

Ardea Biosciences, Inc./DE  
Form 10-Q  
May 09, 2008

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
Form 10-Q**

**Quarterly report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934  
For the period ended March 31, 2008**

**Or**

**Transition report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number 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 Number)

**4939 Directors Place  
San Diego, CA 92121**

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  No   
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting  
company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes  No

There were 13,354,464 shares of the Registrant's common stock, par value \$0.001, outstanding as of March 31, 2008.

**TABLE OF CONTENTS**  
**ARDEA BIOSCIENCES, INC.**  
**FORM 10-Q**  
**QUARTER ENDED MARCH 31, 2008**  
**TABLE OF CONTENTS**

	<b>Page</b>
<u>PART I. FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements</u>	3
<u>Condensed Balance Sheets as of March 31, 2008 (unaudited) and December 31, 2007</u>	3
<u>Condensed Statements of Operations for the Three Months Ended March 31, 2008 and 2007 (unaudited)</u>	4
<u>Condensed Statements of Cash Flows for the Three Months Ended March 31, 2008 and 2007 (unaudited)</u>	5
<u>Notes to Condensed Financial Statements (unaudited)</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
<u>Item 3. Quantitative and Qualitative Disclosure About Market Risk</u>	14
<u>Item 4. Controls and Procedures</u>	14
<u>PART II. OTHER INFORMATION</u>	15
<u>Item 1. Legal Proceedings</u>	15
<u>Item 1A. Risk Factors</u>	15
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
<u>Item 3. Defaults Upon Senior Securities</u>	28
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	28
<u>Item 5. Other Information</u>	28
<u>Item 6. Exhibits</u>	28
<u>SIGNATURES</u>	29
<u>EXHIBIT INDEX</u>	30
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 32.1</u>	

---

**Table of Contents****PART 1. FINANCIAL INFORMATION****ITEM 1. Financial Statements**

**ARDEA BIOSCIENCES, INC.**  
**(formerly IntraBiotics Pharmaceuticals, Inc.)**  
**CONDENSED BALANCE SHEETS**  
**(In thousands, except share and par value data)**

	<b>March 31, 2008 (Unaudited)</b>	<b>December 31, 2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 17,297	\$ 46,384
Short-term investments	38,867	19,831
Receivables	401	1,224
Prepaid expenses and other current assets	398	210
<b>Total current assets</b>	<b>56,963</b>	<b>67,649</b>
Property and equipment, net	2,084	879
Other assets	321	312
<b>Total assets</b>	<b>\$ 59,368</b>	<b>\$ 68,840</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,961	\$ 2,200
Accrued clinical liabilities	1,589	456
Accrued payroll and employee liabilities	1,145	1,612
Other accrued liabilities	834	833
<b>Total current liabilities</b>	<b>6,529</b>	<b>5,101</b>
Contingencies (Note 7)		
Stockholders' equity:		
Convertible preferred stock, \$ 0.001 par value: 5,000,000 shares authorized; 300 shares outstanding and \$3,000 aggregate liquidation preference at March 31, 2008 and December 31, 2007	1,634	1,634
Common stock, \$0.001 par value: 70,000,000 shares authorized at March 31, 2008 and December 31, 2007; 13,354,464 and 13,312,686 shares outstanding at March 31, 2008 and December 31, 2007, respectively	13	13
Additional paid-in capital	324,933	323,566
Accumulated other comprehensive income	183	14
Accumulated deficit	(273,924)	(261,488)

Total stockholders' equity	52,839	63,739
Total liabilities and stockholders' equity	\$ 59,368	\$ 68,840

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

3

---

**Table of Contents**

**ARDEA BIOSCIENCES, INC.**  
**(formerly IntraBiotics Pharmaceuticals, Inc.)**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(In thousands, except per share amounts)**  
**(Unaudited)**

	<b>Three Months Ended March</b>	
	<b>2008</b>	<b>31,</b> <b>2007</b>
Collaboration revenues	\$ 260	\$ 893
Operating expenses:		
Research and development	9,745	3,513
General and administrative	3,632	1,544
Total operating expenses	13,377	5,057
Operating loss	(13,117)	(4,164)
Interest income	607	611
Other income	135	184
Net loss	(12,375)	(3,369)
Non-cash dividends on Series A preferred stock	(60)	(60)
Net loss applicable to common stockholders	\$ (12,435)	\$ (3,429)
Basic and diluted net loss per share applicable to common stockholders	\$ (0.93)	\$ (0.37)
Shares used to compute basic and diluted net loss per share applicable to common stockholders	13,337	9,373

