Ardea Biosciences, Inc./DE
Form 10-Q
November 04, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

OR

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

For the transition period from _____ to _____

Commission file number: 1-33734

ARDEA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes þ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer þ
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ¨ No þ

The number of shares of the registrant s common stock, par value $0.001 per share, outstanding as of October 28, 2011 was 26,862,050.

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ARDEA BIOSCIENCES, INC.

FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2011

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS UNAUDITED

ARDEA BIOSCIENCES, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	September 30, 2011 (Unaudited)	December 31, 2010 (See Note)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,230	$ 15,926
Short-term investments, available-for-sale	104,502	64,686
Receivables	1,918	16,959
Prepaids and other current assets	2,260	518
Total current assets	126,910	98,089
Property and equipment, net	2,562	2,007
Other assets	323	358
Total assets	$ 129,795	$ 100,454
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,222	$ 3,073
Accrued clinical liabilities	7,502	5,681
Accrued payroll and employee liabilities	3,135	2,802
Other accrued liabilities	2,839	1,550
Current portion of deferred revenue	3,229	4,306
Current portion of long-term debt	899	3,310
Total current liabilities	19,826	20,722
Deferred rent	214	205
Non-current portion of deferred revenue		2,153
Non-current portion of long-term debt	205	251
Commitments and contingencies (see Note 5)		
Stockholders equity:		
Common stock	27	23
Additional paid-in capital	554,491	466,110
Accumulated other comprehensive income (loss)	(32)	31
Accumulated deficit	(444,936)	(389,041)
Total stockholders equity	109,550	77,123

Total liabilities and stockholders equity	$ 129,795	$ 100,454

Note: The condensed consolidated balance sheet at December 31, 2010 has been derived from the audited financial statements as of that date, but does not include all of the information and disclosures required by accounting principles generally accepted in the U.S.

See accompanying notes.

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ARDEA BIOSCIENCES, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
License fees	$ 1,076	$ 2,171	$ 3,229	$ 7,024
Sponsored research	96		319	
Reimbursable research and development costs	518	1,123	2,088	3,064
Total revenues	1,690	3,294	5,636	10,088
Operating expenses:				
Research and development	19,293	14,687	47,534	37,822
General and administrative	4,907	6,669	13,926	12,915
Total operating expenses	24,200	21,356	61,460	50,737
Loss from operations	(22,510)	(18,062)	(55,824)	(40,649)
Other income (expense):				
Interest income	95	100	300	281
Interest expense	(60)	(204)	(292)	(693)
Other income, net		1	9	26
Total other income (expense)	35	(103)	17	(386)
Net loss	$ (22,475)	$ (18,165)	$ (55,807)	$ (41,035)
Basic and diluted net loss per share	$ (0.84)	$ (0.79)	$ (2.11)	$ (1.92)
Shares used in computing basic and diluted net loss per share	26,805	22,902	26,432	21,355

See accompanying notes.

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ARDEA BIOSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2011	2010
Operating activities:		
Net loss	$ (55,807)	$ (41,035)
Adjustments to reconcile net loss to net cash (used for) provided by operating activities:		
Share-based compensation	7,791	8,954
Depreciation and amortization	524	430
Amortization of debt discount and debt issuance costs	91	228
Deferred rent	9	36
Amortization of premium on short-term investments, net	710	638
Realized gain on short-term investments	(15)	(23)
Change in operating assets and liabilities:		
Receivables	15,041	(1,359)
Prepaids and other assets	(1,762)	(465)
Accounts payable	(851)	96
Accrued clinical liabilities	1,821	292
Accrued payroll and employee liabilities	333	564
Other accrued liabilities	1,289	18
Deferred revenue	(3,230)	(7,025)
Net cash used for operating activities	(34,056)	(38,651)
Investing activities:		
Purchases of short-term investments	(190,808)	(104,131)
Proceeds from sale or maturity of short-term investments	150,234	59,538
Proceeds from sale of property and equipment	12	25
Purchases of property and equipment	(1,091)	(492)
Net cash used for investing activities	(41,653)	(45,060)
Financing activities:		
Payments on long-term debt	(2,493)	(2,218)
Net proceeds from issuance of common stock	80,506	80,482
Net cash provided by financing activities	78,013	78,264
Net increase (decrease) in cash and cash equivalents	2,304	(5,447)
Cash and cash equivalents at beginning of period	15,926	11,562
Cash and cash equivalents at end of period	$ 18,230	$ 6,115
Supplemental disclosure of cash flow information:		
Interest paid	$ 224	$ 487

Supplemental schedule of non-cash information:		
Capital lease obligation incurred for property and equipment	$	$ 144
Net unrealized gain (loss) on short-term investments	$ (63)	$ 24

See accompanying notes.

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ARDEA BIOSCIENCES, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Ardea Biosciences, Inc. and its wholly-owned subsidiary (collectively, the Company) have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2011. For more complete financial information, these unaudited condensed consolidated financial statements and the notes thereto should be read in conjunction with the audited financial statements for the year ended December 31, 2010 included in the Company s Form 10-K filed with the Securities and Exchange Commission (SEC).

2. Accounting Policies

Principles of Consolidation

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

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and disclosures made in the accompanying notes to the unaudited condensed consolidated financial statements. The Company s critical accounting policies that involve significant judgment and estimates include revenue recognition, accrued clinical liabilities and share-based compensation. Actual results could differ materially from those estimates.

Revenue Recognition

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

Revenue from upfront, nonrefundable license fees is recognized over the period that any related services are to be provided by the Company.

Amounts received for research funding are recognized as revenue as the research services that are the subject of such funding are performed.

Revenue derived from reimbursement of research and development costs in transactions where the Company acts as a principal are recorded as revenue for the gross amount of the reimbursement, and the costs associated with these reimbursements are reflected as a component of research and development expense in the consolidated statements of operations.

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Accounting Standard Codification (ASC) Topic 605-28, *Revenue Recognition Milestone Method* (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved based in whole or in part on either the Company s performance or on the occurrence of a specific outcome resulting from the Company s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the Company. The determination that a milestone is substantive is judgmental and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is (i) commensurate with either the Company s performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from the Company s performance to achieve the milestone, (ii) relates solely to past performance and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner s performance are not considered milestones under ASC 605-28. In accordance with ASC Topic 605-25, *Revenue Recognition Multiple-Element Arrangements* (ASC 605-25), such payments will be recognized as revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; price is fixed or determinable; and collectability is reasonably assured.

Revenues recognized for royalty payments, if any, are based upon actual net sales of the licensed compounds, as provided by the collaboration arrangement, in the period the sales occur.

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

Earnings Per Share

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

Because the Company has incurred a net loss for all periods presented in the unaudited condensed consolidated statements of operations, outstanding stock options, unvested common shares subject to repurchase and warrants are not included in the computation of net loss per share because their effect would be anti-dilutive. For the periods ended September 30, 2011 and 2010, the number of outstanding stock options, unvested common shares subject to repurchase and warrants not included in the computation totaled 4,490,522 and 3,909,549, respectively.

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Comprehensive Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$ (22,475)	$ (18,165)	$ (55,807)	$ (41,035)
Net unrealized gains (losses) on short-term investments	(32)	26	(63)	24
Comprehensive net loss	$ (22,507)	$ (18,139)	$ (55,870)	$ (41,011)

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income* (Topic 220) (ASU 2011-05). ASU 2011-05 amends the presentation of comprehensive income to allow an entity the option to present the total of comprehensive income, the components of net income, or the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity. ASU 2011-05 is effective on a retrospective basis for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption is permitted. The Company plans to adopt the provisions of ASU 2011-05 in the first quarter of 2012. The Company does not expect the adoption of this ASU to have a material impact on its consolidated results of operations or financial condition.

In May 2011, FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820)* (ASU 2011-04). ASU 2011-04 amends the wording used to describe many of the requirements in GAAP for measuring fair value and for disclosing information about fair value measurements. Additionally, ASU 2011-04 clarifies FASB s intent about the application of existing fair value measurement requirements. ASU 2011-04 is effective on a prospective basis for interim and annual periods beginning after December 15, 2011. Early application is not permitted. The Company plans to adopt the provisions of ASU 2011-04 in the first quarter of 2012. The Company does not expect the adoption of this ASU to have a material impact on its consolidated results of operations or financial condition.

