increase in share-based compensation expense of approximately $0.2 million for the three months ended March 31, 2009 due to increased headcount.

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These increases were partially offset by a decrease of approximately $0.5 million in facility related expenses due to one-time costs incurred in the first quarter of 2008 related to the facility relocation and decreased monthly rent and common area maintenance charges for the San Diego facility which we occupied beginning in March 2008.

General and Administrative Expense

For the three months ended March 31, 2009, general and administrative expense decreased to $2.9 million from $3.4 million for the same period in 2008. The decrease in general and administrative expense was primarily the result of costs incurred in the first quarter of 2008 related to the facility relocation of approximately $0.3 million and a decrease in consulting costs of approximately $0.5 million, partially offset by increased share-based compensation expense and personnel costs of approximately $0.2 million and $0.1 million, respectively, for the three months ended March 31, 2009 as a result of increased headcount.

Other Income (expense)

For the three months ended March 31, 2009, other income (expense) decreased to a $0.2 million net other expense from a $0.7 million net other income for the same period in 2008. The decrease in other income (expense) was primarily a result of a decrease in interest income due to lower average interest rates and lower average cash balances in 2009 as compared to 2008 and an increase in interest expense in connection with our growth capital loan and capital lease obligations entered into in the second half of 2008.

Liquidity and Capital Resources

From inception through March 31, 2009, we have incurred a cumulative net loss of approximately $330.6 million and have financed our operations through public and private offerings of securities, proceeds from our growth capital loan, revenues from collaborative agreements and interest income from invested cash balances.

In May 2009, we committed to a restructuring plan (the Restructuring Plan) intended to conserve our financial resources by focusing on our clinical-stage programs. The Restructuring Plan will result in a reduction of approximately 47% of our workforce with the majority coming from discovery research and associated administrative personnel. Estimated cost savings from the Restructuring Plan, net of severance and related costs, are expected to be $2.3 million in 2009 and $6.6 million per year thereafter.

In April 2009, we entered into the License Agreement with Bayer. Under the terms of the License Agreement, we have granted to Bayer a worldwide, exclusive license to develop and commercialize our MEK inhibitors for all indications. In consideration for the license, Bayer will pay us a committed upfront cash fee of $35 million for the development and commercialization rights to our MEK inhibitors. We are 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 for worldwide sales of products covered under the License Agreement.

In December 2008, we raised $30.5 million by selling 2,737,336 newly issued unregistered shares of our common stock and warrants to purchase 684,332 shares of common stock at a total purchase price of approximately $11.17 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.25 shares of common stock at an exercise price of $11.14 per share. On January 13, 2009, we filed a registration statement with the SEC covering the resale of these shares and the shares issuable upon exercise of the warrants. This registration statement was declared effective by the SEC on January 21, 2009.

In November 2008, we entered into an agreement with Oxford Finance Corporation and Silicon Valley Bank, (collectively the Lenders), pursuant to which the Lenders provided us with an approximately three-year, $8.0 million growth capital loan. Interest accrues at a rate of 12% per annum, with monthly interest only payments required during a period that began on the loan funding date and continued through February 28, 2009, followed thereafter by equal monthly payments of principal and interest over a period of 33 months. In addition, we are required to pay a total loan commitment fee of approximately $0.5 million, of which $0.1 million was paid upon entering into the loan agreement and the remaining $0.4 million is due at the end of the term of the loan. We have the option to prepay the outstanding balance of the loan in full, subject to a prepayment fee.

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The loan is collateralized by our general assets, excluding intellectual property. There are no financial covenants associated with the loan. In connection with the loan, we issued to the Lenders warrants to purchase up to an aggregate of 56,010 shares of our common stock at an exercise price of $8.57 per share. The warrants are currently exercisable and expire seven years from the date of issuance.

In July 2008, we entered into a capital lease agreement for approximately $318,000 to finance the purchase of certain equipment. The agreement is secured by the equipment, bears interest at 6.05% per annum, and is payable in monthly installments of principal and interest of approximately $10,000 for 36 months beginning in September 2008.

We lease our office and laboratory facilities and certain equipment under operating leases. In March 2008, we exercised our right under our sublease agreement to borrow from the sublessor approximately $250,000 for costs incurred and paid for certain tenant improvements. The note bears interest at 7.00% per annum and is payable in monthly installments of principal and interest of approximately $4,000 for 84 months beginning in June 2008.

As of March 31, 2009, we had $45.1 million in cash, cash equivalents, and short-term investments compared to $57.7 million as of December 31, 2008. Our March 31, 2009 cash, cash equivalents, and short-term investments balance does not include the $35 million, non-refundable, upfront license fee from Bayer. The decrease in cash, cash equivalents and short-term investments for the first three months of 2009 was due to the use of our financial resources to fund our clinical stage programs, personnel costs, and for other general corporate purposes.

