

Ardea Biosciences, Inc./DE  
Form 10-Q  
May 08, 2007

**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 quarterly period ended March 31, 2007**  
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 0-29993  
ARDEA BIOSCIENCES, INC.  
(Exact name of Registrant as specified in its charter)**

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

94-3200380  
(I.R.S. Employer Identification Number)

**2131 Palomar Airport Road, Suite 300  
Carlsbad, CA 92011**

Registrant's telephone number including area code:  
(760) 602-8422

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 checkmark whether registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (check one)

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

No

There were 9,376,799 shares of the Registrant's common stock, par value \$0.001, outstanding as of March 31, 2007.

**TABLE OF CONTENTS**  
**ARDEA BIOSCIENCES, INC.**  
**FORM 10-Q**  
**QUARTER ENDED MARCH 31, 2007**  
**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements</u>	1
<u>Condensed Balance Sheets as of March 31, 2007 (unaudited) and December 31, 2006</u>	1
<u>Condensed Statements of Operations for the Three months ended March 31, 2007 and 2006 (unaudited)</u>	2
<u>Condensed Statements of Cash Flows for the Three months ended March 31, 2007 and 2006 (unaudited)</u>	3
<u>Notes to Condensed Financial Statements</u>	4
<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>	15
<u>Item 4. Controls and Procedures</u>	15
 <b><u>PART II. OTHER INFORMATION</u></b>	 17
 <u>Item 1. Legal Proceedings</u>	 17
<u>Item 1A. Risk Factors</u>	17
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
<u>Item 3. Defaults Upon Senior Securities</u>	29
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	29
<u>Item 5. Other Information</u>	29
<u>Item 6. Exhibits</u>	29
 <b><u>SIGNATURES</u></b>	 30
 <b><u>EXHIBIT INDEX</u></b>	 31
<u>EXHIBIT 10.1</u>	
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

---

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

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

	<b>March 31, 2007 (Unaudited)</b>	<b>December 31, 2006 (Note 1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,908	\$ 14,779
Short-term investments	35,390	33,890
Prepaid expenses and other current assets	1,666	845
Total current assets	46,964	49,514
Property and equipment, net	695	726
Total assets	\$ 47,659	\$ 50,240
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,029	\$ 234
Accrued clinical liabilities	4	4
Accrued employee liabilities	244	
Other accrued liabilities	521	938
Total current liabilities	1,798	1,176
Commitments and 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, 2007 and December 31, 2006	1,634	1,634
Common stock, \$0.001 par value: 70,000,000 shares authorized at March 31, 2007 and December 31, 2006; 9,376,799 and 9,362,191 shares outstanding at March 31, 2007 and December 31, 2006, respectively	9	9
Additional paid-in capital	283,823	283,594
Accumulated other comprehensive income	1	4
Accumulated deficit	(239,606)	(236,177)
Total stockholders' equity	45,861	49,064
Total liabilities and stockholders' equity	\$ 47,659	\$ 50,240

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

**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>31,</b>	
	<b>2007</b>	<b>2006</b>
Revenue	\$ 893	\$
Operating expenses:		
Research and development (includes non-cash stock- based compensation of \$28 and \$0, respectively)	\$ 3,513	7
General and administrative (includes non-cash stock- based compensation of \$141 and \$135, respectively)	1,544	660
Total operating expenses	5,057	667
Operating loss	(4,164)	(667)
Interest income	611	518
Other income (expense), net	184	(1)
Net loss	(3,369)	(150)
Non-cash dividends on Series A preferred stock	(60)	(60)
Net loss applicable to common stockholders	\$ (3,429)	\$ (210)
Basic and diluted net loss per share applicable to common stockholders	\$ (0.37)	\$ (0.02)
Shares used to compute basic and diluted net loss per share applicable to common stockholders	9,373	9,298

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>2007</b>	<b>2006</b>
<b>Operating activities</b>		
Net loss	\$ (3,369)	\$ (150)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	169	135
Depreciation and amortization	58	
Gain on disposal of property and equipment	(184)	
Change in assets and liabilities:		
Prepaid expenses and other current assets	(821)	83
Other assets		
Accounts payable	795	(2)
Accrued clinical liabilities		(91)
Accrued employee liabilities	244	
Other accrued liabilities	(417)	(51)
Net cash used in operating activities	(3,525)	(76)
<b>Investing activities</b>		
Capital expenditures	(27)	
Proceeds from sale of property and equipment	184	
Purchase of short-term investments	(35,496)	(59,712)
Proceeds from sale or maturity of short-term investments	33,993	57,730
Net cash used in investing activities	(1,346)	(1,982)
Net decrease in cash and cash equivalents	(4,871)	(2,058)
Cash and cash equivalents at beginning of the period	14,779	2,772
Cash and cash equivalents at end of the period	\$ 9,908	\$ 714
<b>Supplemental disclosure of non-cash information:</b>		
Issuance of common stock dividend on Series A preferred stock	\$ (60)	\$ (60)

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

**Table of Contents**

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

**Note 1. Basis of Presentation and Summary of Significant Accounting Policies**

The accompanying condensed financial statements are unaudited and have been prepared by Ardea Biosciences, Inc. (the Company) in accordance with the rules and regulations of the Securities and Exchange Commission for interim financial information, and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X.

Certain information and footnote disclosures normally included in the Company's annual audited financial statements (as required by accounting principles generally accepted in the United States) have been condensed or omitted. The interim condensed financial statements, in the opinion of management, reflect all adjustments (consisting entirely of normal recurring adjustments) necessary for a fair presentation of the Company's financial position as of March 31, 2007, the results of its operations for the three months ended March 31, 2007 and 2006 and cash flows for the three months ended March 31, 2007 and 2006.

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 interim condensed financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2006, which are contained in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 2, 2007. The condensed balance sheet as of December 31, 2006 is derived from such audited financial statements.

***Use of Estimates***

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes, including amounts accrued for stock-based compensation.

The Company's estimate of accrued costs is 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.