In April 2010, FASB issued ASU No. 2010-17, *Revenue Recognition Milestone Method (Topic 605): Milestone Method of Revenue Recognition* (ASU 2010-17). ASU 2010-17 codifies the consensus reached in Emerging Issues Task Force Issue No. 08-9, Milestone Method of Revenue Recognition. ASU 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and non-substantive milestones, and each milestone should be evaluated individually to determine if it is substantive. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. The Company elected early adoption of the provisions of ASU 2010-17, in the fourth quarter of 2010. The adoption of ASU 2010-17 did not have a material impact on the Company s consolidated results of operations or financial condition.

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In September 2009, FASB issued ASU No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements* (ASU 2009-13). ASU 2009-13 requires an entity to allocate arrangement consideration at the inception of an arrangement to all of its deliverables based on their relative selling prices. ASU 2009-13 eliminates the use of the residual method of allocation and requires the relative-selling-price method in all circumstances in which an entity recognizes revenue for an arrangement with multiple deliverables. ASU 2009-13 is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning after June 15, 2010. Early adoption is permitted. On January 1, 2011, the Company adopted the provisions of ASU 2009-13, which did not have a material impact on the Company s consolidated results of operations or financial condition.

3. Fair Value Measurements

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

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

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

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

The Company measures the following financial assets at fair value on a recurring basis. The fair values of these financial assets at September 30, 2011 and December 31, 2010 (in thousands) were as follows:

		Fair Value Measurements at Reporting Date Using		
	Balance at September 30, 2011	Quoted prices in active markets for identical assets (Level 1)*	Significant other observable inputs (Level 2)*	Significant unobservable inputs (Level 3)
Money market funds	$ 17,725	$ 17,725	$	$
U.S. government and agency obligations	34,187		34,187	
U.S. corporate debt securities	33,141		33,141	
U.S. commercial paper	25,485		25,485	
Foreign commercial paper	11,689		11,689	
Total	$ 122,227	$ 17,725	$ 104,502	$

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	Fair Value Measurements at Reporting Date Using			
	Balance at December 31, 2010	Quoted prices in active markets for identical assets (Level 1)*	Significant other observable inputs (Level 2)*	Significant unobservable inputs (Level 3)
Money market funds	$ 9,909	$ 9,909	$	$
U.S. government and agency obligations	51,431	4,998	46,433	
U.S. corporate debt securities	8,257		8,257	
U.S. commercial paper	5,497		5,497	
Foreign commercial paper	5,299		5,299	
Total	$ 80,393	$ 14,907	$ 65,486	$

* There were no significant transfers between level 1 and level 2 investments for the periods ended September 30, 2011 and December 31, 2010.

As of September 30, 2011, the Company s short-term investments consisted of approximately $68,360,000 of available-for-sale securities with contractual maturities of one year or less and approximately $36,142,000 with contractual maturities not to exceed 15 months.

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

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

Unrealized gains and losses associated with the Company s investments, if any, are reported in stockholders equity. For the three and nine months ended September 30, 2011, the Company recognized approximately $32,000 and $63,000, respectively, in net unrealized losses on its short-term investments. For the three and nine months ended September 30, 2010, the Company recognized approximately $26,000 and $24,000 in net unrealized gains, respectively, on its short-term investments.

Realized gains and losses associated with the Company s investments, if any, are reported in the statement of operations. For the three and nine months ended September 30, 2011, the Company recognized approximately $13,000 and $15,000, respectively, in net realized gains associated with its short-term investments. The Company did not recognize any realized gains or losses on it short-term investments for the three months ended September 30, 2010. For the nine months ended September 30, 2010, the Company recognized approximately $23,000 in net realized gains on its short-term investments.

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4. Bayer Relationship

In April 2009, the Company entered into a Development and Commercialization License Agreement (the License Agreement) with Bayer HealthCare AG (Bayer). Under the terms of the License Agreement, the Company granted to Bayer a worldwide, exclusive license to develop and commercialize the Company s mitogen-activated ERK kinase (MEK) inhibitors for all indications. In partial consideration for the license, Bayer paid the Company an upfront cash fee of $35.0 million. The Company is eligible to receive additional cash payments totaling up to $372.5 million upon the occurrence of certain development-, regulatory- and sales-based contingent events, as well as low double-digit royalties on worldwide sales of products covered under the License Agreement. The Company is responsible for the completion of the Phase 1 and Phase 1/2 studies of BAY 86-9766 (RDEA119) that were underway at the time the License Agreement was entered into. Bayer is responsible for reimbursing the Company for third-party development costs associated with the studies, up to a specified amount. During the fourth quarter of 2010, Bayer agreed to reimburse a portion of the personnel costs of employees involved in the development of BAY 86-9766 (RDEA119). The reimbursements will be recognized as the services are performed.

The $35.0 million upfront payment was originally being recognized on a straight-line basis over a period of approximately 13 months, which was the original period over which the Company expected to complete all of its obligations under the License Agreement. In December 2009 and again in September 2010, the Company revised its estimate of the length of this period as a result of design modifications to its ongoing BAY 86-9766 (RDEA119) clinical trials, extending it to a 38-month period ending in June 2012. The deferred balance of the license fee as of the date of the latest change in estimate of approximately $7,738,000 is being recognized over the revised timeline. For the three and nine months ended September 30, 2011, the Company recognized revenue of approximately $1,076,000 and $3,229,000, respectively, and $2,171,000 and $7,024,000 for the same periods in 2010, as license fees in the unaudited condensed consolidated statement of operations.

Participants in a collaborative arrangement are required to report costs incurred and revenues generated from transactions with third parties in each entity s respective income statement based on whether the participant is considered a principal or an agent. Under the terms of the License Agreement and as it pertains to the completion of the Phase 1 and Phase 1/2 studies, the Company is the principal as the Company is the primary obligor with respect to the third parties, has latitude in establishing price, has discretion in supplier selection and is involved in the determination of product or service specifications. As such, the Company records the gross amount of the reimbursement of third-party development costs for the ongoing clinical trials as revenue and the costs associated with these reimbursements are reflected as a component of research and development expense in the Company s consolidated statement of operations. In July 2010 and again in May 2011, the ongoing clinical trial cost reimbursement amount was increased to include the effect of study design changes previously agreed to by both parties. For the three and nine months ended September 30, 2011, the Company recognized revenue of approximately $518,000 and $2,088,000, respectively, and $1,123,000 and $3,064,000 for the same periods in 2010, as reimbursable research and development costs in the unaudited condensed consolidated statement of operations.

For the three and nine months ended September 30, 2011, the Company recognized $96,000 and $319,000, respectively, in reimbursed personnel costs, as sponsored research in its unaudited condensed consolidated statements of operations. The Company did not recognize any revenue for sponsored research for the three and nine months ended September 30, 2010.

The Company evaluated the development-, regulatory- and sales-based contingent event-based payments under the License Agreement to determine if each payment met the definition of a milestone and should be considered substantive under the guidance of ASC 605-28. The Company determined that only the first two development-based contingent event-based payments (a $15.0 million payment upon dosing of the first patient in the first Phase 2 or Phase 3 trial for the first indication and a $7.5 million payment upon dosing of the first patient in the first Phase 2 or Phase 3 trial for the second indication) met the definition of a milestone, as there was substantive uncertainty at the time the License Agreement was entered into that these events would be achieved; the achievement of each event was dependent upon the Company s performance or a specific outcome resulting from the Company s performance and each event would result in additional payments being made to the Company.

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Further, these milestones were considered substantive as they related solely to the Company s past performance; were reasonable relative to all of the deliverables and payment terms of the License Agreement and were commensurate with the enhancement of BAY 86-9766 (RDEA119) s value as a result of the milestone achievement.

Accordingly, revenue for the first milestone of $15.0 million was recognized in its entirety in 2010 upon achievement of the milestone and revenue from the second milestone of $7.5 million will be recognized in its entirety in the period when, and if, it is achieved.

Other contingent event-based payments under the terms of the License Agreement for which payment is based solely upon the results of Bayer s performance will not be accounted for using the milestone method because such payments are not contingent on the Company s performance. Such payments will be recognized as revenue when the underlying contingent event has occurred and collectability is reasonably assured.

For the three and nine months ended September 30, 2011 and 2010, the Company did not recognize any revenue from milestones or other contingent payments under its License Agreement with Bayer.