Under the asset purchase agreement with Valeant, we will be required to pay Valeant $2.0 million after the first patient is dosed in the first Phase 2b study for the NNRTI program.

We also enter into agreements from time to time with clinical sites and contract research organizations for the conduct of our clinical trials. We make payments to these sites and organizations based upon the number of patients enrolled and the length of their participation in the clinical trials. Under certain of these agreements, we may be subject to penalties in the event that we prematurely terminate performance under these agreements. At this time, due to the variability associated with clinical site and contract research organization agreements, we are unable to estimate with certainty the future costs we will incur. We intend to use our current financial resources to fund our obligations under these commitments.

In addition, we entered into employment agreements with our executive officers and certain other key employees that, under certain circumstances, provide for the continuation of salary and certain other benefits if terminated under special circumstances. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. As of March 31, 2009, no events have occurred resulting in the obligation to make any such payments.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors may include, but are not limited to, the following: the rate of progress and cost of our clinical trials and other research and development activities; the scope, prioritization and number of clinical development and research programs we pursue; the terms and timing of any collaborative, licensing and other arrangements that we may establish; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; the costs and timing of regulatory approvals; the cost of establishing or contracting for manufacturing, sales and marketing capabilities; and the effect of competing technological and market developments.

We anticipate that our existing cash, cash equivalents, and short-term investments, plus the $35 million, non-refundable, upfront license fee from Bayer will be sufficient to fund our operating activities through the first quarter of 2011. This current financial projection includes forecasted expenses associated with the RDEA594 Phase 2 and Phase 3 programs anticipated for that period, combined with expense reductions from our recent restructuring. This projection does not include any milestone payments under our global agreement with Bayer, proceeds from future partnering activities or financings.

We have no current means of generating material cash flows from operations. There can be no assurance that our product development efforts with respect to any of our product candidates will be successfully completed, that required regulatory approvals will be obtained or that any products, if introduced, will be successfully marketed or achieve commercial acceptance. Accordingly, we will continue to seek capital by various means, including by selling our equity securities, additional debt

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financing and by establishing one or more collaborative or licensing arrangements. However, there can be no assurance that additional financing will be available to us on acceptable terms, if at all.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our consolidated financial condition, expenses, consolidated results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital to fund operations, while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of March 31, 2009, we owned financial instruments that are sensitive to market risk, including interest rate risk, as part of our investment portfolio. To minimize our exposure to market risk, we have generally limited our investments to cash and securities of the government of the United States of America and its federal agencies, or high-grade corporate and municipal bonds with maturity dates of less than one year. Due to the short-term nature of our investments, a 50-basis point movement in market interest rates over the three-month period following March 31, 2009 would not have a material impact on the fair value of our portfolio as of March 31, 2009. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk. We also do not invest in any derivative financial instruments, derivative commodity instruments, auction rate securities or other market risk sensitive instruments, positions or transactions.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports, filed under the Securities Exchange Act of 1934, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by the SEC Rule 13a-15(b), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this quarterly report on Form 10-Q and in our other filings with the SEC. If any of the following events, described as risks, actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our securities. An investment in our securities is speculative and involves a high degree of risk. You should not invest in our securities if you cannot bear the economic risk of your investment for an indefinite period of time and cannot afford to lose your entire investment. The risks described below include certain additions and revisions to the risks set forth in our annual report on Form 10-K for the fiscal year ended December 31, 2008 and our subsequent filings with the SEC. Risk factors containing such revisions are marked with an asterisk.

Risks Related to Our Business

Development of our products will take years; we may never attain product sales; and we expect to continue to incur net operating losses.

We have incurred, and expect to continue to incur, substantial operating losses for the foreseeable future. We expect that most of our resources for the foreseeable future will be dedicated to research and development and preclinical and clinical testing of compounds. The amounts paid to advance the preclinical and clinical development of our product candidates, including RDEA594, RDEA806, RDEA427, RDEA119, RDEA436 and our other compounds, may continue to increase. Any compounds we advance through preclinical and clinical development will require extensive and costly development, preclinical testing and clinical trials prior to seeking regulatory approval for commercial sales. Our most advanced product candidates, RDEA594, RDEA806, RDEA427, RDEA119, RDEA436, and any other compounds we advance further into development, may never be approved for commercial sales. The time required to achieve product sales and profitability is lengthy and highly uncertain and we cannot assure you that we will be able to achieve or maintain product sales.

We are not currently profitable and may never become profitable.