**Note 2. Stock-Based Compensation**

***Stock Plans***

The Company's 2004 Stock Incentive Plan (the 2004 Plan) was adopted in May 2004, and replaced the 2000 Equity Incentive Plan (the 2000 Plan), which in turn had replaced the 1995 Incentive Stock Plan (the 1995 Plan) collectively the Predecessor Plans). The termination of the Predecessor Plans had no effect on the options that were granted thereunder. The terms of awards granted under the Predecessor Plans were substantially similar to those granted under the 2004 Plan. The 2004 Plan allows for the granting of options to purchase stock, stock bonuses and rights to acquire restricted stock of up to 2,050,000 shares of common stock to employees, consultants, and directors. The number of shares of common stock available for issuance under the 2004 Plan shall automatically increase on the first trading day of January each calendar year during the term of the 2004 Plan, beginning with calendar year 2005. The shares available for issuance under the 2004 Plan were increased by 543,302 on January 1, 2006, and 547,027 on January 1, 2007. All options granted under the 2004 Plan must have exercise prices equal to the fair market value of the common stock on the option grant date, and are to have a term not greater than 10 years from the grant date. Options granted under the 2004 Plan vest ratably over periods ranging from 3 months to six years. Options granted under the Predecessor Plans vest ratably over periods ranging from 18 months to six years.

The 2002 Non-Officer Equity Incentive Plan (the 2002 Plan) was adopted in August 2002 and allows for the granting of stock awards, stock bonuses and rights to acquire restricted stock of up to 56,250 shares of common stock to employees of the Company who are not officers, to executive officers not previously employed by the Company as an inducement to entering into an employment contract with the Company, and to consultants of the Company. All options are to have a term not greater than 10 years from the grant date.



**Table of Contents**

To cover the exercise of vested options the Company issues new shares from its authorized but unissued share pool. As of March 31, 2007, there were 1,803,337 and 56,250 shares of common stock available for issuance (grant) under the 2004 Plan and the 2002 Plan, respectively.

No cash proceeds were received from the sales of common stock under employee option plans for the three months ended March 31, 2007 or March 31, 2006. No income tax benefits were realized from the sales of common stock during the three months ended March 31, 2007. In accordance with SFAS 123 (R), the Company presents excess tax benefits from the exercise of stock options, if any, as financing cash flows rather than operating cash flows.

***Adoption of SFAS No. 123 (R)***

Effective January 1, 2006, the Company adopted Financial Accounting Standards Board Statement of Financial Accounting Standards ( SFAS ) 123(R) Share-Based Payment , a revision of SFAS 123, Accounting for Stock-Based Compensation which superseded Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. SFAS 123(R) establishes standards for the accounting for transactions where an entity exchanges its equity instruments for goods or services. The principal focus of SFAS 123(R) is the accounting for transactions in which an entity obtains employee services in share-based payment transactions, and where the measurement of the cost of employee (or member of the Board of Directors) services received in exchange for an award of equity instruments is based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee (or director) is required to provide service in exchange for the award the requisite service period and unless observable market prices for the same or similar instruments are available, will be estimated using option-pricing models adjusted for the unique characteristics of the instruments. If an equity award is modified after the grant date, incremental compensation cost will be recognized in an amount equal to the excess of the fair value of the modified award over the fair value of the original award immediately before the modification.

***Stock Compensation Expense***

Under SFAS 123(R), we determined the appropriate fair value model to be used for valuing share-based payments and the amortization method for compensation cost. The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006. The Company's Consolidated Financial Statement for the three months ended March 31, 2007 reflects the impact of SFAS 123(R). During the three months ended March 31, 2007 and 2006, the Company recognized \$169,000 and \$136,000, respectively, in compensation expense related to options granted to employees and directors. There were no tax benefits from share-based compensation since the Company has substantial tax loss carry forwards and sustained a loss to stockholders for the three months ended March 31, 2007. The impact of stock based compensation on both basic and diluted earnings per share for the three months ended March 31, 2007 was \$0.02.

At March 31, 2007, the total compensation cost related to unvested stock-based awards granted to employees under the stock option plans but not yet recognized was approximately \$2.1 million, after estimated forfeitures. The cost will be recognized on a straight-line basis over an estimated weighted average period of approximately 3.5 years for stock options and will be adjusted if necessary for forfeitures and cancellations.

***Determining Fair Value***

*Valuation and amortization method* The Company estimates the fair value using a Black-Scholes option pricing formula and a single option award approach. This fair value is then amortized ratably over the requisite service periods of the awards, which is generally the vesting period.

*Expected Term* The expected term of options is derived from the output of the option valuation model and represents the period of time that options granted are expected to be outstanding; which results from certain groups of employees exhibiting different behavior.

*Expected Volatility* The Company's expected volatility for the quarter ended March 31, 2007 is based on Company's historical volatility.

*Risk-Free Interest Rate* The risk-free interest rate used in the Black-Scholes option valuation method is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term of the option.



**Table of Contents**

*Expected Dividend* The dividend yield reflects that the Company has not paid any dividends on common stock and has no intention to pay dividends on common stock in the foreseeable future.

*Estimated Forfeiture* Because of the cessation of operations from June of 2005 through December of 2006, the Company has no reliable information at this time to estimate forfeiture.

In the three months ended March 31, 2007, the fair value of each option grant was estimated on the date of grant using the Black-Scholes option valuation model using a dividend yield of 0% and the following weighted average assumptions:

	<b>Three Months Ended March 31, 2007</b>
Risk-free interest rate	4.66%
Volatility	0.15
Dividend yield	0.00%
Expected life of option	6.1 years

Stock options for 734,000 shares were granted to employees during the three months ended March 31, 2007. There were no post-vesting restrictions.

**Stock Options and Awards Activities**

The following is a summary of the Company's stock option activity under the stock option plans as of March 31, 2007 and related information:

	<b>Number of Shares</b>	<b>Outstanding Options Weighted Average Exercise Price</b>	<b>Remaining Contract Life</b>	<b>Aggregate Intrinsic Value (000 \$)</b>
Balance at December 31, 2006	1,345,834	\$5.45	8.58	1,763,077
Granted	734,000	\$4.63	9.76	437,740
Exercised				
Forfeitures and cancellations				
Balance at March 31, 2007	2,079,834	\$5.16	8.67	\$2,200,817
Vested and expected to Vest at March 31, 2007	2,079,834	\$5.16	8.67	\$2,200,817
Exercisable at March 31, 2007	444,583	\$7.51	5.8	\$ 608,827

The weighted-average grant date fair value of options granted for the three months ended March 31, 2007 was \$4.63. The aggregate intrinsic value in the table above represents the total pretax intrinsic value, based on the Company's closing stock price of \$5.25 at March 31, 2007, which would have been received by option holders had all option holders exercised their options that were in-the-money as of that date. The total number of in-the-money options exercisable as of March 31, 2007 was 270,834 shares. The aggregate intrinsic value of options exercised during the three month period ending March 31, 2007 was zero, since there were no options exercised.