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

**Table of Contents**

**ARDEA BIOSCIENCES, INC.**  
**(formerly IntraBiotics Pharmaceuticals, Inc.)**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(In thousands)**  
**(Unaudited)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Operating activities</b>		
Net loss	\$ (12,375)	\$ (3,369)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,015	169
Stock compensation arising from Employee Stock Purchase Plan	95	
Depreciation and amortization	89	58
Gain on disposal of property and equipment		(184)
Change in assets and liabilities:		
Receivables	823	
Prepaid expenses and other current assets	(188)	(821)
Other assets	(9)	
Accounts payable	761	795
Accrued clinical liabilities	1,133	
Accrued payroll and employee liabilities	(467)	244
Other accrued liabilities	1	(417)
<b>Net cash used in operating activities</b>	<b>(9,122)</b>	<b>(3,525)</b>
<b>Investing activities</b>		
Capital expenditures	(1,294)	(27)
Proceeds from sale of property and equipment		184
Purchase of short term investments	(21,327)	(35,496)
Proceeds from sale or maturity of short-term investments	2,459	33,993
<b>Net cash used in investing activities</b>	<b>(20,162)</b>	<b>(1,346)</b>
<b>Financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	96	
Proceeds from issuance of common stock upon exercise of options	101	
<b>Net cash provided by financing activities</b>	<b>197</b>	
<b>Net decrease in cash and cash equivalents</b>	<b>(29,087)</b>	<b>(4,871)</b>
Cash and cash equivalents at beginning of period	46,384	14,779
<b>Cash and cash equivalents at end of period</b>	<b>\$ 17,297</b>	<b>\$ 9,908</b>

**Supplemental disclosure of non-cash information:**

Issuance of common stock dividend on Series A preferred stock	\$	(60)	\$	(60)
---------------------------------------------------------------	----	------	----	------

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

5

---



**Table of Contents**

**ARDEA BIOSCIENCES, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(Unaudited)**

**Note 1. Basis of Presentation**

We have prepared the condensed unaudited financial statements in accordance with U.S. generally accepted accounting principles ( GAAP ) and with the rules and regulations of the Securities and Exchange Commission ( SEC ) for interim financial reporting 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. The balance sheet as of December 31, 2007, has been derived from the audited financial statements at that date but does not include all information and footnotes required by GAAP for complete financial statements. The interim financial statements reflect all adjustments, consisting only of normal recurring adjustments, which in the opinion of management, are necessary for a fair presentation of our financial position and operating results and cash flows for the periods presented.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the entire fiscal year. These financial statements and notes should be read in conjunction with our audited financial statements and notes thereto for the year ended December 31, 2007, included in our Form 10-K filed with the Securities and Exchange Commission on March 24, 2008.

**Note 2. Summary of Significant Accounting Policies**

***Revenue Recognition***

Our revenue recognition policies are in compliance 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.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates under different assumptions or conditions.

***Stock-Based Compensation***

We report stock-based compensation in accordance with Financial Accounting Standards Board Statement of Financial Accounting Standards ( SFAS ) 123(R) Share-Based Payment. SFAS 123(R) requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. Accordingly, we value the portion of the award that is ultimately expected to vest and recognize the expense over service periods associated with the vesting of each award in our Statements of Operations. The Company has continued to use the simplified method in developing the estimate for expected term due to its limited history of forfeitures.

**Note 3. Stock-Based Compensation**

Stock-based compensation expense, related to our three stock-based compensation plans, amounted to \$1,015,000 and \$169,000, respectively, during the three-month periods ended March 31, 2008 and 2007. There were no tax benefits from stock-based compensation since we have substantial tax loss carry-forwards and have sustained a loss to stockholders for the three-month periods ended March 31, 2008 and 2007. The impact of stock-based compensation on both basic and diluted earnings per share for the three-month periods ended March 31, 2008 and 2007 was \$0.08 and \$0.02, respectively.

At March 31, 2008, total unrecognized estimated compensation expense related to unvested stock options granted prior to that date was approximately \$11.6 million. This cost is expected to be recognized over an estimated weighted average period of approximately 3.3 years, and will be adjusted, if necessary, for forfeitures and cancellations.

**Table of Contents**

Stock options for 857,000 shares were granted to employees during the three months ended March 31, 2008. There were no post-vesting restrictions.

**Note 4. Comprehensive Loss**

The components of comprehensive loss in each period presented are as follows:

	<b>Three Months Ended March</b>	
	<b>31,</b>	
	<b>2008</b>	<b>2007</b>
Net loss	\$ (12,375)	\$ (3,369)
Unrealized gain/(loss) on available-for-sale securities	168	(3)
<b>Comprehensive loss</b>	<b>\$ (12,207)</b>	<b>\$ (3,372)</b>

**Note 5. Net Loss Per Share**

Basic and diluted net income (loss) per share applicable to common stockholders is presented in accordance with Financial Accounting Standards Board Statement No. 128, *Earnings Per Share*, and is calculated using the weighted-average number of shares of common stock outstanding during the period. Net profit or loss per share applicable to common stockholders includes the impact of potentially dilutive securities (stock options, warrants and convertible preferred stock). However, as our potentially dilutive securities were anti-dilutive for all loss periods presented, they are not included in the calculations of diluted net loss per share applicable to common stockholders for those loss periods. Potentially dilutive shares used to compute 2008 first quarter basic and diluted net income per share were calculated using the net exercise method. The total number of shares underlying the stock options, warrants and convertible preferred stock excluded from the calculations of net loss per share applicable to common stockholders was 3,805,415 for the three months ended March 31, 2008, and 3,941,027 for the three months ended March 31, 2007.

**Note 6. Stockholders Equity**

On December 19, 2007, we raised \$40.0 million by selling 3,018,868 unregistered shares of newly issued common stock, \$0.001 par value, at \$13.25 per share. This resulted in net cash proceeds to us of \$37.2 million after deduction of placement fees and issuance costs of \$2.8 million. On January 18, 2008, we filed a registration statement with the SEC covering the resale of approximately 1.9 million of these shares. This registration statement was declared effective by the SEC on February 1, 2008.