To date, we have generated limited revenues and we do not anticipate generating significant revenues for at least several years, if ever. We may increase our operating expenses over at least the next several years as we plan to advance our product candidates, including RDEA594, RDEA806, RDEA427, RDEA119, RDEA436, into further clinical trials, and may expand our development activities and acquire or license new technologies and product candidates. As a result, we expect to continue to incur significant and potentially increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with our research and product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

Because the results of preclinical studies are not necessarily predictive of future results, we can provide no assurances that, even if our product candidates are successful in preclinical studies, such product candidates will have favorable results in clinical trials or receive regulatory approval.

Positive results from preclinical studies should not be relied upon as evidence that clinical trials will succeed. Even if our product candidates achieve positive results in clinical studies, we will be required to demonstrate through clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. If any product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, then we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts of any of our product

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candidates, then we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

Delays in the commencement of clinical testing of our current and potential product candidates could result in increased costs to us and delay our ability to generate revenues.*

Our product candidates will require preclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. Delays in the commencement of clinical testing of our product candidates could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including:

- delays in demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- delays in manufacturing quantities of a product candidate sufficient for clinical trials;
- delays in obtaining approval of an Investigational New Drug application (IND) from the United States Food and Drug Administration (the FDA) or similar foreign approval;
- delays in obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- insufficient financial resources.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. Finally, we may delay the commencement of clinical trials with respect to product candidates, as we have with RDEA806 and RDEA427, until we enter into a collaboration or license agreement with a third party to fund the clinical trials of such product candidates.

Delays in the completion of, or the termination of, clinical testing of our current and potential product candidates could result in increased costs to us and delay or prevent us from generating revenues.

Once a clinical trial for any current or potential product candidate has begun, it may be delayed, suspended or terminated by us or the FDA, or other regulatory authorities due to a number of factors, including:

- ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated retention rate of patients in clinical trials;
- the imposition of a clinical hold;

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lack of adequate funding to continue clinical trials;

negative results of clinical trials;

insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials; or

serious adverse events or other undesirable drug-related side effects experienced by clinical trial participants.

Many of these factors that may lead to a delay, suspension or termination of clinical testing of a current or potential product candidate may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays in the completion of, or termination of, clinical testing, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to generate revenues from those products will be delayed.

If our internal discovery and development efforts are unsuccessful, we may be required to obtain rights to new products or product candidates from third parties, which we may not be able to do.

Our long-term ability to earn product revenue depends on our ability to successfully advance our product candidates through clinical development and regulatory approval and to identify and obtain new products or product candidates through internal development or licenses from third parties. If the development programs we acquired from Valeant and our internal development programs are not successful, we may need to obtain rights to new products or product candidates from third parties. We may be unable to obtain suitable product candidates or products from third parties for a number of reasons, including:

we may be unable to purchase or license products or product candidates on terms that would allow us to make a sufficient financial return from resulting products;

competitors may be unwilling to assign or license products or product candidate rights to us (in particular, if we are not able to successfully advance the further development of the product candidates we acquired from Valeant); or

we may be unable to identify suitable products or product candidates within, or complementary to, our areas of interest relating to the treatment of gout, HIV, cancer and inflammatory diseases.

If we are unable to obtain rights to new products or product candidates from third parties, our ability to generate product revenues and achieve profitability may suffer.

Even if we successfully initiate and complete clinical trials for any product candidate, there are no assurances that we will be able to submit, or obtain regulatory approval of, a new drug application.

There can be no assurance that if our clinical trials of any potential product candidate are successfully initiated and completed, we will be able to submit a New Drug Application (NDA) to the FDA in the United States or similar application to other regulatory authorities elsewhere in the world, or that any applications we submit will be approved by these regulatory authorities in a timely manner, if at all. If we are unable to submit an NDA or similar application with respect to any future product candidate, or if any NDA or similar application we submit is not approved by the FDA or other regulatory authorities elsewhere in the world, we will be unable to commercialize that product. These authorities can and do reject new drug application and require additional clinical trials, even when product candidates have performed well or have achieved favorable results in clinical trials. If we fail to commercialize any future product candidate in clinical trials, we may be unable to generate sufficient revenues to attain profitability and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

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If we successfully develop products, but those products do not achieve and maintain market acceptance, our business will not be profitable.

Even if any of our product candidates are approved for commercial sale by the FDA or other regulatory authorities, our profitability and growth will depend on the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors, which will in turn depend on a number of factors, including:

our ability to provide acceptable evidence of safety and efficacy of our products;

relative convenience and ease of administration of products;

the prevalence and severity of any adverse side effects from the products;

the availability of alternative treatments;

pricing and cost effectiveness of products; and

our ability to obtain sufficient third-party insurance coverage or reimbursement.

In addition, even if any of our potential products achieve market acceptance, we may not be able to maintain that market acceptance over time if:

new products or technologies are introduced that are more favorably received than our potential future products, are more cost effective or render our potential future products obsolete; or

complications arise with respect to use of our potential future products.