The exercise prices for options outstanding and exercisable as of March 31, 2007 and their weighted average remaining contractual lives were as follows:

**Table of Contents**

Exercise Prices	Number of Shares	Options Outstanding		Options exercisable		
		Weighted-Average Remaining Contractual Life (years)	Weighted Average	Exercise Price	Number of Shares	Exercise Price
\$ 2.76	203,334	3.76		2.76	203,334	\$ 2.76
\$ 3.50	37,500	8.87		3.50	37,500	\$ 3.50
\$ 3.90	865,000	9.73		3.90	10,000	\$ 3.90
\$ 4.08	20,000	7.76		4.08	20,000	\$ 4.08
\$ 4.24	424,000	9.76		4.24		\$ 4.24
\$ 5.20	190,000	9.96		5.20		\$ 5.20
\$ 5.10	120,000	9.96		5.10		\$ 5.10
\$13.06	100,000	7.1		13.06	70,833	\$13.06
\$13.93	40,000	7.2		13.93	36,666	\$13.93
\$16.49	80,000	6.84		16.49	66,250	\$16.49
Totals	2,079,834	8.67		5.16	444,583	\$ 7.51

**Note 3. Comprehensive Income (Loss)**

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

	Three Months Ended March 31,	
	2007	2006
	(In thousands)	
Net loss	\$ (3,369)	\$ (150)
Unrealized gain (loss) on available-for-sale securities	(3)	16
Comprehensive loss	\$ (3,372)	\$ (134)

**Note 4. Net Income (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). As the Company's 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 2007 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 income (loss) per share applicable to common stockholders was 3,941,027 and 2,436,535 for the three months ended March 31, 2007 and 2006.

**Note 5. Stockholders Equity**

The Company's quotation for its common stock appears in the Pink Sheets under the trading symbol ARDC.

In January 2007, the Company issued 14,608 shares of common stock in connection with dividends payable to holders of preferred stock on December 31, 2006.

**Note 6. Acquisition**

On December 21, 2006, the Company acquired intellectual property and other assets related to three distinct pharmaceutical research and development programs from Valeant, hired a new senior management team, including Barry D. Quart, Pharm.D., who replaced Denis Hickey as Chief Executive Officer, and changed its name from IntraBiotics Pharmaceuticals, Inc. to Ardea

**Table of Contents**

Biosciences, Inc. With these developments, the Company is pursuing pharmaceutical research and development focused on the development of novel treatments for viral diseases, cancer and inflammatory diseases. The Company is providing research services to Valeant in connection with a preclinical program in the field of neuropharmacology pursuant to a services agreement with Valeant. This agreement, which has a two-year term subject to Valeant's option to terminate the agreement after the first year, provides that the Company will receive quarterly payments totaling up to \$3.5 million per year and up to \$1.0 million in milestone payments.

Under the Asset Purchase Agreement with Valeant, the Company is also obligated to make development-based milestone payments and sales-based royalty payments to Valeant. There is one set of milestones for the 800 and 900 Series Programs and a separate set of milestones for the 100 Series Program (see ITEM 2, Recent Developments for discussion of these programs). Assuming the successful commercialization of a product incorporating a compound from the 800 Series Program or the 900 Series Program, the milestone payments for these two programs combined could total \$25 million. For the 100 Series Program, milestone payments could total \$17 million, assuming the successful commercialization of a product from that program. For each program, milestones are paid only once regardless of how many compounds are developed or commercialized. In each program, the first milestone payment would be due after the completion of a proof-of-concept clinical study in patients, and more than half of the total milestone payments would be due after regulatory approval. The royalty rates on all products are in the mid-single digits.

As part of the purchase of assets from Valeant, the Company received fixed assets valued at approximately \$4.3 million and goodwill and intangible assets valued at \$800,000. For these assets, the Company paid no upfront consideration and did not assume any liabilities except for liabilities under certain contracts related to the assets. The Company's costs for professional fees in connection with the transaction were approximately \$500,000. The transaction was initially recorded at fair market value as follows:

Fixed assets of approximately \$4.3 million,

Intangible assets of approximately \$300,000, and

Goodwill of approximately \$500,000.

These assets were acquired without upfront consideration. Therefore, the fair value of the assets acquired exceeded the cost of upfront consideration paid. The excess of \$4.6 million (net of transaction costs) was allocated in its entirety as reductions to the amounts initially assigned to the acquired non-current assets pursuant to paragraph 44 of Statement of Financial Accounting Standards No. 141 (SFAS 141).

**Note 7. Commitments and contingencies**

As discussed in footnote 6, under the Asset Purchase Agreement with Valeant, the Company is obligated to make development-based milestone payments and sales-based royalty payments to Valeant. The contingent liability of up to \$42 million in milestone payments for the 800, 900 and 100 Series Programs was considered a liability in the ordinary course of business, to be recorded when the contingency is resolved and consideration is issued or becomes assumable.

In December 2006, the Company entered into a lease for its Costa Mesa research facility. This leased property, which is located at 3300 Hyland Avenue, Costa Mesa, California 92626, is being used in connection with the Company's research and development activities. The facility occupies approximately 64,000 square feet of laboratory and office space and the monthly base rent is approximately \$90,000. The lease expires in March 2008.

The Company recently entered into a lease for 2,900 square feet of space in Carlsbad, California, at a monthly rent approximating \$3,000 after sublease income. This facility houses the Company's corporate offices.