Bayer is further obligated to pay the Company royalties on annual net sales of licensed compounds. To date, no licensed compounds have been approved for marketing by the FDA or other regulatory agencies and therefore no royalty fees have been earned under the License Agreement.

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

5. Commitments and Contingencies

Under the Asset Purchase Agreement (the Asset Purchase Agreement) between Valeant Research and Development, Inc. (Valeant) and the Company, dated December 21, 2006, the Company is obligated to make development- and regulatory-based contingent event-based payments and sales-based royalty payments to Valeant upon subsequent development of certain products. The aggregate contingent liability of up to $42,000,000 in contingent event-based payments for the programs covered under the Asset Purchase Agreement is considered a liability in the ordinary course of business. Each payment will be recorded when, and if, the related contingency is resolved and consideration is issued or becomes issuable. During the fourth quarter of 2010, the first contingent event-based payment under the Asset Purchase Agreement, for dosing of the first patient in the first Phase 2 study for the MEK inhibitor program, was achieved. Accordingly, the Company recorded $1,000,000 to research and development expense in its consolidated statement of operations for the year ended December 31, 2010. The $1,000,000 payment was paid to Valeant in January 2011 reducing the total of potential future development- and regulatory-based contingent event-based payments under the Asset Purchase Agreement to $41,000,000.

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6. Long-term Debt

The following is a summary of the Company s long-term debt obligations as of September 30, 2011:

	Notes Payable	Capital Lease
Years ended December 31,		
2011 (remaining three months of the year)	$ 1,269	$ 11
2012	46	45
2013	45	45
2014	45	45
2015	19	22
Total	1,424	168
Less unamortized discount	(2)	
Less amount representing interest	(437)	(49)
Total balance	985	119
Less current portion	(875)	(24)
Noncurrent portion of long-term debt	$ 110	$ 95

7. Stockholders Equity

Common Stock

In February 2011, the Company completed an underwritten public offering of 3,162,500 shares of its common stock, including the full exercise of the overallotment option granted to the underwriters, at a price of $26.00 per share. The net proceeds to the Company from the sale of shares in this offering were approximately $78,062,000 after deducting underwriting discounts and commissions and offering expenses.

For the three and nine months ended September 30, 2011, approximately 56,000 and 268,000 shares of common stock, respectively, were issued pursuant to the exercise of stock options resulting in proceeds to the Company of approximately $574,000 and $2,192,000, respectively.

Share-Based Compensation

The following table summarizes share-based compensation expense for the three and nine months ended September 30, 2011 and 2010 related to employee and director stock options, restricted stock awards and Employee Stock Purchase Plan (ESPP) purchase rights by expense category (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	$ 1,180	$ 1,401	$ 3,263	$ 2,828
General and administrative	1,448	4,097	4,528	6,126
Share-based compensation expense included in operating expenses	$ 2,628	$ 5,498	$ 7,791	$ 8,954

Included in share-based compensation expense for both the three and nine months ended September 30, 2010 is share-based compensation expense of approximately $3,832,000 incurred in connection with the departure of certain employees during the third quarter of 2010.

As of September 30, 2011, there was approximately $19,278,000 of total unrecognized compensation cost related to non-vested, share-based payment awards granted under all of the Company s equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize this compensation cost over a period of 2.6 years, which is the weighted-average vesting period for all share-based compensation awards.

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

Options:	September 30, 2011	2010
Risk-free interest rate	2.1%	2.6%
Dividend yield	0.0%	0.0%
Volatility	72.7%	78.7%
Expected life (years)	5.5-6.1	5.5-6.1

The Company estimates the fair value of each purchase right granted under the ESPP at the beginning of each new offering period using the Black-Scholes option valuation model. A new offering period begins every six months in May and November of each year. For the three months ended September 30, 2011 and 2010, there were no new offering periods or ESPP purchase rights granted.

8. Income Taxes

Deferred income tax assets and liabilities are recognized for temporary differences between financial statements and income tax carrying values using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding the Company s ability to generate future taxable income and consequently realize such deferred income tax assets, a full valuation allowance has been established. The Company continues to maintain a full valuation allowance against its deferred tax assets as of September 30, 2011.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant tax authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There have been no material changes in the Company s unrecognized tax benefits since December 31, 2010 and as such, disclosures included in the Company s 2010 Annual Report on Form 10-K continue to be relevant for the period ended September 30, 2011.

9. Subsequent Events

There were no subsequent events that were required to be recognized or disclosed in the unaudited condensed consolidated financial statements.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and related notes included in this quarterly report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2010 included in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission, or SEC, on March 11, 2011.

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

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Overview and Business Strategy

Ardea Biosciences, Inc., of San Diego, California, is a biotechnology company focused on the development of small-molecule therapeutics for the treatment of serious diseases. The current status of our development programs is as follows:

Product Portfolio

Product Candidate	Target Indication	Development Status
Lesinurad (RDEA594)	Gout	Phase 2 completed*
RDEA3170	Gout	Phase 1 ongoing
BAY 86-9766 (RDEA119)	Cancer	Phase 2 ongoing

* Phase 2 extension studies are ongoing

GOUT

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

Drugs currently used to treat the underlying cause of gout work by lowering blood or serum uric acid (sUA) levels and are referred to as urate-lowering therapies (ULTs). Approximately 90 percent of gout patients are considered to have a defect in their ability to excrete sufficient amounts of uric acid and are classified as under-excreters of uric acid, which leads to excessive levels of sUA.

Lesinurad

Lesinurad, our most advanced product candidate, previously called RDEA594, is an inhibitor of URAT1, a transporter in the kidney that regulates uric acid excretion from the body. Lesinurad normalizes the amount of uric acid excreted by gout patients. Since the majority of gout patients are under-excreters , normalizing uric acid excretion by moderating URAT1 transporter activity with lesinurad may provide the most physiologically appropriate means of reducing sUA levels. In addition, because increasing the excretion of sUA is additive to the effects of ULTs that decrease the production of uric acid, such as allopurinol and febuxostat (Uloric®, Takeda Pharmaceutical Company Limited), lesinurad in combination with such drugs has the potential to treat the significant portion of the gout patient population that is not adequately treated with existing therapies.

Approximately 2.6 million gout patients in the U.S. are prescribed ULTs annually. Allopurinol, the most commonly prescribed ULT in the U.S., currently accounts for more than 90 percent of U.S. unit sales of all ULTs. However, in recent controlled clinical studies, only 30-40 percent of gout patients responded adequately to allopurinol, defined as achieving sUA levels of less than 6 mg/dL, the medically recommended target. Febuxostat, the most recently approved, orally-administered ULT in the U.S., has similar response rates in clinical practice according to a 2010 BioTrends Research Group, Inc. report. We are developing lesinurad to be used in combination with allopurinol to treat the large number of patients who do not reach target sUA levels while on this agent or as a monotherapy for those patients who are intolerant to allopurinol. We are also developing lesinurad to be used in combination with febuxostat in patients with tophaceous gout, a condition characterized by the presence of disfiguring deposits of uric acid crystals in and around the joints.

Lesinurad has been evaluated in a comprehensive Phase 2 development program designed to demonstrate its clinical utility. Results from this program have shown the following:

- Positive results from the main portion of a 28-day Phase 2b study (Study 203) in 208 allopurinol-refractory gout patients demonstrated that adding lesinurad to allopurinol produced highly statistically significant reductions in sUA of up to 30 percent at the highest lesinurad dose tested, compared to a 3 percent increase on allopurinol plus placebo. This

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resulted in a response rate of 79 percent for the 600 mg dose using the more rigorous intent-to-treat (ITT) analysis, which considers all patients without efficacy results at week 4 as non-responders, including those who discontinue for any reason. Using a last observation carried forward (LOCF) analysis, which was the method utilized for the U.S. approval of febuxostat, 87 percent of patients taking the combination reached the medically recommended target of reducing sUA to below 6 mg/dL at the highest dose tested. Response rates on this study increased in a dose-related manner and were highly clinically and statistically significant at all dose levels when compared to allopurinol alone.

Results from the ongoing extension portion of Study 203 demonstrated that of those patients who had reached week 28 of the extension period, 91 percent of those patients receiving lesinurad in combination with allopurinol achieved sUA levels below the medically recommended target of 6 mg/dL. Importantly, continued reductions in sUA were observed beyond the initial 28 days of dosing with a majority of the responding patients remaining on a 200 mg dose of lesinurad. The combination of lesinurad and allopurinol was generally well tolerated in the main 28-day dosing period and has been well tolerated in the ongoing extension period. Adverse events were infrequent, not dose related and comparable between the groups receiving lesinurad and placebo.