We will need substantial additional funding and may be unable to raise capital when needed, or at all, which would force us to delay, reduce or eliminate our research and development programs or commercialization efforts.*

We anticipate that our existing cash, cash equivalents, and short-term investments, plus the $35 million, non-refundable, upfront license fee from Bayer will be sufficient to fund our operating activities through the first quarter of 2011. This current financial projection includes forecasted expenses associated with the RDEA594 Phase 2 and Phase 3 programs anticipated for that period, combined with expense reductions from our recent restructuring. This projection does not include any milestone payments under our global agreement with Bayer, proceeds from future partnering activities or financings. However, our business and operations may change in a manner that would consume available resources at a greater rate than anticipated. In particular, because most of our resources for the foreseeable future will be used to advance our product candidates, we may not be able to accurately anticipate our future research and development funding needs. We will need to raise substantial additional capital in the future to, among other things:

fund our development programs;

advance our product candidates into and through clinical trials and the regulatory review and approval process;

establish and maintain manufacturing, sales and marketing operations;

commercialize our product candidates, if any, that receive regulatory approval; and

acquire rights to products or product candidates, technologies or businesses.

Our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

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the rate of progress and cost of our development activities;

the scope, prioritization and number of preclinical studies and clinical trials we pursue;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the costs and timing of regulatory approval;

the costs of establishing or contracting for manufacturing, sales and marketing capabilities;

the effects of competing technological and market developments;

the terms and timing of any collaborative, licensing and other arrangements that we may establish; and

the extent to which we acquire or license new technologies, products or product candidates.

We do not anticipate that we will generate significant continuing revenues for at least several years, if ever. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Our ability to obtain new financing may be constrained by the current unprecedented volatile economic conditions affecting financial markets. If funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts.

We have decreased the size of our organization and may need to do so again in the future, and we may experience difficulties in managing these organizational changes.*

We have decreased the size of our organization and may need to do so again in the future in response to the recent global financial crisis or other adverse events. If our staffing is inadequate because of additional, unanticipated attrition or because we fail to retain the staffing level required to accomplish our business objectives we may be delayed or unable to continue the development or commercialization of our product candidates, which could impede our ability to generate revenues and achieve profitability.

Additionally, employees whose positions are eliminated in connection with any reduction may seek future employment with our competitors. Although all of our employees are required to sign a confidentiality agreement with us at the time of hire, we cannot assure you that the confidential nature of our proprietary information will be maintained in the course of such future employment. Any drop in employee morale or other potential operational disruptions resulting from our restructuring efforts could divert the attention of our management away from our operations. Our restructuring efforts may harm our reputation and actually increase our expenses in the short term. We cannot assure you that any restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from restructuring activities.

Raising additional funds by issuing securities or through additional collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.*

We may raise additional funds through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders ownership will be diluted. Any debt financing we obtain may involve

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covenants that restrict our operations. These restrictive covenants may include, among other things, limitations on borrowing, specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens on our assets, pay dividends on or redeem our capital stock or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to us or relinquish potentially valuable rights to our potential products or proprietary technologies. For example, under our license agreement with Bayer we granted to Bayer an exclusive, worldwide license to develop and commercialize all of our MEK inhibitors for all indications. We may be required in future collaborations to relinquish all or a portion of our sales and marketing rights with respect to other potential products or license intellectual property that enables licensees to develop competing products in order to complete any such transaction.

The investment of our cash balance and investments in marketable securities are subject to risks which may cause losses and affect the liquidity of these investments.*

Our short-term investments consist of securities of the United States government, its federal agencies, entities controlled by the federal government and United States corporate debt securities. These investments are subject to general credit, liquidity, market and interest rate risks, which may further be exacerbated by United States sub-prime mortgage defaults and other factors, which have recently affected various sectors of the financial markets and caused credit and liquidity issues. During the period ended March 31, 2009, we determined that any declines in the fair value of our investments were temporary. There may be further declines in the value of these investments, which we may determine to be other-than-temporary. These market risks associated with our investment portfolio may have a material adverse effect on our results of operations, liquidity and financial condition.

We depend on collaborations with third parties to develop and commercialize selected product candidates and to provide substantially all of our revenues.*

We expect that, for at least the next few years, our ability to generate significant revenues will depend in large part upon the success of our existing collaboration with Bayer HealthCare and our ability to enter into new collaborations. Future revenues from our collaboration with Bayer will depend on the achievement of development, regulatory and sales-based milestones and royalty payments, if any. We will not receive additional revenues from our existing collaboration if Bayer s development and commercialization efforts are unsuccessful.