**Note 8. 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.

**Note 9. Recent Accounting Pronouncements**

In July 2006, the FASB issued Financial Interpretation No. 48, Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109 (FIN 48), which is a change in accounting for income

taxes. FIN 48 specifies

**Table of Contents**

how tax benefits for uncertain tax positions are to be recognized, measured, and derecognized in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim period guidance, among other provisions. FIN 48 is effective for fiscal years beginning after December 15, 2006. We do not anticipate that this FASB will have any material impact on our financial condition or results of operations.

In September 2006, the FASB issued SFAS No. 157 ( SFAS 157 ), Fair Value Measurements. Among other requirements, SFAS No. 157 defines fair value and establishes a framework for measuring fair value and also expands disclosure about the use of fair value to measure assets and liabilities. SFAS No. 157 is effective beginning the first fiscal year after November 15, 2007. The Company is currently evaluating the impact of SFAS No. 157 on its financial position and results of operations.

In September 2006, the SEC issued SAB No. 108, Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements ( SAB 108 ), which provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The guidance is applicable for fiscal years ending after November 15, 2006. We do not anticipate that this SAB will have any material impact on our financial condition or results of operations.

In September, 2006, the FASB issued SFAS No 158, Employers Accounting for Defined Benefit Pension and Other Postretirement Plans ( FAS 158 ). FAS 158 requires companies to fully recognize the obligations associated with single-employer defined benefit pension, retiree healthcare and other postretirement plans in their financial statements. As we do not have defined benefit pensions or other postretirement plans, FAS 158 will have no impact on our financial statements or results of operations. In July 2006, the FASB issued FASB Staff Position (FSP) No. FAS 13-2, Accounting for a Change or Projected Change in the Timing of Cash Flows Relating to Income Taxes Generated by a Leveraged Lease Transaction, that provides guidance on how a change or a potential change in the timing of cash flows relating to income taxes generated by a leveraged lease transaction affects the accounting by a lessor for the lease. This staff position was adopted by the Company on January 1, 2007. The Company does not expect the adoption of this provision to have a material effect on its financial position, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities . The objective of this statement is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of SFAS 159, but does not expect adoption to have a material impact on its consolidated financial position, results of operations or cash flows.

**Note 10. Income Taxes**

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, on January 1, 2007. 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.

**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 financial statements and related notes appearing elsewhere in this Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2006 included with our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC. 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. 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.*

**Table of Contents****Overview and Business Strategy**

Ardea is focused on the development of small-molecule drugs that address large pharmaceutical markets. We plan to source these development candidates from both our internal drug discovery programs and our continued in-licensing efforts. Our initial therapeutic areas of focus are viral diseases, cancer and inflammatory diseases. We believe that we are well-positioned to create shareholder value through our development activities given our ability to achieve clinical proof-of-concept relatively quickly and cost-effectively in these disease areas. The Company currently is pursuing three development programs and has a goal of initiating clinical studies on three or more compounds this year. These development programs include the following:

**800 Series Program.** Our 800 Series Program is our lead program and is directed toward the discovery and development of non-nucleoside reverse transcriptase inhibitors (NNRTIs) for the potential treatment of HIV. The lead product candidate from this program is RDEA806. *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 preclinical 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 initiated a Phase I clinical study of RDEA806 in March 2007 and plan to report initial results from this study in the third quarter of 2007.

**900 Series Program.** Our 900 Series Program, which is in preclinical development, is also directed toward the discovery and development of NNRTIs for the potential treatment of HIV. The compounds in our 900 Series Program are from a chemical class that is distinct from the chemical class being investigated in our 800 Series Program. Based on early preclinical data, we believe that the compounds in our 900 Series Program may have the potential to share certain of the positive attributes of the compounds in our 800 Series Program, but also appear to have even greater activity against a wide range of drug-resistant viral isolates. We plan to select one or more development candidates from this program in the second quarter of 2007 and to initiate a clinical study in the fourth quarter of 2007.

**100 Series Program.** Our 100 Series Program, which is in preclinical development, is directed toward the discovery and development of small-molecule kinase inhibitors for the potential treatment of both cancer and inflammation. RDEA119 is our lead development candidate from our 100 Series Program. *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, as well as inflammatory cell signaling. *In vivo* preclinical tests have shown RDEA119 to have potent anti-tumor activity. In other preclinical tests, RDEA119 and one of our follow-on MEK inhibitors have been shown to have potent anti-inflammatory activity. Finally, preclinical data suggest that RDEA119 may have favorable pharmaceutical properties, including the potential for convenient oral dosing. We plan to initiate a Phase I clinical study of RDEA119 in the third quarter of 2007.

**Market Opportunity**

We believe that there is a significant market opportunity for our products, should they be successfully developed, approved and commercialized.

In 2005, the worldwide market for HIV antivirals was approximately \$8.0 billion, according to IMS Health Incorporated. While the treatment of HIV has improved dramatically over the past decade, we believe that there remains a significant need for new treatments that are effective against drug-resistant virus, well-tolerated and convenient to take. We believe that our 800 and 900 Series NNRTIs have the potential to meet this market need.

We also believe that there is a growing interest in the potential for targeted therapies, including kinase inhibitors, for the treatment of both cancer and inflammatory disease. In 2005, the worldwide market for targeted therapies for cancer was \$7.5 billion, according to Datamonitor plc, and the worldwide market for targeted therapies for inflammatory diseases was more than \$8.0 billion, according to IMS Health Incorporated. Given the role that MEK appears to play in cancer and inflammatory diseases and the increasing preference for oral therapies, we believe that

RDEA119 and our follow-on MEK inhibitors, if successfully developed, approved and commercialized, could participate in these growing markets.

**Table of Contents****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, reduced our work force, and evaluated strategic alternatives, including potential mergers, acquisitions, in-licensing opportunities and liquidation.

On May 5, 2005, after considering a variety of strategic alternatives, none of which was determined by our management and Board of Directors to be in the best interests of us and our stockholders, our Board of Directors decided to reduce operating expenses to a minimum appropriate level. In accordance with these plans, we terminated all of our remaining regular employees on June 15, 2005, 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, and appointed Denis Hickey of Hickey & Hill, Inc. as our Chief Executive Officer and Chief Financial Officer.