In a 21-day, Phase 1b clinical pharmacology study evaluating the use of lesinurad in combination with febuxostat (Study 111) in 21 gout patients with hyperuricemia (sUA greater than or equal to 8 mg/dL), 100 percent of patients receiving the combination of lesinurad and febuxostat achieved sUA levels below the medically recommended target level of 6 mg/dL, compared to 67 percent and 56 percent for patients receiving 40 mg and 80 mg, respectively, of febuxostat alone. At the highest combination doses tested (600 mg lesinurad combined with 80 mg febuxostat), 100 percent of patients reached sUA levels below 4 mg/dL, with 58 percent achieving levels below 3 mg/dL. No patient achieved these reduced sUA levels on either dose of febuxostat alone. The combination of lesinurad and febuxostat was also generally well tolerated, with no serious adverse events or discontinuations due to adverse events and no clinically relevant drug interactions between lesinurad and febuxostat observed.

In a 20-patient, 21-day, Phase 1b clinical pharmacology study evaluating the use of lesinurad in combination with 300 mg of allopurinol (Study 110) in gout patients with hyperuricemia (sUA greater than or equal to 8mg/dL), 100 percent of patients at all combination doses evaluated achieved sUA levels below the target of 6 mg/dL, compared to 20 percent of patients on allopurinol alone. The combination of lesinurad and allopurinol was generally well tolerated, with no serious adverse events or discontinuations that were considered possibly related to lesinurad or the combination.

When administered as a single agent in a 28-day, Phase 2b study (Study 202), lesinurad was generally well tolerated and produced significant reductions in uric acid in the blood. In this randomized, double-blind, placebo-controlled, dose-escalation study of 123 gout patients with hyperuricemia, uric acid levels decreased and response rates increased in a dose-related manner and were highly clinically and statistically significant at the two highest doses tested. At the highest dose, the response rate was 60 percent, compared to 0 percent for placebo ($p < 0.0001$). Lesinurad was also generally well tolerated in this study, with no serious adverse events and only two discontinuations due to adverse events on lesinurad.

Results from multiple studies have indicated that the activity of lesinurad is not diminished in patients with mild to moderate renal impairment. Lesinurad was generally safe and well tolerated in these studies with a similar safety profile in subjects with normal or impaired renal function.

Based on findings thus far, single and multiple doses of lesinurad from 5 mg to 600 mg appear to be generally well tolerated, both alone and in combination with allopurinol or febuxostat.

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We are currently preparing to conduct a Phase 3 development program that includes the following main studies:

An open-label, Phase 4 interventional study of allopurinol in gout patients, called **LASSO**. This study is currently underway. Given the low response rate typically observed with allopurinol and its well-established side effect profile, we expect a substantial number of patients from this study will be eligible to enroll directly into our Phase 3 studies.

A combination study in North America of lesinurad in allopurinol standard of care inadequate responders, called **CLEAR #1** a Phase 3, randomized, placebo-controlled trial of lesinurad added to allopurinol in patients not reaching target sUA levels with allopurinol alone. Patients will be dosed for a total of 12 months in this study. The primary endpoint will be the proportion of subjects with sUA levels below 6.0 mg/dL after six months of dosing. Key secondary endpoints will include an assessment of gout flare rate, tophi resolution and quality of life measurements after 12 months of dosing.

A global combination study of lesinurad in allopurinol standard of care inadequate responders, called **CLEAR #2** a Phase 3, randomized, placebo-controlled trial of lesinurad added to allopurinol in patients not reaching target sUA levels with allopurinol alone. Patients will be dosed for a total of 12 months in this study. The primary endpoint will be the proportion of subjects with sUA levels below 6.0 mg/dL after six months of dosing. Key secondary endpoints will include an assessment of gout flare rate, tophi resolution and quality of life measurements after 12 months of dosing.

A global monotherapy study of lesinurad in gout patients for whom allopurinol or febuxostat treatment is not advised, or contraindicated, called **LIGHT** a Phase 3, randomized, placebo-controlled trial of lesinurad as monotherapy in gout patients for whom febuxostat or allopurinol treatment is contraindicated due to factors such as intolerance, co-morbidities, or the risk of significant drug interactions. Patients will be dosed for a total of six months in this study and the primary endpoint will be the proportion of subjects with sUA levels below 6.0 mg/dL after the end of the dosing period.

A global combination study of lesinurad and febuxostat in patients with tophaceous gout, called **CRYSTAL** a randomized, placebo-controlled study of lesinurad in combination with febuxostat for the treatment of hyperuricemia in gout patients. Patients will be dosed for a total of 12 months in this study. The primary endpoint will be the proportion of subjects with sUA levels below 5.0 mg/dL after six months of dosing. Key secondary endpoints will include the proportion of patients with resolution of tophi, an assessment of gout flare rate and quality of life measurements after 12 months of dosing.

Lesinurad will need to successfully complete these pivotal Phase 3 clinical trials, as well as potential additional non-pivotal clinical trials, in order to be approved for marketing by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities around the world.

RDEA3170

We are also developing RDEA3170, a next-generation inhibitor of the URAT1 transporter for the chronic treatment of gout. Based on preclinical results, RDEA3170 demonstrates many of the same positive attributes as lesinurad, but with greater potency against the URAT1 transporter. A Phase 1 clinical trial of RDEA3170 is ongoing.

CANCER

Mitogen-activated ERK kinase (MEK) is believed to play an important role in cancer cell proliferation, programmed cell death and the spread of cancer from one organ or body part to another non-adjacent organ or body part. BAY 86-9766, formerly known as RDEA119, is a potent and highly selective inhibitor of MEK currently in Phase 2 development for the treatment of cancer.

Preclinical and clinical data suggest that BAY 86-9766 (RDEA119) has favorable properties, including once-daily oral dosing and excellent selectivity. In addition, BAY 86-9766 (RDEA119) has been shown to suppress tumor cell growth *in vitro* and *in vivo.* Preclinical *in vitro* and *in vivo* oncology studies of BAY 86-9766 (RDEA119) have demonstrated significant potential synergy across multiple tumor types when used in combination with other anti-cancer agents, including sorafenib (Nexavar®, Bayer HealthCare AG (Bayer) and Onyx Pharmaceuticals, Inc.).

We have completed a Phase 1 study of BAY 86-9766 (RDEA119) as a single agent in advanced cancer patients with different tumor types and we have identified the maximum tolerated dose (MTD) of BAY 86-9766 (RDEA119) in a Phase 1/2 study in combination with sorafenib. Dosing in the MTD expansion cohort of the Phase 1/2 study is ongoing.

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Phase 1 results to date in refractory patients with advanced solid tumors have demonstrated that BAY 86-9766 (RDEA119) is generally well tolerated and a number of patients have achieved stable disease or partial response to treatment. Based on the promising preclinical and Phase 1 and Phase 1/2 results, a Phase 2 study of BAY 86-9766 (RDEA119) in combination with sorafenib as first-line therapy for primary liver cancer and a Phase 1/2 study of BAY 86-9766 (RDEA119) in combination with gemcitabine in patients with advanced pancreatic cancer was recently initiated by our global development and commercialization licensee, Bayer.

Bayer Relationship

In April 2009, we entered into the License Agreement with Bayer to develop and commercialize our small-molecule MEK inhibitors, including BAY 86-9766 (RDEA119), for all indications. Potential payments under the License Agreement could total up to $407.5 million, including the $35.0 million non-refundable license fee and the $15.0 million development milestone for initiation of Phase 2 studies of BAY 86-9766 (RDEA119) that we have received to date. We will also be eligible to receive low double-digit royalties on worldwide sales of products under the License Agreement. Under the terms of the License Agreement, we are responsible for completion of the Phase 1 and Phase 1/2 studies that were underway when we entered into it. Bayer is responsible for reimbursing us for third-party development costs associated with these studies, as well as a portion of the personnel costs of employees involved in the development of BAY 86-9766 (RDEA119), up to a specified amount. Thereafter, Bayer will be responsible for the further development and commercialization of BAY 86-9766 (RDEA119) and any of our other MEK inhibitors. BAY 86-9766 (RDEA119) is currently being evaluated in a Phase 2 study in combination with sorafenib in patients with hepatocellular carcinoma and a Phase 1/2 study in combination with gemcitabine in patients with advance pancreatic cancer.