In January 2008, we issued 4,007 shares of common stock in dividends payable to holders of preferred stock as of December 31, 2007.

In February 2008, warrants to purchase 55,200 shares of our common stock were exercised, using the net exercise method, resulting in the issuance of 13,952 shares of common stock. There were no cash proceeds resulting from this transaction.

**Note 7. Contingencies**

Under the Asset Purchase Agreement between Valeant Research and Development, Inc. and us dated December 21, 2006, we are obligated to make development-based milestone payments and sales-based royalty payments to Valeant upon subsequent development of products. The contingent liability of up to \$42.0 million in milestone payments for the RDEA806 Program, the 2<sup>nd</sup> Generation NNRTI Program, the RDEA119 Program and the 2<sup>nd</sup> Generation MEK Inhibitor Program is considered a liability in the ordinary course of business, to be recorded when the contingency is resolved and consideration is issued or becomes assumable, which has not occurred as of March 31, 2008.

**Note 8. Recent Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS 159 ). SFAS 159 amends SFAS 115 and permits fair value measurement of financial instruments and certain other items. SFAS 159 is effective beginning the first fiscal year that begins after November 15, 2007. The adoption of this statement did not have a material impact on our financial position

and results of operations.

**Table of Contents**

In June 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development ( R&D ) activities to be recorded as assets and the payments to be expensed when the R&D activities are performed. EITF 07-3 applies prospectively for new contractual arrangements entered into in fiscal years beginning after December 15, 2007. The adoption of EITF 07-3 did not have a material impact on our financial position or results of operations.

In December 2007, the FASB issued *Summary of Statement No. 141 (revised 2007)*, which replaces SFAS No. 141, *Business Combinations*, to improve the relevance and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. Statement No. 141 retains the fundamental requirements that the acquisition method of accounting (which SFAS No. 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. This statement requires an acquirer to recognize the assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. This replaces SFAS No. 141's cost-allocation process, which required the cost of an acquisition to be allocated to the individual assets acquired and liabilities assumed based on their estimated fair values. SFAS No. 141's guidance resulted in not recognizing some assets and liabilities at the acquisition date, and it also resulted in measuring some assets and liabilities at amounts other than their fair values at the acquisition date. This Summary Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008; it may not be applied before that date. We have not yet determined the effect, if any, of the adoption of this statement on our future financial position or results of operations.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* ( SFAS No. 160 ), which establishes accounting and reporting standards for the noncontrolling interest (minority interest) in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. The amount of net income attributable to the noncontrolling interest is to be included in consolidated net income on the face of the income statement. SFAS No. 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS No. 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008; it may not be applied before that date. We have not yet determined the effect, if any, of the adoption of this statement on our future financial position or results of operations.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* ( SFAS 161 ). SFAS 161 is intended to improve the current disclosure framework in SFAS 133 by requiring enhanced disclosures about an entity's derivative and hedging activities, and how they affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years that begin after November 15, 2008. We do not expect that the adoption of this statement will have a material impact on our financial position and results of operations.

**Note 9. Income Taxes**

Effective January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109*, or FIN 48, which clarifies the accounting for uncertainty in tax positions. We did not have any unrecognized tax benefits and there was no effect on our financial condition or results of operations as a result of implementing FIN 48.

We file income tax returns in the U.S. federal jurisdiction and in California.

Our policy is that we recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of the date of adoption of FIN 48, we did not have any accrued interest or penalties associated with any unrecognized tax benefits, nor was any interest expense recognized during the quarter. Our effective tax rate is zero because of current losses and tax carry forwards.

**Note 10. Subsequent Event**

Ardea had 300 shares of Series A preferred stock outstanding as of March 31, 2008. These shares are convertible, at any time, into an aggregate of 1,578,346 shares of our common stock. Additionally, these shares automatically convert into shares of our common stock on the tenth day after the day that the closing sale price of our common stock on the NASDAQ Global Market has reached at least \$8.28 and has remained at such level for 20 consecutive trading days.

On May 7, 2008, the above-described conditions were met, and all 300 shares of Series A preferred stock automatically converted into 1,578,346 shares of common stock as of such date.

**Table of Contents****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 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, 2007 included in our Annual Report for the year ended December 31, 2007 filed with the Securities and Exchange Commission, or SEC on March 24, 2008.*

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

**Overview and Business Strategy**

Ardea Biosciences, Inc., headquartered in San Diego, California, is a biotechnology company focused on the discovery and development of small-molecule therapeutics for the treatment of HIV, cancer and inflammatory diseases, including gout. We believe that we are well-positioned to create stockholder value through our development activities given our ability to achieve clinical proof-of-concept relatively quickly and cost-effectively in these disease areas. We are currently pursuing multiple development programs, including the following:

**Product Portfolio**

<b>Product candidate</b>	<b>Target indication</b>	<b>Development status</b>
RDEA806	HIV	Phase 2a
2nd generation NNRTI (RDEA427)	HIV	Phase 0*
RDEA806	Gout	Entering Phase 2
RDEA119	Cancer	Phase 1
RDEA119	Inflammation	Phase 1
2nd generation MEK inhibitor (RDEA436)	Cancer/Inflammation	Phase 0*

\* First in human micro-dose pharmacokinetic study

**RDEA806 (HIV).** RDEA806 is our lead non-nucleoside reverse transcriptase inhibitor (NNRTI) for the potential 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<sup>®</sup>, Bristol-Myers Squibb), the most widely prescribed NNRTI, in addition to other currently available NNRTIs. Based on both preclinical and clinical data, we anticipate that this compound could be amenable to a patient-friendly oral dosing regimen, may have limited pharmacokinetic interactions with other drugs and may be readily co-formulated with other HIV antiviral drugs.