From June 15, 2005 until December 21, 2006, Denis Hickey handled the administration of our affairs, while our Board of Directors and selected consultants searched for and evaluated strategic alternatives for our business. During that period, we evaluated several strategic alternatives in the biotechnology industry with the support of consultants, including Barry D. Quart, Pharm.D., our current President and Chief Executive Officer, and the active participation of our Board of Directors.

**Transaction with Valeant**

On December 21, 2006, we acquired intellectual property and other assets related to three distinct pharmaceutical research and development programs (the 800 Series Program, the 900 Series Program, and the 100 Series Program) from Valeant Research & Development, Inc., or Valeant, pursuant to an Asset Purchase Agreement, hired a new senior management team, including Barry D. Quart, Pharm.D., who replaced Denis Hickey as Chief Executive Officer, and changed our name from IntraBiotics Pharmaceuticals, Inc. to Ardea Biosciences, Inc. With these developments, we are pursuing pharmaceutical research and development focused on novel treatments for viral diseases, cancer and inflammatory diseases, as discussed above.

In consideration for the purchased assets 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 800 and 900 Series Programs and a separate set of milestones for the 100 Series Program. Assuming the successful commercialization of a product incorporating a compound from the 800 Series Program or the 900 Series Program, the milestone payments for these two programs combined could total \$25 million. For the 100 Series Program, milestone payments could total \$17 million, assuming the successful commercialization of a product from that program. For each program, milestones are paid only once regardless of how many compounds are developed or commercialized. In each program, the first milestone payment would be due after the completion of a proof-of-concept clinical study in patients, and more than half of the total milestone payments would be due after regulatory approval. 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 to our first NNRTI derived from the acquired intellectual property to advance to Phase III. If Valeant exercises this option, which it can do following the completion of Phase IIb but prior to the initiation of Phase III, the Company would be responsible for completing the Phase III studies and for the registration of the product in the U.S. and European Union. Valeant would pay us a \$10.0 million option fee, up to \$21.0 million in milestone payments based on regulatory approvals, and a mid-single-digit royalty on product sales in the Valeant territories.

We also entered into a research 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. Valeant will own all intellectual property under this research program. We also entered into a lease agreement for space formerly held by Valeant.

**Table of Contents**

The assets we acquired from Valeant include equipment, intellectual property, contracts, permits, licenses and items necessary for us to pursue our three pharmaceutical research and development programs. The fixed assets we received from Valeant were valued at approximately \$4.3 million, and goodwill and intangible assets were valued at approximately \$800,000. For these assets, we paid no upfront consideration and assumed no liabilities except for liabilities under certain contracts related to the assets. Our costs for professional fees in connection with the transaction were approximately \$500,000. Since the fair value of the assets acquired exceeded the cost of the upfront consideration paid, we initially recorded the excess of \$4.6 million (net of transaction costs) as negative goodwill and then subsequently allocated this amount in its entirety to reduce the amounts initially assigned to the acquired non-current assets pursuant to paragraph 44 of Statement of Financial Accounting Standards No. 141 (SFAS 141). As a result, \$500,000 of gross fixed assets associated with the transaction remains on our records. We also have a contingent liability of up to \$42 million related to our obligations to make milestone payments for the 800, 900 and 100 Series Programs, to be recorded if and when the milestones become payable.

**Financial Outlook**

On March 31, 2007, the Company had a total of \$45.3 million in cash, cash equivalents, and short-term investments and recorded liabilities of \$1.8 million. The Company continues to expect negative cash flow of between \$16 million and \$20 million for all of 2007, and to end 2007 with approximately \$28 million to \$32 million in cash, cash equivalents and short-term investments. We currently expect that our current cash resources will fund operations through 2008. Actual cash usage may vary as a result of costs associated with any strategic endeavors of the Company. There can be no assurance that such cash projections will be achieved, as actual expenditures and interest income may differ significantly from projected levels.

We intend that the following discussion of our results of operations and financial condition will provide information to assist in the understanding of our financial statements, the changes in certain key items in those financial statements from year to year, and the primary factors that accounted for those changes, as well as how certain accounting principles, policies and estimates affect our 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.

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 accounting principles generally accepted in the United States of America. 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**

Effective January 1, 2006, the Company adopted Financial Accounting Standards Board Statement of Financial Accounting Standards ( SFAS ) 123(R) Share-Based Payment , a revision of SFAS 123, Accounting for Stock-Based Compensation which superseded Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. SFAS 123(R) establishes standards for the accounting for transactions where an entity exchanges its equity instruments for goods or services. The principal focus of SFAS 123(R) is the accounting for transactions in which an entity obtains employee services in share-based payment transactions, and where the measurement of the cost of employee (or member of the Board of Directors) services

received in exchange for an award of equity instruments is based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee (or director) is required to provide service in exchange for the award the requisite service period and unless observable market prices for the same or similar instruments are available, will be estimated using option-pricing models adjusted for the unique characteristics of the instruments. If an equity award is modified after the grant date, incremental compensation cost will be recognized in an amount equal to the excess of the fair value of the modified award over the fair value of the original award immediately before the modification.

**Table of Contents**

Under SFAS 123(R), we determined the appropriate fair value model to be used for valuing share-based payments and the amortization method for compensation cost. The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006. The Company's Consolidated Financial Statement for the three months ended March 31, 2007 reflects the impact of SFAS 123(R). During the three months ended March 31, 2007 and 2006, the Company recognized \$169,000 and \$136,000, respectively, in compensation expense related to options granted to employees and directors. There were no tax benefits from share-based compensation since the Company has substantial tax loss carry forwards and sustained a loss to stockholders for the three months ended March 31, 2007. The impact of stock based compensation on both basic and diluted earnings per share for the three months ended March 31, 2007 was \$0.02.

***Clinical Trial Accruals***

We accrued costs for clinical trial activities are 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, 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, 2007 and 2006******Research and Development***

Research and development expenses primarily include research and development payroll expense, drug substance expense, facilities costs and non-cash stock compensation charges. Research and development expenses were \$3.5 million during the three months ended March 31, 2007 as compared to \$7,000 for the three months ended March 31, 2006. The increase is due to the purchase of assets from Valeant Research and Development and resulting expenses reflecting ongoing operations, such as payroll (\$1.3 million), facilities (\$0.6 million), chemicals, supplies, and outside services (\$1.4 million), and employee stock compensation (\$28,000).