Typically, collaborators, including Bayer, will control the development and commercialization of partnered compounds after entering into a collaboration or license agreement. In addition, we may not have complete access to information about the results and status of our collaborators clinical development and regulatory programs and strategies. Our collaborators may not devote adequate resources to the development of our compounds and may not develop or implement a successful clinical or regulatory strategy. We cannot guarantee that any development, regulatory or sales-based milestones in our existing or future collaborations will be achieved in the future, or that we will receive any payments for the achievement of any milestones or royalties on sales of products. In addition, collaborations, including our existing collaboration with Bayer, may be terminated early in certain circumstances, in which case, we may not receive future milestone or royalty payments.

Finally, our ability to enter into new collaborations depends on the outcome of preclinical and clinical testing, which we do not control. Even if our testing is successful, pharmaceutical companies may not partner with us on terms that we believe are acceptable until we have advanced our drug candidates into the clinic and, possibly, through later-stage clinical trials, if at all.

Conflicts may arise between us and any of our collaborators that could delay or prevent the development or commercialization of our product candidates.*

Conflicts may arise between our collaborators and us, such as conflicts concerning the interpretation of clinical data or the achievement of milestones. If any conflicts arise with Bayer or any future collaborators, they may act in their self-interest, which may be adverse to our best interests. Any such disagreement between us and a collaborator could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating sufficient revenues to achieve or maintain profitability:

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unwillingness on the part of a collaborator to pay us milestone payments or royalties we believe are due to us under our collaboration agreement,

unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities, or

slowing or cessation of a collaborator s development or commercialization efforts with respect to our product candidates.

We do not have internal manufacturing capabilities, and if we fail to develop and maintain internal capabilities or supply relationships with collaborators or other outside manufacturers, we may be unable to develop or commercialize any products.

Our ability to develop and commercialize any products we may develop will depend in part on our ability to manufacture, or arrange for collaborators or other parties to manufacture, our products at a competitive cost, in accordance with regulatory requirements, and in sufficient quantities for clinical testing and eventual commercialization. We currently do not have any significant manufacturing arrangements or agreements, as our current product candidates will not require commercial-scale manufacturing for at least several years, if ever. Our inability to enter into or maintain manufacturing agreements with collaborators or capable contract manufacturers on acceptable terms could delay or prevent the development and commercialization of our products, which would adversely affect our ability to generate revenues and would increase our expenses.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may be unable to generate product revenue.

We do not currently have a sales organization for the sales, marketing and distribution of pharmaceutical products. In order to commercialize any products, we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We have not yet determined whether we will attempt to establish internal sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop. The establishment and development of our own sales force to market any products we may develop will be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capacity. If we are unable to establish our sales and marketing capability or any other non-technical capabilities necessary to commercialize any product we may develop, we will need to contract with third parties to market and sell any products we may develop. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

If we are unable to attract and retain key management and scientific staff, we may be unable to successfully develop or commercialize our product candidates.

We are a small company, and our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. In particular, our research and drug discovery and development programs depend on our ability to attract and retain highly skilled chemists, biologists and preclinical personnel, especially in the fields of gout, HIV, cancer and inflammatory diseases. If we are unable to hire or retain these employees, we may not be able to advance our research and development programs at the pace we anticipate. We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical businesses, particularly in the San Diego, California area. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our research and development objectives. In addition, all of our employees are at will employees, which means that any employee may quit at any time and we may terminate any employee at any time. Currently, we do not have employment agreements with any employees or members of senior management that provide

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us any guarantee of their continued employment. If we lose members of our senior management team, we may not be able to find suitable replacements and our business may be harmed as a result.

Our quarterly results and stock price may fluctuate significantly.

We expect our results of operations and future stock price to continue to be subject to significant fluctuations. The level of our revenues, if any, our results of operations and our stock price at any given time will be based primarily on the following factors:

- whether or not we achieve specified research or commercialization milestones under any agreement that we enter into with collaborators and the timely payment by potential commercial collaborators of any amounts payable to us or by us to Valeant or any other party, including the milestone payments that we may make to Valeant;
- the addition or termination of research or development programs or funding support;
- the status of development of our product candidates, including results of preclinical studies and any future clinical trials;
- variations in the level of expenses related to our product candidates or potential product candidates during any given period;
- our execution of collaborative, licensing or other arrangements, and the timing and accounting treatment of payments we make or receive under these arrangements;
- our recommendation of additional compounds for preclinical development; and
- fluctuations in the stock prices of other companies in the biotechnology and pharmaceuticals industries and in the financial markets generally.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. In particular, if our quarterly operating or financial results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If we engage in any acquisition, we will incur a variety of costs, and we may never realize the anticipated benefits of the acquisition.