We successfully completed Phase 1 single-ascending-dose, multiple-ascending-dose, food effect, and drug-interaction clinical studies of RDEA806 in August 2007 and initiated a Phase 2a proof-of-concept trial in the fourth quarter of 2007. In this Phase 2a, randomized, double-blind, placebo-controlled monotherapy trial, we are evaluating the antiviral activity, pharmacokinetics, safety and tolerability of RDEA806 versus placebo over seven days of treatment in HIV-positive patients who are naive to antiretroviral treatment. Nine out of 12 patients in each cohort will receive RDEA806; the remaining three will receive placebo. The primary efficacy endpoint is the change from baseline in plasma viral load. Preliminary results, which include those from the first ten evaluable patients in the 400 mg twice daily cohort and the first eight evaluable patients in the 600 mg

once daily cohort, showed the following:

Patients receiving 400 mg twice daily had a 2.0 log placebo-adjusted mean reduction in plasma viral load;

Patients receiving 600 mg once daily had a 1.7 log placebo-adjusted mean reduction in plasma viral load;

There were no serious adverse events reported in either cohort;

There were no ECG-related adverse events reported in either cohort;

There were no discontinuations in either cohort;

## Table of Contents

None of the typical side effects associated with other NNRTIs were reported in either cohort, such as drug-related rash or abnormal dreams; and

The percentage of patients with adverse events that were possibly drug-related was lower in patients receiving drug than in those receiving placebo.

Based on these preliminary results, further cohorts of patients will be evaluated in the Phase 2a study, and we plan to initiate a Phase 2b, dose-ranging study in HIV-positive patients who are naive to antiretroviral treatment in the second quarter of 2008, in which we will evaluate RDEA806 in standard combination therapy over six months of treatment.

**RDEA427 (HIV).** The lead compound in our 2nd 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 have the potential to share certain of the positive attributes of RDEA806, but also appears to have even greater activity against a wide range of drug-resistant viral isolates. We evaluated RDEA427 in a Phase 0 study in the first quarter of 2008 and have selected RDEA427 as a development candidate.

**RDEA806 (Gout).** In a Phase 1 multiple-ascending-dose study, RDEA806 demonstrated statistically significant, exposure-dependent reductions in serum uric acid in patients dosed for either 10 or 14 days. At the dose that resulted in the highest drug exposure, there was a 50.9% placebo-adjusted mean reduction in serum uric acid. We plan to initiate a Phase 2 dose-ranging study of RDEA806 in patients with hyperuricemia and a history of gout in the second quarter of 2008. We are also investigating the action moiety and mechanism of action responsible for this pharmacological effect.

**RDEA119 (Cancer).** *In vitro* preclinical tests have shown RDEA119 to be a potent and selective inhibitor of mitogen-activated ERK kinase, or 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. Preclinical data also suggest that RDEA119 may have favorable pharmaceutical properties, including the potential for convenient oral dosing. We initiated a Phase 1 study of RDEA119 in advanced cancer patients in November 2007. Once the maximum tolerated dose is reached, we will look at activity in hepatocellular, sarcoma, glioma, non-small cell lung, colon, pancreatic or thyroid cancer or melanoma.

**RDEA119 (Inflammation).** *In vitro* preclinical tests have shown RDEA119 to be a potent and selective inhibitor of MEK, which, in addition to its potential anti-cancer properties, is also believed to play an important role in inflammatory cell signaling. *In vivo* preclinical tests have shown RDEA119 to have potent anti-inflammatory activity. Preclinical data also suggest that RDEA119 may have favorable pharmaceutical properties, including the potential for convenient oral dosing. We initiated a Phase 1 study of RDEA119 in healthy volunteers in March 2008, which will include the evaluation of RDEA119's effect on pro-inflammatory biomarkers.

**RDEA436 (Inflammation).** The lead compound in our 2nd 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 have the potential to share certain of the positive attributes of RDEA119, but also appears to have even greater potency. We evaluated RDEA436 in a Phase 0 study in the first quarter of 2008 and have selected RDEA436 as a development candidate.

## **Company History**

We were incorporated in the State of Delaware in 1994. From our inception through May 5, 2005, we devoted substantially all of our efforts to the research and development of anti-microbial drugs and generated no product revenues. From the fourth quarter of 2002 until June 2004, we focused our attention on developing Iseganan, an anti-microbial peptide, for the prevention of ventilator-associated pneumonia, or VAP. In June 2004, we discontinued



our clinical trial of Iseganan for the prevention of VAP following a recommendation of our independent data monitoring committee. Subsequently, we terminated the Iseganan development program, laid off our work force, and engaged Hickey & Hill, Inc. of Lafayette, California, a firm specializing in managing companies in transition, to assume the responsibilities of our day-to-day administration while our Board of Directors evaluated strategic alternatives in the biotechnology industry.