***General and Administrative***

General and administrative costs currently include payroll expense, outside contractors, legal and accounting fees, insurance, non-cash stock compensation charges, expenses associated with the evaluation of strategic options, and other general administrative expenses. General and administrative expenses were \$1.5 million and \$660,000, respectively, during the three months ended March 31, 2007 and 2006. The increase between the three-month periods is the result an increased level of spending due to our purchase of assets from Valeant and startup of operations, such as payroll (\$478,000), professional and consulting (\$100,000), patent costs associated with filing patents internationally (\$151,000), and implementing new systems to accommodate the transactional load of the new organization (\$250,000). Stock compensation expense was \$141,000 and \$135,000 during the three months ended March 31, 2007 and 2006, respectively.

***Interest Income***

Interest income was \$611,000 and \$518,000, respectively, during the three months ended March 31, 2007 and 2006. Interest income increased primarily because of higher average interest rates during 2007, offset somewhat by a decrease in cash balances in the first quarter of 2007.

***Loss Applicable to Common Stockholders***

Net loss applicable to common stockholders was \$3.4 million and \$210,000 during the three months ended March 31, 2007 and 2006, respectively. The difference in 2007 versus 2006 is primarily attributable to the substantial increase of research and development and general and administrative expenses as described above. Net loss applicable to common stockholders also includes the impact of Series A preferred stock dividends of \$60,000 for the three months ended March 31, 2007 and 2006, respectively. Preferred stock dividends represent the 8% annual dividends payable quarterly in common stock to the holders of our Series A preferred stock.



## **Table of Contents**

### **Liquidity and Capital Resources**

As of March 31, 2007, we had total cash, cash equivalents, and short-term investments of \$45.3 million versus \$48.7 million as of December 31, 2006. The decrease was the result of the cash required to fund increased operations. Short-term investments were \$35.4 million as of March 31, 2007 as compared to \$33.9 million as of December 31, 2006. We had no debt outstanding as of March 31, 2007. We invest excess funds in short-term money-market funds and securities pursuant to our investment policy guidelines.

Net cash used by operating activities for the three months ended March 31, 2007 and 2006 was \$3.5 million and \$76,000, respectively. The cash used in 2007 was due primarily to the restart of operations. The cash used in 2006 consisted primarily of the net loss adjusted for non-cash stock compensation expense and changes in prepaid expenses and accrued clinical liabilities.

Net cash used in investing activities was \$3.8 million and \$2 million, respectively, during the three months ended March 31, 2007 and 2006. The cash used in both periods primarily represents purchases of short-term investments offset by proceeds from the sale or maturity of short-term investments.

No cash was provided by financing activities during the three months ended March 31, 2007 or 2006.

We expect to continue to incur operating losses and will not receive any product revenues in the foreseeable future, other than milestone payments from Valeant research projects currently underway. Based on current projections, the Company expects cash, cash equivalents and short-term investments as of December 31, 2007 to be in the range of \$28 million to \$32 million. Actual cash may be lower as a result of costs associated with any strategic alternative we pursue. We currently anticipate our cash, cash equivalents and short-term investments to be sufficient to fund our operations through 2008. This forecast is a forward-looking statement that involves risks and uncertainties, and actual results could vary.

### **Contractual Obligations**

Under the Asset Purchase Agreement with Valeant, the Company is also obligated to make development-based milestone payments and sales-based royalty payments to Valeant. There is one set of milestones for the 800 and 900 Series Programs and a separate set of milestones for the 100 Series Program. Assuming the successful commercialization of a product incorporating a compound from the 800 Series Program or the 900 Series Program, the milestone payments for these two programs combined could total \$25 million. For the 100 Series Program, milestone payments could total \$17 million, assuming the successful commercialization of a product from that program. For each program, milestones are paid only once regardless of how many compounds are developed or commercialized. In each program, the first milestone payment would be due after the completion of a proof-of-concept clinical study in patients, and more than half of the total milestone payments would be due after regulatory approval. The royalty rates on all products are in the mid-single digits. The contingent liability of up to \$42 million in milestone payments for the 800, 900 and 100 Series Programs was considered a liability in the ordinary course of business, to be recorded when the contingency is resolved and consideration is issued or becomes assumable.

In December 2006, the Company entered into a lease for its Costa Mesa research facility. This leased property, which is located at 3300 Hyland Avenue, Costa Mesa, California 92626, is being used in connection with the Company's research and development activities. The facility occupies approximately 64,000 square feet of laboratory and office space and the monthly base rent is approximately \$90,000. The lease expires in March 2008.

The Company recently entered into a lease for 2,900 square feet of space in Carlsbad, California, at a monthly rent approximating of \$3,000 after sublease income. This facility houses the Company's corporate offices.

The holders of our Series A preferred stock are entitled to receive cumulative dividends at the rate of 8% per annum of the original purchase price of \$10,000 per share of Series A preferred stock. Based on the number of shares of preferred stock outstanding as of March 31, 2007 this equates to \$240,000 per year. The dividends are payable quarterly in shares of common stock, and the number of shares payable are determined based on the average closing sale price of the common stock on the NASDAQ National Market or other market on which our common stock is traded for each of the five trading days immediately preceding the applicable dividend payment date. We do not currently anticipate paying any cash dividends in the foreseeable future.



**Table of Contents****Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements (as that term is defined in Item 303 of Regulation S-K) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

**Indemnifications**

In the ordinary course of business, we enter into contractual arrangements under which we may agree to indemnify the third party to such arrangement from any losses incurred relating to the services they perform on behalf of the Company 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 Hickey & Hill. 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, 2007, 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, 2007 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, 2007. 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**

As of the end of the period covered by this quarterly report, an evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Section 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the design and operation of these disclosure controls and procedures were effective.

There have been no significant changes in the Company's internal control over financial reporting that occurred during the Company's first fiscal quarter that has materially affected or is reasonably likely to materially affect the Company's internal control over financial reporting.

**Disclosure Controls and Procedures**

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosure.