In 2006, we acquired pharmaceutical research and development programs, including our most advanced product candidates, from Valeant, and there is no guarantee that we will be able to successfully develop the acquired product candidates. We may attempt to acquire businesses, technologies, services or other products or in-license technologies that we believe are a strategic fit with our existing development programs, at the appropriate time and as resources permit. In any acquisition, the process of integrating the acquired business, personnel, technology, service or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention away from our ongoing business operations. Other operational and financial risks associated with acquisitions include:

- assumption and exposure to unknown liabilities of the acquired business;
- disruption of our business and diversion of our management s time and attention to acquiring and developing acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;

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increased amortization expenses;

negative effect on our earnings (or loss) per share;

difficulty and cost in combining and integrating the operations and personnel of any acquired businesses with our operations and personnel;

impairment of relationships with key suppliers, contractors or customers of any acquired businesses due to changes in management and ownership; and

inability to retain key employees of any acquired businesses.

We may fail to realize the anticipated benefits of any completed acquisition or devote resources to potential acquisitions that are never completed. If we fail to successfully identify strategic opportunities, complete strategic transactions or integrate acquired businesses, technologies, services or products, then we may not be able to successfully expand our product candidate portfolio to provide adequate revenue to attain and maintain profitability.

Earthquake damage to our facilities could delay our research and development efforts and adversely affect our business.

Our research and development facility in San Diego, California, is located in a seismic zone, and there is the possibility of an earthquake, which could be disruptive to our operations and result in delays in our research and development efforts. In the event of an earthquake, if our facilities or the equipment in our facilities are significantly damaged or destroyed, we may not be able to rebuild or relocate our facility or replace any damaged equipment in a timely manner and our business, financial condition and results of operations could be materially and adversely affected.

Valeant s exercise of its option to repurchase commercialization rights in territories outside the United States and Canada (the Valeant Territories) could limit the market for our first NNRTI product and adversely affect our business.

Under the asset purchase agreement that we entered into with Valeant on December 21, 2006, Valeant retains a one-time option to repurchase commercialization rights in the Valeant Territories for our first NNRTI product derived from the acquired intellectual property to advance to a Phase 2b HIV clinical trial. If Valeant exercises this option, which it can do following the completion of a Phase 2b clinical trial, but prior to the initiation of a Phase 3 clinical trial, Valeant would pay us a $10.0 million option fee, up to $21.0 million in milestone payments based on regulatory approvals, and a mid-single-digit royalty on product sales in the Valeant Territories. However, Valeant would then own all commercialization rights in the Valeant Territories, which may adversely impact the amount of aggregate revenue we may be able to generate from sales of our NNRTI product and may negatively impact our potential for long-term growth. Also, if Valeant exercises its option to repurchase commercialization rights in the Valeant Territories and experiences difficulties in commercializing our NNRTI product in the Valeant Territories, then our commercialization efforts in the United States and Canada may be adversely impacted. Finally, Valeant s option may adversely impact any efforts we may undertake to license our NNRTI product to a potential commercial partner who requires worldwide rights to the product.

Failure to comply with our minimum commitments under the asset purchase agreement with Valeant could expose us to potential liability or otherwise adversely affect our business.

Under the terms of the Valeant asset purchase agreement, we agreed to use commercially reasonable efforts to develop the product candidates in the pharmaceutical research and development programs we acquired from Valeant, with the objective of obtaining marketing approval for RDEA806, RDEA119 and the lead product candidates from the next generation NNRTI and MEK inhibitor programs in the United States, the United Kingdom, France, Spain, Italy and Germany. If we fail to make sufficient effort to develop the product candidates, then we may be subject to a potential lawsuit or lawsuits from Valeant under the asset purchase agreement. If such a lawsuit was successful, we may be subject to financial losses, our reputation within the pharmaceutical research and development community may be

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negatively impacted and our business may suffer.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

Section 404 of the Sarbanes-Oxley Act requires on-going management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accounting firm that provides their assessment of the effectiveness of our internal controls. Testing and maintaining internal controls involves significant costs and can divert our management s attention from other matters that are important to our business. We and our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. Failure to achieve and maintain an effective internal control environment could harm our operating results and could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the price of our stock.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations on all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in cost-effective control systems, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the price of our stock.

Risks Related to Our Industry

Because our product candidates and development and collaboration efforts depend on our intellectual property rights, adverse events affecting our intellectual property rights will harm our ability to commercialize products.

Our commercial success depends in significant part on obtaining and maintaining patent protection and trade secret protection of our product candidates and their uses, as well as successfully defending these patents against challenges. We will only be able to protect our product candidates and their uses from unauthorized use by other parties to the extent that valid and enforceable patents or effectively protected trade secrets cover them.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even with respect to patents that have issued or will issue, we cannot guarantee that the claims of these patents are, or will be valid, enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. For example:

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we might not have been the first to make, conceive or reduce to practice the inventions covered by any or all of our pending patent applications;

we might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that none of our pending patent applications will result in issued patents;

our issued or acquired patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by other parties;

our issued patents may not be valid or enforceable; or

the patents of others may have an adverse effect on our business.