**Table of Contents**

On December 21, 2006, we acquired intellectual property and other assets related to the RDEA806 Program, the 2nd Generation NNRTI Program, the RDEA119 Program and the 2nd Generation MEK Inhibitor Program from Valeant Research & Development, Inc. ( Valeant ), 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, subject to 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 the RDEA806 Program and the 2nd Generation NNRTI Program and a separate set of milestones for the RDEA119 Program and the 2nd Generation MEK Inhibitor Program. Assuming the successful commercialization of a product incorporating RDEA806 or a compound from the 2nd Generation NNRTI Program, resulting milestone payments could total \$25 million. Assuming the successful commercialization of a product incorporating RDEA119 or a compound from the 2nd Generation MEK Inhibitor Program, resulting milestone payments could total \$17 million. For each program, milestones are paid only once regardless of how many compounds are developed or commercialized. In each program, the first milestone payment of \$1.0 million to \$2.0 million would be due after the first patient is dosed in the first Phase 2b study, and approximately 80% of the total milestone payments would be due upon FDA acceptance and approval of a NDA. The royalty rates on all products are in the mid-single digits. We agreed to further develop the programs 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 U.S. 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 Phase 3 studies, we would be responsible for completing the Phase 3 studies and for the registration of the product in the U.S. and European Union. Valeant would pay us a \$10 million option fee, up to \$21 million in milestone payments based on regulatory approvals, and a mid-single-digit royalty on product sales in the Valeant Territories.

We also entered into a master services agreement with Valeant under which we will advance a preclinical program in the field of neuropharmacology on behalf of Valeant. Under the agreement, which has a two-year term, subject to Valeant's option to terminate the agreement after the first year, Valeant will pay us quarterly payments totaling up to \$3.5 million per year to advance the program, and we are entitled to development-based milestone payments of up to \$1.0 million. The first milestone totaling \$500,000 was reached in July 2007 when a clinical candidate was selected from the compounds Ardea had designed under this agreement. With the earlier-than-anticipated identification of a compound meeting all the criteria for clinical development described in the master services agreement, resources have been shifted away from designing new compounds. Accordingly, we earned research support payments of approximately \$260,000 in the first quarter of 2008. Valeant will own all intellectual property and commercial rights under this research program. Due to changing priorities at Valeant, we do not anticipate any additional research activities to be conducted during the second year of this agreement.

On December 19, 2007, we raised \$40.0 million by selling 3,018,868 unregistered shares of newly issued common stock, \$0.001 par value, at \$13.25 per share. This resulted in net cash proceeds of \$37.2 million after placement fees and issuance costs of \$2.8 million. On January 18, 2008, we filed a registration statement with the SEC covering the resale of approximately \$1.9 million of these shares. This registration statement was declared effective by the SEC on February 1, 2008.

**Recent Accounting Pronouncements**

Recent accounting pronouncements are detailed in Note 8 to our Condensed Financial Statements.

**Critical Accounting Policies and Estimates**

An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. Management believes the following critical accounting policies reflect its more significant estimates and assumptions used in the preparation of the financial statements. We review the accounting policies used in our financial statements on a regular basis.



**Table of Contents**

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an ongoing basis, we evaluate these estimates, including those related to clinical trial accruals, income taxes, restructuring costs and stock-based compensation. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

***Stock-Based Compensation***

We report stock-based compensation in accordance with Financial Accounting Standards Board Statement of Financial Accounting Standards ( SFAS ) 123(R) Share-Based Payment. SFAS 123(R) requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. Accordingly, we value the portion of the award that is ultimately expected to vest and recognize the expense over service periods associated with the vesting of each award in our Statements of Operations.

We estimate the fair value of stock options granted using the Black-Scholes option valuation model, and amortize this fair value over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including the option's expected life and the price volatility of the underlying stock.

The following variables are used in the valuation model:

*Expected Term* The expected term of options is calculated utilizing the simplified method provided by SAB No. 107, and represents the period of time that options granted are expected to be outstanding.

*Expected Volatility* At the beginning of each calendar quarter, our expected volatility is determined on the basis of our historical stock price data and the historical stock price data of our peer group companies.

*Risk-Free Interest Rate* The risk-free interest rate used is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term that approximates the expected term of the option.

*Expected Dividend* The dividend yield is set to zero since we have not paid any dividends and have no intention to pay dividends in the foreseeable future.

The Black-Scholes model requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from these estimates. Changes in our forfeiture assumption and the other assumptions used in the Black-Scholes option valuation model could cause actual results to differ materially from those estimated under the currently used assumptions.

***Contract Accruals***

We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CROs) or other clinical trial service providers that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, or fixed amounts per milestone or deliverable, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. All estimates may differ significantly from the actual amount subsequently invoiced. No adjustments for material changes in estimates have been recognized in any period presented.

**Results of Operations*****Three Months Ended March 31, 2008 and 2007******Revenues***

Revenues were \$260,000 and \$893,000 for the three-month periods ended March 31, 2008 and 2007, respectively. These revenues resulted from services provided under our master services agreement with Valeant for their preclinical neuropharmacology program. The decrease in revenues is due to the earlier-than-anticipated identification of a compound meeting the criteria for clinical development described in the master services agreement.