**Scope of the Controls Evaluation**

During the evaluation of our controls and procedures, we looked to identify data errors, control problems or acts of fraud and confirm that appropriate corrective action (including process improvements) was being undertaken. This evaluation is performed on a quarterly basis so that the conclusions of management, including the Chief Executive Officer and the Chief Financial Officer, concerning the effectiveness of the disclosure controls and procedures can be disclosed to our Board of Directors and to our independent auditors, and reported in our Quarterly Reports on Form 10-Q and in our Annual Report on Form 10-K.



**Table of Contents**

**Future Requirements**

The regulations implementing Section 404 of the Sarbanes-Oxley Act of 2002 require management's assessment of the effectiveness of the Company's internal control over financial reporting beginning with our Annual Report on Form 10-K for the fiscal year ending December 31, 2007. The Company's independent auditors will be required to confirm in writing whether management's assessment of the effectiveness of the internal control over financial reporting is fairly stated in all material respects, and separately report on whether they believe management maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008. This process will be resource and time consuming, and will require significant attention of management. If a material weakness is discovered, corrective action may be time consuming, costly and further divert the attention of management. The disclosure of a material weakness, even if quickly remedied, could reduce the market's confidence in the Company's financial statements and harm the Company's stock price, especially if a restatement of financial statements for past periods is required.

**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. Risk factors that have changed since issuing the Form 10-K are designated with a star (\*).

**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, 2007 was \$240 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 to use approximately \$16.0 million to \$20.0 million in cash through the end of 2007 to advance the preclinical and clinical development of the product candidates we acquired from Valeant, including to further develop RDEA806 and RDEA119. 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 the product candidates we acquired from Valeant, 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 (investigational new drug) 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 that we acquired from Valeant 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 an 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.

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.

**Table of Contents**

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

We believe that our existing cash and cash equivalents will be adequate to fund our anticipated levels of operations through 2008. 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 the product candidates acquired from Valeant that we only recently acquired, we may not be able to accurately anticipate our future research and development funding needs. We will need to raise substantial additional capital at least within the next two years 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 research services agreement after the first year;

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

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

the costs and timing of regulatory approval;

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

the effects of competing technological and market developments;

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

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

We do not anticipate that we will generate significant continuing revenues for at least several years, if ever. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. 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

20

---

**Table of Contents**

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.

***If we fail to establish additional research and development capability internally or through collaborations, we may not generate sufficient revenue to attain profitability.***

We do not currently possess the resources necessary to independently conduct research and development activities for all of the product candidates we are pursuing. We will either have to establish additional research and development resources, or enter into agreements with collaboration partners. The establishment of additional research and development capability would be expensive and time consuming and may not be successful. Establishing strategic collaborations is also difficult and time-consuming and any collaboration we develop may not be on favorable terms. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. If we fail to establish internal research and development capability or adequate collaborations, we will have to forego product development opportunities and may not generate sufficient revenue to attain profitability.

***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 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 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 and Costa Mesa, California areas. 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 2006 and for the first three months of 2007, our closing stock prices ranged from a low of \$3.25, to a high of \$6.45. 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 research services agreement after the first year;

our addition or termination of research 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.



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

We recently completed the acquisition of our pharmaceutical research and development programs, including our 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 the development programs we acquired from Valeant, 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

**Table of Contents**

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.

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

Our research and development facility in Costa Mesa, 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 territories outside the U.S. and Canada for our first NNRTI derived from the acquired intellectual property to advance to Phase III clinical trials. If Valeant exercises this option, which it can do following the completion of Phase IIb clinical trials but prior to the initiation of Phase III 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 those 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.

***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 the 800 Series Program and the 100 Series Program in the United States, the United

Kingdom, France, Spain, Italy and Germany. Our efforts

## **Table of Contents**

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.***

We have not yet started the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which, beginning with our fiscal year ending December 31, 2007, will require annual management assessments of the effectiveness of our internal controls over financial reporting and, beginning with our fiscal year ending December 31, 2008, a report by our independent auditors that both addresses management's assessments and provides for the independent auditor's assessment of the effectiveness of our internal controls. During the course of our testing, we may identify deficiencies which we may not be able to remediate in time to meet the deadline for compliance with Section 404. Testing and maintaining internal controls also 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.

### **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.

**Table of Contents**

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 acquired from Valeant 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 we acquired from Valeant 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.

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 infected 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 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 if 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 drug discovery 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 drug discovery programs may be adversely affected and the further development of our product candidates may be delayed. In addition, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

***Risks Related to Our Common Stock***

***The delisting of our common stock in October 2005 may be adversely affecting the price and liquidity of our common stock.***

On October 14, 2005, our common stock was delisted from The Nasdaq Global Market (formerly known as the Nasdaq National Market). The delisting decision was made by the Nasdaq Listings Qualifications Panel, following our appeal of a prior determination by the staff of the Nasdaq Stock Market, LLC that we were a public shell, raising public interest concerns pursuant to Marketplace Rule 4300. Our quotation for our common stock currently appears in the pink sheets under the trading symbol ARDC. The delisting of our common stock may be adversely affecting and may continue to adversely affect the price and liquidity of our common

**Table of Contents**

stock. We cannot assure you that we will be able to meet the listing standards of any stock exchange, or that we will be able to maintain any such listing. Until our common stock is listed on an exchange, we expect that it would be continue to be eligible to be quoted in the pink sheets. In this venue, however, an investor may find it difficult to obtain accurate quotations as to the market value of our common stock. In addition, if we failed to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect its liquidity. This would also make it more difficult for us to raise additional capital.