Patent applications in the United States are maintained in confidence for at least 18 months after their filing. Consequently, we cannot be certain that the patent applications we are pursuing will lead to the issuance of any patent or be free from infringement or other claims from other parties. In the event that another party has also filed a United States patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the United States Patent Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our United States patent position. Furthermore, we may not have identified all United States and foreign patents or published applications that affect our business either by blocking our ability to commercialize our product candidates or by covering similar technologies that affect our market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates.

Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us.

Other companies may obtain patents and/or regulatory approvals to use the same drugs to treat diseases, other than gout, HIV, cancer and inflammatory diseases. As a result, we may not be able to enforce our patents effectively because we may not be able to prevent healthcare providers from prescribing, administering or using another company s product that contains the same active substance as our products when treating patients with gout, HIV, cancer or inflammatory diseases.

Our business depends upon not infringing the rights of others.

If we are sued for infringing intellectual property rights of others, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of other parties. We may be exposed to future litigation by other parties based on claims that our product candidates or activities infringe the intellectual property rights of others. There are numerous United States and foreign issued patents and pending patent applications owned by others in gout, HIV, cancer, inflammatory diseases and the other fields in which we may develop products. We cannot assure you that parties holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

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There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. Any litigation or claims against us, with or without merit, may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. In addition, intellectual property litigation or claims could result in substantial damages and force us to do one or more of the following if a court decides that we infringe on another party s patent or other intellectual property rights:

cease selling, incorporating or using any of our product candidates that incorporate the challenged intellectual property;

obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or

redesign our processes so that they do not infringe, which could be costly and time-consuming and may not be possible.

If we find during clinical evaluation that our product candidates for the treatment of gout, HIV, cancer or inflammatory diseases should be used in combination with a product covered by a patent held by another company or institution, and that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the other party s patents covering the product recommended for co-administration with our product. In that case, we may be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on reasonable terms, or at all.

If we fail to obtain any required licenses or make any necessary changes to our technologies, we may be unable to develop or commercialize some or all of our product candidates.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our employees, consultants and other advisors. These agreements may not effectively prevent disclosure of confidential information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Many of our competitors have significantly more resources and experience, which may harm our commercial opportunity.

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug and chemical companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources, experience and expertise in:

research and development;

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preclinical testing;

clinical trials;

regulatory approvals;

manufacturing; and

sales and marketing of approved products.

Smaller or early stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced.

If our competitors develop treatments for gout, HIV, cancer or inflammatory diseases that are approved faster, marketed better or demonstrated to be safer or more effective than any products that we may develop, our commercial opportunity will be reduced or eliminated.

We believe that a significant number of drugs are currently under development and may become available in the future for the treatment of gout, HIV, cancer and inflammatory diseases. Potential competitors may develop treatments for gout, HIV, cancer or inflammatory diseases or other technologies and products that are safer, more effective or less costly than our product candidates or that would make our technology and product candidates obsolete or non-competitive. Some of these products may use therapeutic approaches that compete directly with our most advanced product candidates.

If we cannot establish pricing of our product candidates acceptable to the United States or foreign governments, insurance companies, managed care organizations and other payors, or arrange for favorable reimbursement policies, any product sales will be severely hindered.

The continuing efforts of the United States and foreign governments, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect our ability to generate adequate revenues and gross margins to make the products we develop commercially viable. Our ability to commercialize any product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of any products and related treatments.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the United States Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. The trend toward managed health care in the United States, which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care, control pharmaceutical prices or reduce government insurance programs, may result in lower prices for our product candidates. While we cannot predict whether any legislative or regulatory proposals affecting our business will be adopted, the announcement or adoption of these proposals could have a material and adverse effect on our potential revenues and gross margins.

Product liability claims may damage our reputation and, if insurance proves inadequate, the product liability claims may harm our results of operations.

We face an inherent risk of product liability exposure when we test our product candidates in human clinical trials, and we will face an even greater risk if we sell our product candidates commercially.

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If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities, our reputation may be harmed and we may be unable to commercialize our product candidates. We have product liability insurance that covers the conduct of our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Any claims relating to our improper handling, storage or disposal of biological, hazardous and radioactive materials could be time-consuming and costly.

Our research and development involves the controlled use of hazardous materials, including chemicals that cause cancer, volatile solvents, radioactive materials and biological materials that have the potential to transmit disease. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products. If we fail to comply with these laws and regulations or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial financial liability or be required to suspend or modify our operations. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources. In addition, we may have to incur significant costs to comply with future environmental laws and regulations. We do not currently have a pollution and remediation insurance policy.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our research and drug discovery and development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our research and drug discovery and development programs may be adversely affected and the further development of our product candidates may be delayed. In addition, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

Risks Related to Our Common Stock

Directors, executive officers, principal stockholders and affiliated entities beneficially own or control a significant majority of our outstanding voting common stock and together control our activities.