**Table of Contents***Research and Development Expenses*

Research and development expenses primarily include research and development payroll expense, drug substance expense, chemicals, outside services for contract research organizations (CROs) and manufacturing, facilities costs, legal costs associated with patents, and non-cash stock compensation charges. Research and development expenses were \$9.7 million and \$3.5 million, respectively during the three-month periods ended March 31, 2008 and 2007, respectively. The increase between the three-month periods in comparative years of \$6.2 million is due to continued progress in pre-clinical and clinical candidates and the related increase in payroll (\$2.3 million and \$1.3 million, respectively), stock-based compensation (\$450,000 and \$28,000, respectively), outside services including CRO s (\$6.0 million and \$1.5 million, respectively), and other expenses supporting our operations.

*General and Administrative Expenses*

General and administrative costs currently include payroll expense, outside contractors, legal and accounting fees, insurance, non-cash stock compensation charges, expenses associated with business development activities, and other general administrative expenses. General and administrative expenses were \$3.6 million and \$1.5 million, respectively, during the three-month periods ended March 31, 2008 and 2007. The increase between the three-month periods of \$2.1 million is the result of an increased level of spending to support our operations, including our recent relocation to the new facility in San Diego County, continued support of Company-wide operating systems and intellectual property filings.

*Interest Income*

Interest income was \$607,000 and \$611,000, respectively, during the three-month periods ended March 31, 2008 and 2007.

*Loss Applicable to Common Stockholders*

Net loss applicable to common stockholders was \$12.4 million and \$3.4 million during the three-month periods ended March 31, 2008 and 2007, respectively. The difference of \$9.0 million in 2008 versus 2007 is primarily attributable to significant progress in our core research and development programs, increased headcount, facility relocation and operating expenses. Net loss applicable to common stockholders also includes the impact of stock dividends of \$60,000 in the aggregate paid to holders of our Series A preferred stock for each of the three-month periods ended March 31, 2008 and 2007, respectively. These stock dividends represent the 8% annual dividends payable quarterly in common stock to the holders of our Series A preferred stock.

**Liquidity and Capital Resources**

As of March 31, 2008, we had total cash, cash equivalents, and short-term investments of \$56.2 million versus \$66.2 million as of December 31, 2007. The decrease was the result of \$10.0 million used to fund increased operations. Short-term investments were \$38.9 million as of March 31, 2008, as compared to \$19.8 million as of December 31, 2007. We had no debt outstanding as of March 31, 2008. We invest excess funds in short-term money-market funds and securities pursuant to our investment policy guidelines. We do not have any exposure in our investment portfolio relating to auction rate securities or derivatives.

Net cash used in operating activities for the three months ended March 31, 2008 was \$9.1 million, versus \$3.5 million for the three months ended March 31, 2007. The increase in cash used in 2008 was due primarily to our preclinical and clinical programs, increased headcount, facility relocation and operations.

Net cash used in investing activities was \$20.2 million during the three months ended March 31, 2008, versus \$1.3 million used during the first three months of 2007. The increase results from \$18.9 million in net purchases of short term investments and \$1.3 million of capital expenditures.

Net cash provided by financing activities during the three months ended March 31, 2008 was \$197,000, attributable to proceeds from the exercise of options and reduction of a prior accrual for financing expenses associated with our recent private placement transaction. No cash was provided by financing activities during the three months ended March 31, 2007.

**Table of Contents**

We expect to continue to incur operating losses and will not receive any product revenues in the foreseeable future, other than a potential milestone payment under our master services agreement with Valeant. However, we do not anticipate any additional research activities to be conducted under this master services agreement. Based on current projections and excluding any funds that we may receive from future business development activities, we anticipate 2008 net cash usage to be between \$45 million and \$50 million and our cash, cash equivalents and short-term investments to be sufficient to fund our operations into the second quarter of 2009. Actual cash usage may vary as a result of costs associated with any strategic alternative we pursue or other uncertainties. Accordingly, we will need to raise substantial additional capital within the next twelve to fifteen months, the source of which may be a public or private equity offering, debt financing, corporate collaboration or licensing arrangement. This forecast is a forward-looking statement that involves risks and uncertainties, and actual results could vary.

**Indemnifications**

In the ordinary course of business, we enter into contractual arrangements under which we may agree to indemnify the other party to such arrangement from any losses incurred relating to the services they perform on behalf of us or for losses arising from certain events as defined within the particular contract, which may include, for example, litigation or claims relating to past performance. Such indemnification obligations may not be subject to maximum loss clauses. Historically, payments made related to these indemnifications have been immaterial. In addition, we have entered into indemnity agreements with each of our directors and executive officers and Denis Hickey, our former Chief Financial Officer. Such indemnity agreements contain provisions, which are in some respects broader than the specific indemnification provisions contained in Delaware law. We also maintain an insurance policy for our directors and executive officers insuring against certain liabilities arising in their capacities as such.

**ITEM 3. Quantitative and Qualitative Disclosure 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, 2008, we own financial instruments that are sensitive to market risk as part of our investment portfolio. To minimize this risk and to avoid classification as an investment company under the Investment Company Act of 1940, we have generally limited our investments to cash and securities of the government of the United States of America and its federal agencies. The average duration of our investment portfolio as of March 31, 2008 was less than six months. Due to the short-term nature of these investments, a 50 basis point movement in market interest rates would not have a material impact on the fair value of our portfolio as of March 31, 2008. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk.

