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

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

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

Or

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

Commission File Number 1-33734
ARDEA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	94-3200380
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification 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 þ No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer þ	Smaller reporting company o

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes o No þ
There were 13,354,464 shares of the Registrant s common stock, par value $0.001, outstanding as of March 31, 2008.

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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)

	March 31, 2008 (Unaudited)	December 31, 2007
ASSETS		
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
Total current assets	56,963	67,649
Property and equipment, net	2,084	879
Other assets	321	312
Total assets	$ 59,368	$ 68,840
LIABILITIES AND STOCKHOLDERS EQUITY		
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
Total current liabilities	6,529	5,101
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.

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

	Three Months Ended March 31,	
	2008	**2007**
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.

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

	Three Months Ended March 31,	
	2008	**2007**
Operating activities		
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)
Net cash used in operating activities	(9,122)	(3,525)
Investing activities		
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
Net cash used in investing activities	(20,162)	(1,346)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	96	
Proceeds from issuance of common stock upon exercise of options	101	
Net cash provided by financing activities	197	
Net decrease in cash and cash equivalents	(29,087)	(4,871)
Cash and cash equivalents at beginning of period	46,384	14,779
Cash and cash equivalents at end of period	$ 17,297	$ 9,908

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.

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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.

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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:

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

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 2nd Generation NNRTI Program, the RDEA119 Program and the 2nd 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.

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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.

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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

Product candidate	Target indication	Development status
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® , 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;

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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 moeity 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.

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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.

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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.

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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.

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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.

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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.

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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 regula