Our directors, executive officers, principal stockholders and affiliated entities currently beneficially own or control a significant majority of our outstanding securities. These stockholders, if they determine to vote in the same manner, would control the outcome of any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions or terms of any liquidation.

Future sales of our common stock may cause our stock price to decline.

Our principal stockholders and affiliated entities hold a substantial number of shares of our common stock that they are able to sell in the public market. In addition, they currently own outstanding warrants exercisable as of June 17, 2009 for additional shares of our common stock. The exercise of these warrants or the sale by our current stockholders of a substantial number of shares, or the expectation that such exercises or sales may occur, could significantly reduce the market price of our common stock.

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Anti-takeover provisions in our charter documents and under Delaware law may make it more difficult to acquire us.

Provisions in our certificate of incorporation and bylaws could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions:

allow the authorized number of directors to be changed only by resolution of our Board of Directors;

require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;

establish advance notice requirements for nominations to our Board of Directors or for proposals that can be acted on at stockholder meetings;

authorize our Board of Directors to issue blank check preferred stock to increase the number of outstanding shares; and

limit who may call stockholder meetings.

In addition, because we are incorporated in Delaware, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit large stockholders from consummating a merger with, or acquisition of us. These provisions may prevent a merger or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our common stock.

We have never paid cash dividends on our common stock and we do not anticipate paying dividends in the foreseeable future.

We have paid no cash dividends on any of our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

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ITEM 6. EXHIBITS

Exhibit Number	Description
2.1	Asset Purchase Agreement with Valeant Research & Development and Valeant Pharmaceuticals International dated December 21, 2006 (1)
3.1	Restated Certificate of Incorporation filed with the Delaware Secretary of State on September 10, 2008 (2)
3.2	Amended and Restated Bylaws (3)
4.1	Registration Rights Agreement, dated December 19, 2007, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto (4)
4.2	Registration Rights Agreement, dated January 4, 2008, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto (5)
4.3	Form of Warrant issued by the Company pursuant to the Loan and Security Agreement dated November 12, 2008 (6)
4.4	Form of Warrant issued by the Company pursuant to the Securities Purchase Agreement dated December 17, 2008 (7)
4.5	Registration Rights Agreement, dated December 17, 2008, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto (8)
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment request has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on December 28, 2006.

(2) Incorporated by reference to our Form 10-Q (File No. 001-33734) filed with the Securities and Exchange Commission on November 13, 2008.

(3) Incorporated by reference to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on August 2, 2007.

(4) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 20, 2007.

(5) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on

January 10, 2008.

(6) Incorporated by reference to our Form 10-K (File No. 001-33734) filed with the Securities and Exchange Commission on March 13, 2009.

(7) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 19, 2008.

(8) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 22, 2008.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Ardea Biosciences, Inc.

Date: May 11, 2009

/s/ Barry D. Quart
Barry D. Quart, Pharm.D.
President and Chief Executive Officer
(On behalf of the Registrant)

/s/ John W. Beck
John W. Beck, C.P.A.
Senior Vice President, Finance and Operations and Chief Financial Officer
(As Principal Financial and Accounting Officer)

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ARDEA BIOSCIENCES, INC.
INDEX TO EXHIBITS

Exhibit Number	Description
2.1	Asset Purchase Agreement with Valeant Research & Development and Valeant Pharmaceuticals International dated December 21, 2006 (1)
3.1	Restated Certificate of Incorporation filed with the Delaware Secretary of State on September 10, 2008 (2)
3.2	Amended and Restated Bylaws (3)
4.1	Registration Rights Agreement, dated December 19, 2007, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto (4)
4.2	Registration Rights Agreement, dated January 4, 2008, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto (5)
4.3	Form of Warrant issued by the Company pursuant to the Loan and Security Agreement dated November 12, 2008 (6)
4.4	Form of Warrant issued by the Company pursuant to the Securities Purchase Agreement dated December 17, 2008 (7)
4.5	Registration Rights Agreement, dated December 17, 2008, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto (8)
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment request has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange

Commission.

(1) Incorporated by reference to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on December 28, 2006.

(2) Incorporated by reference to our Form 10-Q (File No. 001-33734) filed with the Securities and Exchange Commission on November 13, 2008.

(3) Incorporated by reference to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on August 2, 2007.

(4) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 20, 2007.

(5) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and

Exchange Commission on January 10, 2008.

(6) Incorporated by reference to our Form 10-K (File No. 001-33734) filed with the Securities and Exchange Commission on March 13, 2009.

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(7) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 19, 2008.

(8) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 22, 2008.