***\* Directors, executive officers, principal stockholders and affiliated entities beneficially own or control at least 68% of our outstanding voting common and preferred stock and may be able to exert control over our activities, and the results of our operations and financial condition may suffer.***

As of March 31, 2007, our directors, executive officers, principal stockholders and affiliated entities beneficially owned or controlled securities representing, in the aggregate, approximately 68% of our common equivalent shares, including approximately 3 million shares underlying outstanding convertible preferred stock and options or warrants exercisable within 60 days of March 31, 2007. These stockholders, if they determine to vote in the same manner, may be able to 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 current stockholders hold a substantial number of shares of our common stock that they will be able to sell in the public market in the near future. In addition, our Series A Preferred Stock is convertible as of March 31, 2007 into 1,578,346 shares of common stock, and outstanding warrants are exercisable as of December 31, 2006 into 1,148,138 shares of common stock. Significant portions of these shares are held by a small number of stockholders. The conversion of Series A Preferred Stock, exercise of warrants, or sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

***\* The holders of our Series A preferred stock have a liquidation preference and other rights that are adverse to the interests of our common stockholders and could be detrimental to our business.***

The holders of our Series A preferred stock have rights to designate two members of our Board of Directors. In addition, upon our liquidation or dissolution (including by way of a merger or acquisition), the holders of our Series A preferred stock are entitled to receive a liquidation preference in an amount equal to the greater of (i) \$10,000 per share of Series A preferred stock plus any declared but unpaid dividends thereon, or (ii) the amount that would have been paid had each such share of Series A preferred stock been converted to common stock immediately prior to such liquidation or dissolution. As of March 31, 2007, this liquidation preference was \$3.0 million. The holders of Series A preferred stock also have a right of first refusal to purchase their pro rata portion of any equity securities we propose to offer to any person. Such right of first refusal is subject to certain customary exclusions, including shares issued pursuant to any options or other stock awards granted to our employees, directors or consultants, equipment leasing arrangements, debt financings, strategic financings and public offerings that have been approved by our Board of Directors. The holders of Series A preferred stock are also entitled to receive cumulative dividends at the rate of 8% per annum of the original per share price of the Series A preferred stock, prior to and in preference to any declaration or payment of a dividend to the holders of common stock. The dividends on the currently outstanding 300 shares of Series A preferred stock are cumulating at a total of \$240,000 per year and are payable in common stock. Additionally, each share of Series A preferred stock automatically converts into shares of common stock on the tenth day after the day that the closing sale price of our common stock on the Nasdaq Global Market (formerly the Nasdaq National Market) has reached at least \$8.28 and has remained at such level for 20 consecutive trading days. If any of the rights and preferences listed above become available to the holders of Series A preferred stock, our common stockholders will be adversely affected.

The holders of our Series A preferred stock also have the right at any time to request that we register for resale the shares of our common stock that they acquire upon conversion of their Series A preferred stock or upon exercise of their warrants to purchase our common stock, subject to certain limitations. A registration statement has been filed

with the Securities and Exchange Commission and is currently effective for the resale of the shares of common stock issuable upon conversion of our Series A preferred stock and upon the exercise of their warrants to purchase our common stock. In addition, the holders of our Series A preferred stock may convert their Series A preferred stock into common stock and sell the shares of the common stock acquired upon such conversion in the public market in reliance upon Rule 144, subject in certain cases to volume and other limitations. Future sales in the public market of such common stock, or the perception that such sales might occur, could adversely affect the market price of our common stock.

**Table of Contents**

For so long as at least 100 shares of Series A preferred stock remain outstanding, we are required to get the consent of the holders of at least a majority of the then outstanding Series A preferred stock for any action that amends our certificate of incorporation (including the filing of a certificate of designation) so as to adversely affect the rights, preferences or privileges of the Series A preferred stock and any authorization or designation of a new class or series of stock which ranks senior to the Series A preferred stock in right of liquidation preference, voting or dividends. The Series A preferred stockholders' right to block the issuance of additional shares of senior preferred stock could impact our ability to raise necessary capital and adversely affect our business.

*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:

provide for a classified Board of Directors of which approximately one-third of the directors will be elected each year;

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 8<sup>th</sup> day of May 2007.

ARDEA BIOSCIENCES, INC.

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

Barry D. Quart, Pharm.D.  
Chief Executive Officer

By: /s/ DENIS HICKEY

Denis Hickey  
Chief Financial Officer

**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	Certificate of Amendment of Amended and Restated Certificate of Incorporation; and 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)
4.1	Amended and Restated Investor Rights Agreement dated October 15, 1999.(5)
4.2	Form of Stock Purchase Agreement by and between the Company and each selling stockholder, dated January 29, 2002.(6)
4.3	Form of Preferred Stock and Warrant Purchase Agreement, dated February 5, 2003, as amended on February 11, 2003.(7)
4.4	Form of Second Amendment to Preferred Stock and Warrant Purchase Agreement of February 5, 2003, dated April 10, 2003.(8)
4.5	Form of Warrant issued by the Company pursuant to Preferred Stock and Warrant Purchase Agreement of February 5, 2003, as amended of February 11, 2003 and April 10, 2003.(8)
4.6	Form of Common Stock and Warrant Purchase Agreement, dated October 6, 2003.(9)
4.7	Form of Warrant issued by the Company pursuant to the Common Stock and Warrant Purchase Agreement of October 6, 2003.(9)
10.1	Employment Agreement with Christopher W. Krueger.*
31.1	Certification of Chief Executive Officer and Chief 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 Chief 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-Q (File No. 000-29993) filed with the Securities and Exchange Commission on November 12, 2003.
- (3) Incorporated by reference to our Form 10-Q (File



- No. 000-29993)  
filed with the  
Securities and  
Exchange  
Commission on  
May 12, 2005.
- (4) Incorporated by  
reference to our  
Form 10-K (File  
No. 000-29993)  
filed with the  
Securities and  
Exchange  
Commission on  
March 10, 2005.
- (5) Incorporated by  
reference to our  
Registration  
Statement on  
Form S-1 (File  
No. 333-95461)  
initially filed  
with the  
Securities and  
Exchange  
Commission on  
January 27,  
2000, as  
subsequently  
amended.
- (6) Incorporated by  
reference to our  
Registration  
Statement on  
Form S-3 (File  
No. 333-82934)  
filed with the  
Securities and  
Exchange  
Commission on  
February 15,  
2002.
- (7) Incorporated by  
reference to  
Appendix B to  
the Definitive  
Proxy Statement

for the Special  
Meeting of  
Stockholders

(File  
No. 000-29993)  
filed with the  
Securities and  
Exchange  
Commission on  
March 3,  
2003.(8)

Incorporated by  
reference to our  
Form 10-Q (File  
No. 000-29993)  
filed with the  
Securities and  
Exchange  
Commission on  
May 14, 2003.

- (9) Incorporated by  
reference to our  
Form 8-K (File  
No. 000-29993)  
filed with the  
Securities and  
Exchange  
Commission on  
October 9, 2003.