Valeant Relationship

In December 2006, we acquired intellectual property and other assets from Valeant Research & Development, Inc., or Valeant, related to RDEA806, a non-nucleoside reverse transcriptase inhibitor (NNRTI) that had been developed for the treatment of human immunodeficiency virus, or HIV, and our next generation NNRTI program, as well as BAY 86-9766 (RDEA119) and our next generation MEK inhibitor program. In consideration for the assets purchased from Valeant, and subject to the satisfaction of certain conditions, Valeant received certain rights, including the right to receive from us development- and regulatory-based contingent event-based payments and sales-based royalty payments. There is one set of potential contingent event-based payments totaling up to $25.0 million for RDEA806 and the next generation NNRTI program, and a separate set of potential contingent event-based payments totaling up to $17.0 million for BAY 86-9766 (RDEA119) and the next generation MEK inhibitor program. As of December 31, 2010, the first, and only Phase 2 development-based contingent event-based payment related to BAY 86-9766 (RDEA119) had been achieved and the Company recorded $1.0 million to research and development expense in the fourth quarter of 2010. The $1.0 million payment to Valeant was subsequently made in January 2011, reducing the total of potential development- and regulatory-based contingent event-based payments related to BAY 86-9766 (RDEA119) and our next-generation MEK inhibitor program to $16.0 million. The royalty rates on the products covered by our agreement with Valeant are in the mid-single digits.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition

Our collaboration arrangements may contain multiple revenue elements and we may be eligible for payments made in the form of upfront license fees, research funding, cost reimbursement, contingent event-based payments and royalties.

Revenue from upfront, nonrefundable license fees is recognized over the period that any related services are provided.

Amounts received for research funding are recognized as revenue as the research services that are the subject of such funding are performed.

Revenue derived from reimbursement of research and development costs in transactions where we act as a principal are recorded as revenue for the gross amount of the reimbursement, and the costs associated with these reimbursements are reflected as a component of research and development expense in the consolidated statements of operations.

Accounting Standard Codification (ASC) Topic 605-28, *Revenue Recognition Milestone Method* (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to us. The determination that a milestone is substantive is judgmental and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is (i) commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner s performance are not considered milestones under ASC 605-28. Such payments will be recognized as revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; price is fixed or determinable; and collectability is reasonably assured.

Revenues recognized for royalty payments, if any, are based upon actual net sales of the licensed compounds, as provided by the collaboration arrangement, in the period the sales occur.

Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue on the consolidated balance sheet.

Accrued Clinical Liabilities

We review and accrue clinical costs based on work performed, which relies on estimates of the services received from other parties and related expenses incurred. Clinical trial-related contracts vary significantly in duration, and may be for a fixed amount, based on the achievement of certain contingent events or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or

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contain a combination of these elements. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development costs, however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

Share-Based Compensation

We grant equity-based awards under three stockholder-approved, share-based compensation plans. We have granted, and may in the future grant, options and restricted stock awards to employees, directors, consultants and advisors under either our 2002 Non-Officer Equity Incentive Plan or our 2004 Stock Incentive Plan. In addition, all of our employees are eligible to participate in our 2000 Employee Stock Purchase Plan, which enables employees to purchase common stock at a discount through payroll deductions.

We estimate the fair value of stock options granted using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including each option s expected life and price volatility of the underlying stock. Expected volatility is based on our historical stock price volatility. The expected life of employee stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method.

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

Recent Accounting Pronouncements

See Note 2 to the unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations

Three and Nine Months Ended September 30, 2011 and 2010

Revenues

For the three and nine months ended September 30, 2011, revenues decreased to $1.7 million and $5.6 million, respectively, from $3.3 million and $10.1 million for the same periods in 2010. The revenue earned in 2010 and 2011 resulted primarily from the recognition of a portion of the upfront, non-refundable license fee and reimbursement of third-party development costs associated with our MEK inhibitor program under the terms of the License Agreement with Bayer. The $35.0 million upfront license fee was originally being recognized on a straight-line basis over a period of approximately 13 months, the period in which we initially expected to complete all of our obligations under the License Agreement. In December 2009 and again in September 2010, we revised our estimate of this period as a result of design modifications to our ongoing BAY 86-9766 (RDEA119) clinical trials. As a result of these revisions, the upfront license fee is now being recognized over a 38-month period ending June 2012. The deferred balance of the license fee as of the date of the change in estimate is being recognized over the revised timeline. The decrease in revenues for the three and nine months ended September 30, 2011 was primarily due to the effect of these changes.

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Research and Development Expense

Research and development expense consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Lesinurad and RDEA3170 related outsourced costs	$ 12,424	$ 8,252	$ 28,244	$ 21,194
BAY 86-9766 (RDEA119) related outsourced costs*	483	1,132	1,937	3,144
Personnel and related costs	3,934	2,659	10,165	7,075
Share-based compensation expense	1,180	1,401	3,263	2,828
Facility related costs	635	640	1,902	1,929
Other miscellaneous	637	603	2,023	1,652
Total Research and Development Expense	$ 19,293	$ 14,687	$ 47,534	$ 37,822

* These amounts represent costs for the ongoing clinical trials of BAY 86-9766 (RDEA119) which are reimbursed by Bayer, under the terms of the License Agreement. The Company records the gross amount of the reimbursement of third-party development costs as revenue and the costs associated with these reimbursements are reflected as a component of research and development expense in the Company s unaudited condensed consolidated statement of operations.

For the three and nine months ended September 30, 2011, research and development expense increased to $19.3 million and $47.5 million, respectively, from $14.7 million and $37.8 million for the same periods in 2010. The increase in research and development expense for the three and nine months ended September 30, 2011 was due primarily to the continued development and progression of lesinurad and RDEA3170, resulting mainly from increased spending on clinical research organizations, investigator grants and consultants of approximately $4.2 million and $7.1 million, respectively. In addition, the increase in research and development expense was due to an increase in personnel and related costs of approximately $1.3 million and $3.1 million, respectively, mainly due to additional headcount and infrastructure to support the increased development activities noted above. These increases were partially offset by a decrease in research and development expense for the BAY 86-9766 (RDEA119) program, as we near completion of the ongoing clinical trials. Under the terms of the License Agreement, after the completion of the ongoing clinical trials, all subsequent development efforts will be performed solely by Bayer.

General and Administrative Expense

For the three months ended September 30, 2011, general and administrative expense decreased to $4.9 million from $6.7 million for the same period in 2010, mainly due to a decrease in non-cash share-based compensation expense of approximately $2.6 million due to the departure of certain employees during the third quarter of 2010. This decrease was partially offset by an increase in consulting and professional outside services of approximately $0.9 million. For the nine months ended September 30, 2011, general and administrative expense increased to $13.9 million from $12.9 million for the same period in 2010, primarily due to an increase in consulting and professional outside services of approximately $2.2 million, partially offset by a decrease in non-cash share-based compensation expense of approximately $1.6 million as discussed above.

Other Income (expense)

Other income (expense) for the three and nine months ended September 30, 2011 was comparable to the same periods in 2010.

Liquidity and Capital Resources

From inception of the Company through September 30, 2011, we have incurred a cumulative net loss of approximately $444.9 million, of which $208.8 million was incurred subsequent to the closing of the asset acquisition from Valeant and the commencement of operating activities as Ardea Biosciences, Inc.

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We have financed our operations through public and private offerings of securities, revenues from collaborative arrangements, proceeds from our growth capital loan, interest income from invested cash balances and a government grant.

In February 2011, we completed an underwritten public offering of 3,162,500 shares of our common stock, including the full exercise of the overallotment option granted to the underwriters, at a price of $26.00 per share. The net proceeds to us from the sale of shares in this offering were approximately $78.1 million after deducting underwriting discounts and commissions and offering expenses.

In November 2010, we received a $0.7 million grant under the Patient Protection and Affordable Care Act.

In April 2010, we completed a public offering of 4,025,000 shares of our common stock, including the full exercise of the overallotment option granted to the underwriters, at a price of $20.00 per share. The net proceeds to us from the sale of shares in the offering were approximately $76.8 million after deducting underwriting discounts and commissions and offering expenses.