**ITEM 4. Controls and Procedures**

Prior to the filing of this quarterly report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, who is also our acting Principal Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Exchange Act) as of the end of the period covered by this quarterly report on Form 10-Q. Disclosure controls and procedures are designed to ensure that information required to be disclosed in our periodic reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based upon that evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this quarterly report on Form 10-Q.

An evaluation was also performed of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our Chief Executive Officer, does not expect that our disclosure controls will prevent all errors or potential fraud. A control system, no matter how well conceived and operated, can provide only reasonable and not absolute assurance that the objectives of the control system are 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 cost. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been or will be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons or by collusion of two or more people. 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, 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.

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. Legal Proceedings**

Currently, we are not a party to any pending legal proceedings, and are not aware of any proceeding against us contemplated by any governmental authority.

**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. 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 risk factors set forth below with an asterisk (\*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in Item 1A of our annual report on Form 10-K for the year ended December 31, 2007, filed with the SEC on March 24, 2008.*

**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.\****

Our accumulated deficit as of March 31, 2008 was \$273.9 million, and we expect 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. We expect that the amounts paid to advance the preclinical and clinical development of our product candidates, including to further develop RDEA806 and RDEA119, will increase materially in 2008. 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, RDEA806 and RDEA119, and any other compounds we advance into further development, may never be approved for commercial sales. The time required to attain 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 expect to increase our operating expenses over at least the next several years as we plan to advance our product candidates, including RDEA806 and RDEA119, into further preclinical testing and clinical trials, expand our research and development activities and acquire or license new technologies and product candidates. As a result, we expect to continue to incur significant and 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 drug 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 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.

**Table of Contents**

***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;

reaching agreement on acceptable terms with prospective contract research organizations and trial sites;

manufacturing sufficient quantities of a product candidate;

obtaining approval of an IND from the FDA or similar foreign approval; and

obtaining institutional review board approval to conduct a clinical trial at a prospective site.

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.

***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;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

lack of adequate funding to continue clinical trials;

negative results of clinical trials;

insufficient supply or deficient quality of drug 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 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 product revenues will be delayed.



**Table of Contents**

***If our internal discovery and development efforts are unsuccessful, we will 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 will 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 an appropriate return from resulting products;

competitors may be unwilling to assign or license product 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 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 FDA 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, or NDA, to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all. If we are unable to submit a NDA with respect to any future product candidate, or if any NDA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject NDAs and requires additional clinical trials, even when drug candidates performed well or 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.

***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, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

our ability to provide acceptable evidence of safety and efficacy;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability of alternative treatments;

pricing and cost effectiveness; and

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

**Table of Contents**

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.\****

Based on current projections and excluding any funds that we may receive from future business development activities, we believe that our existing cash and cash equivalents will be adequate to fund our anticipated levels of operations into the second quarter of 2009. 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 within the next twelve to fifteen months to, among other things:

fund our research, discovery and 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:

the rate of progress and cost of our research and development activities;

whether Valeant terminates our master services agreement after the first year or reduces the amount of services that we provide to Valeant;

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.

## **Table of Contents**

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. 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.

***Raising additional funds by issuing securities or through 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 enter into may involve covenants that restrict our operations. These restrictive covenants would likely 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, pay dividends, redeem capital stocks or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. For example, we might be forced to relinquish all or a portion of our sales and marketing rights with respect to potential products or license intellectual property that enables licensees to develop competing products.

***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 definitively 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.

***We will need to increase the size of our organization, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.***

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our research, development and commercialization efforts and secure collaborations to market and distribute our products. If we continue to grow, it is possible that our management, accounting and scientific personnel, systems and facilities currently in place may not be adequate to support this future growth. To manage any growth, we will be required to continue to improve our operational, financial and management controls, reporting

systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully manage the expansion of our operations or operate on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

**Table of Contents**

***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 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, and we may not be able to perform our obligations under our master services agreement with Valeant. 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 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 be subject to quarterly fluctuations. During the calendar quarter ended March 31, 2008, our closing stock prices ranged from a low of \$11.50 to a high of \$16.20. 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;

whether Valeant terminates our master services agreement after the first year or reduces the amount of services that we provide 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 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.





**Table of Contents**

***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 completed the acquisition of our 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, technology, service or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. These operational and financial risks include:

exposure to unknown liabilities;

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;

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 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.

***Moving our research and development operations was costly and may be disruptive.***

At the end of February 2008, we relocated our research and development activities from our former Costa Mesa, California facility to a building in San Diego, California. The relocation of our operations involved significant expense and may result in on-going disruptions to our operations and the loss of personnel who would be costly to replace. The loss of employees could also have a significant impact on the continuity and progress of our research and development programs. The costs and possible disruptions that may result from this recent relocation may adversely impact our operating results and cash position, interrupt continuing operations, delay or prevent the commercialization of our products and adversely affect our ability to generate revenues, any of which could prevent us from achieving profitability.

**Table of Contents*****Earthquake damage to our facilities could delay our research and development efforts and adversely affect our business.***

Our new 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 for any reason, 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 could limit the market for our products 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 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 Phase 2b clinical trials, but prior to the initiation of Phase 3 clinical trials, 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 products 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 products in these Territories, then our commercialization efforts in the U.S. and Canada may be adversely impacted.