In April 2009, we entered into the License Agreement with Bayer. Under the terms of the License Agreement, we granted Bayer a worldwide, exclusive license to develop and commercialize our MEK inhibitors for all indications. In partial consideration for the license, Bayer paid us a non-refundable upfront cash fee of $35.0 million. Bayer is responsible for reimbursing us for third-party development costs associated with certain ongoing studies as well as a portion of the personnel costs of employees involved in the development of BAY 86-9766 (RDEA119), up to an amount specified in the License Agreement. For the three and nine months ended September 30, 2011, we recognized revenue associated with the reimbursement of these third-party development and internal personnel costs of approximately $0.6 million and $2.4 million, respectively. In May 2011, the ongoing clinical trial cost reimbursement amount was increased to include the effect of study design changes previously agreed to by both parties. We believe that the amount available for reimbursement under the License Agreement will be sufficient to offset all future third-party development costs that we expect to incur through the completion of these studies as currently planned. In January 2011, we received the first milestone payment of $15.0 million under the License Agreement as a result of Bayer s initiation of a Phase 2 study of BAY 86-9766 (RDEA119) in combination with sorafenib in patients with hepatocellular carcinoma, or primary liver cancer. We are also eligible to receive additional cash payments totaling up to $357.5 million upon the occurrence of additional development-, regulatory- and sales-based events, including a $7.5 million milestone payment for the initiation of a second Phase 2 clinical study of BAY 86-9766 (RDEA119) for a different indication, as well as low double-digit royalties on worldwide sales of products covered under the License Agreement.

As of September 30, 2011, we had $122.7 million in cash, cash equivalents, and short-term investments, and $1.9 million in receivables, compared to $80.6 million in cash, cash equivalents, and short-term investments, and $17.0 million in receivables as of December 31, 2010. The net increase in cash, cash equivalents and short-term investments and decrease in receivables in 2011 was due primarily to our public offering of common stock, which was completed in February 2011, resulting in net proceeds to us of $78.1 million, and the receipt in January 2011 of a $15.0 million milestone payment under our license agreement with Bayer. These increases were partially offset by the use of cash to fund our clinical-stage programs, personnel costs and for other general corporate purposes.

Under the asset purchase agreement with Valeant, we made a $1.0 million development-based contingent event-based payment to Valeant in January 2011 after the first patient was dosed in the first Phase 2 study for the MEK inhibitor program. Future payments of up to $41.0 million will be triggered by additional development- and regulatory-based events, should they occur. Each payment will be recorded when, and if, the event occurs and such payment is issued or becomes payable.

We also enter into agreements from time to time with clinical sites and contract research organizations for the conduct of our clinical trials. We make payments to these sites and organizations based in part upon the number of patients enrolled and the length of their participation in the clinical trials.

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Under certain of these agreements, we may be subject to penalties in the event that we prematurely terminate these agreements. At this time, due to the variability associated with clinical site and contract research organization agreements, we are unable to estimate with certainty the future costs we will incur. We intend to use our current financial resources to fund our obligations under these commitments.

In addition, we have from time to time entered into employment agreements with our executives that, under certain cases, provide for the continuation of salary and certain other benefits if these executives are terminated under specified circumstances. These agreements generally expire upon voluntary termination by the executive, termination for cause or when we have met our obligations under these agreements. Payments for the continuation of salary and other benefits under such agreements were triggered by the departure of certain employees in the third quarter of 2010. The Company made the final required payment under these agreements in October 2011.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors may include, but are not limited to, the following: the rate of progress and cost of our clinical trials and other research and development activities; the scope, prioritization and number of clinical development programs we pursue; the terms and timing of any collaborative, licensing and other arrangements that we may establish; the cost of increasing the size of our organization; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; the costs and timing of regulatory approvals; the cost of establishing or contracting for manufacturing, sales and marketing capabilities; and the effect of competing technological and market developments. We anticipate that our existing cash, cash equivalents, and short-term investments will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months.

We have no current means of generating material cash flows from operations. There can be no assurance that our product development efforts related to any of our product candidates will be successfully completed, that required regulatory approvals will be obtained, or that any products, if introduced, will be successfully marketed or achieve commercial acceptance. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Our ability to obtain new financing may be constrained by unfavorable economic conditions currently affecting financial markets and numerous other factors.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital to fund operations, while at the same time maximizing the income we receive from our investments without significantly increasing risk. Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest income is limited to our investments in interest rate-sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities, such as treasury-backed money market funds, corporate bonds, certificates of deposits and commercial paper. Due to the current market conditions, we no longer invest in asset-backed securities. In accordance with our investment policy, we do not invest in auction rate securities. As a result of the generally short-term nature of our 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 September 30, 2011. While changes in our interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our statement of operations until the investment is sold or if a reduction in fair value is determined to be a permanent impairment. We do not have any foreign currency or other derivative financial instruments.

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ITEM 4. CONTROLS AND PROCEDURES

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

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

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

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this quarterly report on Form 10-Q and in our other filings with the SEC. If any of the following events, described as risks, actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our securities. An investment in our securities is speculative and involves a high degree of risk. You should not invest in our securities if you cannot bear the economic risk of your investment for an indefinite period of time and cannot afford to lose your entire investment. The risks described below include certain additions and revisions to the risks set forth in our annual report on Form 10-K for the fiscal year ended December 31, 2010 and our subsequent filings with the SEC. Risk factors containing such revisions are marked with an asterisk.

Risks Related to Our Business

Our success depends substantially on our most advanced product candidate, lesinurad (previously called RDEA594). We cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.*

We are currently focusing substantially all of our development efforts on our product candidate for the treatment of gout, lesinurad, and our near-term prospects depend almost entirely on lesinurad s successful development and commercialization. We currently have no drug products approved for sale

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and we may never be able to develop marketable drug products. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the U.S. and other countries, whose regulations differ from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of a new drug application, or NDA, from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries. We have not received marketing approval for any of our product candidates. Our near-term success is substantially dependent on our ability to successfully complete the approval process for lesinurad. Obtaining this approval is a lengthy, expensive and uncertain process that could require the expenditure of substantial and unanticipated resources.

An approval letter from the FDA authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug s safety or efficacy and may impose other conditions which can affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The FDA has substantial discretion in this drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example the FDA may:

- not deem a product candidate safe and effective;
- not find the data from preclinical studies and clinical trials sufficient to support approval;
- not agree with our interpretation and characterization of efficacy and safety data from our clinical trials;
- require additional preclinical or clinical studies;
- not approve of our third-party manufacturers processes and facilities; or
- change its approval policies, adopt new regulations, or provide new guidance or change its view regarding guidance previously provided.

Lesinurad has been evaluated in a comprehensive Phase 2 development program designed to demonstrate its clinical utility. As part of its Phase 3 clinical development plan, lesinurad will need to successfully complete additional pivotal clinical trials, as well as potential additional non-pivotal clinical trials. We have completed formal End-of-Phase 2 meetings with the FDA and expect to receive shortly advice from the European Medicines Agency, or EMA, regarding our Phase 3 clinical development plan. Based on this advice, we may be requested to complete additional pivotal or non-pivotal clinical trials. Any additional clinical trials that we may decide to conduct as a result of advice received from the EMA may be significantly greater in scope, cost and duration than we have planned or anticipated.

Our product candidates may not be approved even if they achieve their specified endpoints in these and future clinical trials. For example, lesinurad may not be approved even though it achieved its specified endpoints in the Phase 3 clinical trials and met the FDA, EMA or other regulatory authorities guidance on the general efficacy benchmarks required in pivotal trials. The FDA, EMA or other regulatory authorities may disagree with our trial design and our interpretation of efficacy and safety data from the Phase 3 clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for those clinical trials. The FDA, EMA or other regulatory authorities may also approve lesinurad for fewer or more limited indications than we request, may request additional clinical trials prior to approval, or may grant approval contingent on the performance of costly additional clinical trials prior to or after approval.

In addition, the FDA, EMA or other regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of lesinurad. Any failure to obtain regulatory approval of lesinurad would limit our ability to ever generate revenues (and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue) and would have a material and adverse impact on our business.

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

We have incurred, and expect to continue to incur, substantial operating losses for the foreseeable future. We expect that most of our resources for the foreseeable future will be dedicated to further development of lesinurad and research and development and preclinical and clinical testing of next-generation compounds for the chronic treatment of gout, including RDEA3170. The amounts paid to advance lesinurad, RDEA3170 and the preclinical and clinical development of other product candidates will continue to increase and may be higher than anticipated. Lesinurad, RDEA3170 and any other 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 and may never be approved for commercial sales. The time required to achieve product sales and profitability is lengthy and highly uncertain and we cannot assure you that we will be able to achieve or maintain product sales.

We are not currently profitable and may never become profitable.

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

Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, we can provide no assurances that lesinurad, RDEA3170, BAY 86-9766 (RDEA119) or any other of our product candidates will have favorable results in future clinical trials or receive regulatory approval.

Positive results from preclinical studies and early clinical trials should not be relied upon as evidence that later or larger-scale clinical trials will succeed. Even if our product candidates achieve positive results in preclinical 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 an extremely high historical rate of failure of product candidates proceeding through clinical trials in our industry. There is no guarantee that the efficacy of any product candidate, including lesinurad, shown in early patient trials will be replicated or maintained in future trials of longer duration and/or larger patient populations. Similarly, favorable safety and tolerability data seen in short-term studies might not be replicated in studies of longer duration and/or larger patient populations. Data from additional preclinical studies may also reveal unacceptable levels of toxicity of our product candidates. If any product candidate demonstrates insufficient safety, unacceptable interactions with other medications or insufficient efficacy in any clinical trial, then we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts of any of our product candidates, then we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

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

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

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

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

In addition, the commencement of clinical trials may be delayed due to slow or 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, the eligibility criteria for the clinical trial or the failure on the part of clinical investigators or contract research organizations to properly carry out their contractual obligations or meet expected recruitment deadlines.

Finally, we may delay the commencement of clinical trials with respect to product candidates until we enter into a collaboration or license agreement with another party to fund the clinical trials of such product candidates.

Once clinical testing of lesinurad, RDEA3170, BAY 86-9766 (RDEA119) and other potential product candidates has commenced, the termination, or delays in the completion, of clinical testing 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, 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 or requests for supplemental information with respect to our clinical trial results;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated recruitment rate or retention rate of patients in clinical trials;

the imposition of a clinical hold;

lack of adequate funding to continue clinical trials;

negative results of clinical trials;

changes to clinical trials protocols;

failure on the part of clinical investigators or contract research organizations to properly carry out their contractual obligations, adhere to clinical protocols or meet expected deadlines;

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

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

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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, or termination of, clinical testing, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to generate revenues from those products will be delayed.

If our efforts to develop and commercialize lesinurad are unsuccessful, we may be required to obtain rights to new products or product candidates from third parties, which we may not be able to do.*

Our current primary focus is on the advancement of lesinurad through clinical development, regulatory approval and commercialization. If we are not successful, we may seek to identify and obtain 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:

- our inability to purchase or license products or product candidates on terms that would allow us to make a sufficient financial return from resulting products;
- competitors may be unwilling to assign or license products or product candidate rights to us; or
- we may be unable to identify suitable products or product candidates within, or complementary to, our areas of interest or capabilities.

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.

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

There can be no assurance that even if our clinical trials of lesinurad or any other potential product candidate are successfully completed, we will be able to submit a NDA to the FDA in the U.S. or similar application to other regulatory authorities elsewhere in the world, or that any applications we submit will be approved by these regulatory authorities in a timely manner, if at all. If we are unable to submit a NDA or similar application with respect to lesinurad or any other product candidate, or if any NDA or similar application we submit is not approved by the FDA or other regulatory authorities elsewhere in the world, we will be unable to commercialize that product. These authorities can and do reject new drug applications and require additional clinical trials, even when product candidates have performed well or have achieved favorable results in clinical trials. If we fail to commercialize lesinurad or any other product candidate, 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 lesinurad, RDEA3170, BAY 86-9766 (RDEA119) or other product candidates are approved for commercial sale by the FDA or other regulatory authorities, our profitability and growth will depend on the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors, which will in turn depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy of our products;
- relative convenience and ease of administration of products;
- the prevalence and severity of any adverse side effects from the products;

the availability of alternative treatments;

pricing and cost effectiveness of products; and

sufficient third-party insurance coverage or reimbursement.

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

- new products or technologies are introduced that are more favorably received than our potential future products, are more cost effective or render our potential future products obsolete; or
- complications arise with respect to use of our potential future products.

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

We anticipate that our existing cash, cash equivalents, and short-term investments will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. We may need to raise additional capital to complete the development, regulatory review and approval process and commercial launch of lesinurad. Also, our business and operations may change in a manner that would consume available resources at a greater rate than anticipated or require more capital than currently anticipated. For example, the FDA may require unanticipated, additional clinical trials of lesinurad prior to or even after approval. In addition, we may need to raise substantial additional capital in the future to, among other things:

- establish and maintain manufacturing, sales and marketing operations;
- commercialize lesinurad or other 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;
- the scope, prioritization and number of preclinical studies and clinical trials we pursue;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of regulatory approval;
- the costs of establishing or contracting for manufacturing, sales and marketing capabilities;
- the effects of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and

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

We do not anticipate that we will generate significant continuing revenues for at least several years, if ever. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Our ability to obtain new financing may be constrained by unfavorable economic conditions affecting financial markets and numerous other factors. 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 additional collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We have a history of raising funds through security offerings and we may raise additional funds through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders ownership will be diluted. Any debt financing we obtain may involve covenants that restrict our operations. These restrictive covenants may include, among other things, limitations on borrowing, specific restrictions on

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the use of our assets, as well as prohibitions on our ability to create liens on our assets, pay dividends on or redeem our capital stock or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to us or relinquish potentially valuable rights to our potential products or proprietary technologies. We may be required in future collaborations to relinquish all or a portion of our sales and marketing rights with respect to potential products or license intellectual property that enable licensees to develop competing products in order to complete any such transaction.

We have experienced periods of significant growth as well as reductions in the size of our organization and may experiences similar fluctuations again in the future, and we may experience difficulties in managing these organizational changes.*

We may need to expand 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.

Alternatively, we have reduced the size of our organization in the past and may need to do so again in the future in response to internal or external adverse financial conditions or events. If, as a result of a reduction, our staffing is inadequate because of additional, unanticipated attrition or because we fail to retain the staffing level required to accomplish our business objectives we may be delayed or unable to continue the development or commercialization of our product candidates, which could impede our ability to generate revenues and achieve profitability.

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

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

Our short-term investments consist primarily of securities of the U.S. government s federal agencies, entities controlled by the federal government and U.S. and foreign commercial paper, corporate debt securities and certificates of deposits. These investments are subject to general credit, liquidity, market and interest rate risks, which may be further exacerbated by U.S. sub-prime mortgage defaults, concerns regarding the credit-worthiness of the U.S. government and other factors, which have affected various sectors of the financial markets and caused credit and liquidity issues. For the nine months ended September 30, 2011, we determined that any declines in the fair value of our investments were temporary. There may be further declines in the value of these investments, which we may determine to be other than temporary. These market risks associated with our investment portfolio may have a material adverse effect on our results of operations, liquidity and financial condition.

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

We expect that, for at least the next few years, our ability to generate significant revenues will depend in large part upon the success of our existing collaboration with Bayer and our ability to enter into new collaborations. Future revenues from our collaboration with Bayer will depend mainly on the

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achievement of development-, regulatory- and sales-based contingent event-based payments and royalty payments, if any. We will not receive additional revenues from our existing collaboration if Bayer s development and commercialization efforts are unsuccessful.

Typically, collaborators, including Bayer, will control the development and commercialization of partnered compounds after entering into a collaboration or license agreement. In addition, we may not have complete access to information about the results and status of our collaborators clinical development and regulatory programs and strategies. Our collaborators may not devote adequate resources to the development of our compounds and may not develop or implement a successful clinical or regulatory strategy. We cannot guarantee that any development-, regulatory- or sales-based contingent event-based payments in our existing or future collaborations will be achieved on the timelines we anticipate, or at all. We cannot guarantee that we will receive any payments for the achievement of any contingent events or royalties on sales of products. In addition, collaborations, including our existing collaboration with Bayer, may be terminated early in certain circumstances, in which case, we may not receive future contingent event-based or royalty payments. Each of these concerns would also apply in the event we choose to enter into a collaboration with a partner for our gout and hyperuricemia program.