***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.***

We agreed to use 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 the lead product candidates from RDEA806 Program and the 2nd Generation NNRTI Program and the RDEA119 Program and 2nd Generation MEK Inhibitor Program in the United States, the United Kingdom, France, Spain, Italy and Germany. Our efforts will be designed to consistently advance the program with the goal of achieving the first milestone event within 24 months of the closing of the transaction with Valeant. 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 were filed, our reputation within the pharmaceutical research and development community may be 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, beginning with the year ended December 31, 2007, of the effectiveness of our internal controls over financial reporting and, beginning with the year ending December 31, 2009, a report by our independent auditors that both addresses management's assessments and provides our independent auditor's 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 may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404, and our independent auditors may not be able or willing to issue a favorable assessment of our conclusions. 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 trading 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 in all control systems, no evaluation of controls can provide absolute assurance that all control issues and

**Table of Contents**

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 market price of our common 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 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 third-party challenges. We will only be able to protect our product candidates and their uses from unauthorized use by third 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 drug 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:

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 third 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 U.S. 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 third parties. In the event that a third party has also filed a U.S. patent application relating to the product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. 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 U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or

published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

**Table of Contents**

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 drug 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 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 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 third parties. We may be exposed to future litigation by third parties based on claims that our product candidates or activities infringe the intellectual property rights of others. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in HIV, cancer, inflammatory diseases and the other fields in which we are developing products. We cannot assure you that third parties holding any of these patents or patent applications will not assert infringement claims against us for damages or seeking 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.

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 drug candidates for the treatment of 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 third-party 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.

**Table of Contents**

***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 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;

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 or other 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 HIV, cancer or inflammatory diseases, including gout, that are approved faster, marketed better or demonstrated to be 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 HIV, cancer and inflammatory diseases. Potential competitors may develop treatments for HIV, cancer or inflammatory diseases or other technologies and products that are 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.



**Table of Contents**

***If we cannot establish pricing of our product candidates acceptable to the government, 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 government, 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 set a price we believe is fair for any products we may develop and our ability to generate adequate revenues and gross margins. 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 U.S. 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 will face an inherent risk of product liability exposure when we begin testing our product candidates in human clinical trials, and we will face an even greater risk if we sell our product candidates commercially. 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.

***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 liability or 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.

**Table of Contents**

**Risks Related to Our Common Stock**

***Directors, executive officers, principal stockholders and affiliated entities beneficially own or control approximately 75% of our outstanding voting common stock and together control our activities.\****

As of March 31, 2008, our directors, executive officers, principal stockholders and affiliated entities beneficially owned or controlled securities representing, in the aggregate, approximately 75% of our common equivalent shares. 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 own outstanding warrants exercisable as of March 31, 2008 into 97,600 shares of common stock. The exercise of warrants, or sales by our current stockholders of a substantial number of shares, or the expectation that exercises and/or sales may occur, could significantly reduce the market price of our common stock.

**Table of Contents**

***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 governed by 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.

**ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None

**ITEM 3. Defaults Upon Senior Securities**

None

**ITEM 4. Submission of Matters to a Vote of Security Holders**

None

**ITEM 5. Other Information**

None

**ITEM 6. Exhibits**

The exhibits listed on the Exhibit Index (following the signature section of this Quarterly Report) are included, or incorporated by reference, in this Quarterly Report.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Quarterly report to be signed on its behalf by the undersigned thereunto duly authorized on this **9th day of May 2008**.

ARDEA BIOSCIENCES, INC.

By: /s/ BARRY D. QUART, PHARM.D.

Barry D. Quart, Pharm.D.

Chief Executive Officer and

Principal Financial Officer

29

---

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Document Description</b>
2.1	Asset Purchase Agreement with Valeant Research & Development and Valeant Pharmaceuticals International dated December 21, 2006.(1)
3.1	Amended and Restated Certificate of Incorporation and Certificate of Amendment of Amended and Restated Certificate of Incorporation.(2)
3.2	Amended and Restated Bylaws.(3)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation.(4)
3.4	Certificate of Designation filed with the Delaware Secretary of State on May 1, 2003.(4)
3.5	Certificate of Ownership and Merger filed with the Delaware Secretary of State December 21, 2006. (1)
3.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation.(3)
4.1	Form of Warrant issued by the Company pursuant to the Common Stock and Warrant Purchase Agreement of October 6, 2003.
4.2	Registration Rights Agreement dated December 19, 2007, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto.
4.3	Registration Rights Agreement dated January 4, 2008, by and among Ardea Biosciences, Inc. and the stockholders listed on the Signature pages thereto.
31.1	Certification of Chief Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.*
32.1	Certifications of Chief Executive Officer and Principal Financial Officer as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).*

\* Filed herewith.

We have applied for confidential treatment of certain provisions of this exhibit with the Securities and Exchange Commission. The confidential portions of this

exhibit are marked by an asterisk and have been omitted and filed separately with the Securities and Exchange Commission pursuant to our request for confidential treatment.

- (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-K (File No. 000-29993) filed with the Securities and Exchange Commission on March 31, 2003.
- (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 10-Q (File No. 000-29993) filed with the

Securities and  
Exchange  
Commission on  
November 12,  
2003.