Our ability to enter into new collaborations will depend in part on finding appropriate partners for our development programs. There has recently been increased consolidation and strategic realignment among pharmaceutical companies. This has reduced the number of potential partners for our product candidates and may make it more difficult to identify a partner and enter into any potential collaboration. Even if potential partners are interested in our programs, we may be unable to agree with potential partners on the value of our development programs or other material terms of a collaboration. For example, the market size, appropriate pricing and customer demand for lesinurad, if approved, is difficult to estimate. There have only been two new products for the treatment of gout approved and introduced in the U.S. in the last 40 years, so there is very limited data on the gout market available.

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

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

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

- unwillingness on the part of a collaborator to pay us contingent event-based payments or royalties we believe are due to us under our collaboration or license agreement;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;
- slowing or cessation of a collaborator s development or commercialization efforts with respect to our product candidates; or
- costly and time-consuming litigation or dispute resolution.

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We depend on outside parties to conduct our preclinical and clinical trials, which may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing product candidates.

We engage clinical investigators and medical institutions to enroll patients in our clinical trials and contract research organizations to perform data collection and analysis and other aspects of our preclinical studies and clinical trials. As a result, we depend on these clinical investigators, medical institutions and contract research organizations to properly perform the studies and trials. If these parties do not successfully carry out their contractual duties or obligations, meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated. We may not be able to make satisfactory alternative arrangements without undue delays or excessive expenditures. If there are delays in testing or regulatory approvals as a result of the failure to perform by third parties, our drug development costs will increase and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. In addition, we may not be able to maintain any of these existing relationships, or establish new ones on acceptable terms, if at all.

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 lesinurad and any other products we may develop depends 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. Our current manufacturing agreements for lesinurad reflect a much smaller scale than would be required for commercial manufacturing. If our manufacturers do not satisfy their contractual duties or obligations, including with respect to quantity or quality, or meet established deadlines, our clinical trials may be significantly delayed or compromised and costs would increase. If we need to replace an unsatisfactory manufacturer, or increase our capacity, 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 lesinurad and other 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 other 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 lesinurad or any other products, we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with other parties to perform these services. We have not yet determined whether we will attempt to establish internal sales and marketing capabilities or enter into agreements with other 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 other 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 other parties, we may not be able to generate product revenue and may not become profitable.

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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, clinical development, regulatory affairs and scientific personnel. If we are unable to hire or retain these employees, we may not be able to advance our research and development programs at the pace we anticipate. We may not be able to attract or retain qualified management, clinical development, regulatory affairs and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical businesses, particularly in the San Diego, California area. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our research and development objectives. In addition, all of our employees are at will employees, which means that any employee may quit at any time and we may terminate any employee at any time. Currently, we do not have employment agreements with any employees or members of senior management that provide us any guarantee of their continued employment. If we lose members of our senior management team, we may not be able to find suitable replacements and our business may be harmed as a result.

Our quarterly results and stock price may fluctuate significantly.

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

- whether or not we achieve specified events that would trigger contingent event-based payments 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 contingent event-based payments that we may make to Valeant;
- the addition or termination of research or development programs or funding support;
- the status of development of our product candidates, including results of preclinical studies and any future clinical trials;
- variations in the level of expenses related to the development and commercialization of 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 selection of additional compounds for development; and
- fluctuations in the stock prices of other companies in the biotechnology and pharmaceuticals industries and in the financial markets generally.

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

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

In 2006, we acquired two pharmaceutical research and development programs from Valeant, and there is no guarantee that we will be able to successfully develop the acquired product candidates. We may attempt to acquire businesses, technologies, services or other products or

in-license technologies that we believe are a strategic fit with our existing development programs, at the appropriate time and as resources permit. In any acquisition, the process of integrating the acquired business, personnel, technology, service or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention away from our ongoing business operations. Other operational and financial risks associated with acquisitions include:

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assumption and exposure to unknown liabilities of an acquired business;

disruption of our business and diversion of our management s time and attention to acquiring and developing acquired products or technologies;

incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;

disagreements over interpretation of contractual terms in the acquisition agreements;

higher than expected acquisition and integration costs;

increased amortization expenses;

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

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

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

inability to retain key employees of any acquired businesses.

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

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

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

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 development programs. For example, the loss of clinical trial data from completed clinical trials for lesinurad could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 and the further development of our product candidate may be delayed.

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

Under the terms of the Valeant asset purchase agreement, we agreed to use commercially reasonable efforts to develop the product candidates in the pharmaceutical research and development programs we acquired from Valeant, with the objective of obtaining marketing approval for RDEA806, BAY 86-9766 (RDEA119) and the lead product candidates from the next generation NNRTI and MEK inhibitor programs in the U.S., the United Kingdom, France, Spain, Italy and Germany. If we have a disagreement with Valeant on whether we have used commercially reasonable efforts to develop such product candidates, then we may be subject to a potential lawsuit or lawsuits from Valeant under the asset purchase agreement. If such a lawsuit was successful, we may be subject to financial losses, our reputation within the pharmaceutical research and development community may be negatively impacted and our business may suffer.

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

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

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

Risks Related to Our Industry

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

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

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office issued revised regulations affecting prosecution before that office, and various pieces of legislation, including patent reform acts, have been introduced or discussed in the U.S. Senate and Congress in the past few years. If implemented, or following final resolution of pending legislation, new regulations or legislation could, among other things, restrict our ability to prosecute applications in the U.S. Patent and Trademark Office, limit the number of patent claims in applications that we have previously filed or intend to file, and may lower the threshold required for competitors to challenge our patents in the U.S. Patent and Trademark Office after they have been granted. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive

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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 other parties;
- our issued patents may not be valid or enforceable; or
- the patents of others may have an adverse effect on our business.

Patent applications in the U.S. are maintained in confidence for at least 18 months after their filing. Consequently, we cannot be certain that the patent applications we are pursuing will lead to the issuance of any patent or be free from infringement or other claims from other parties. In the event that another party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent Office to determine priority of invention in the U.S. 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 product candidates or by covering similar technologies that affect our market.

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

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

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

Additionally, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on

our business and financial condition.

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Our business depends upon not infringing the rights of others.

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

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 products that incorporate the challenged intellectual property;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our processes so that they do not infringe, which could be costly and time-consuming and may not be possible.

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

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

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

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we 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 U.S. 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.

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

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

- research and development;
- preclinical testing;
- clinical trials;
- regulatory approvals;
- manufacturing; and
- sales and marketing of approved products.

Smaller or early stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business.

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

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

We also face competition from generic products and currently marketed products. For example, several competitors of lesinurad are products that are already approved for the treatment of gout and hyperuricemia, including allopurinol, Uloric and Krystexxa. Allopurinol is a generic product and the current standard of care for most gout patients. As such, allopurinol is sold for a much lower price than we intend to charge for lesinurad, if approved, and could limit the demand, and the price we are able to charge, for lesinurad. Uloric and Krystexxa are two recently approved products for the treatment of gout. Both of these products have advantage of entering and becoming established in the market before lesinurad.

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

The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect our ability to generate adequate revenues and gross margins to make the products we develop commercially viable. Our ability to commercialize any product candidates successfully will depend in part on the extent to

which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of such products and related treatments.

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In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the U.S., comprehensive health care reform legislation has been enacted by the federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. The trend toward managed health care in the U.S. will continue to manifest itself in the preference for less expensive generic products and put pressure on the rate of adoption and pricing of branded prescription pharmaceuticals, which may result in lower prices for our product candidates. For example, the availability of generic allopurinol for the treatment of gout and hyperuricemia will exert negative pressure in the pricing of lesinurad, if it is approved.

While we are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future, or what effect federal health care reform legislation will have on our business, such regulations could have a material adverse effect on our potential revenues and gross margins. We will continue to monitor the effect of federal health care reform legislation to determine its impact on our business and potential revenues.

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

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

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

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

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Risks Related to Our Common Stock

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

Our directors, executive officers, principal stockholders and affiliated entities currently beneficially own or control a significant majority of our outstanding securities. Two of our directors and their affiliated entities own collectively approximately 36% of our outstanding shares of common stock. These stockholders, if they determine to vote in the same manner, would control the outcome of any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions or terms of any liquidation.

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

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

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

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

- allow the authorized number of directors to be changed only by resolution of our Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for nominations to our Board of Directors or for proposals that can be acted on at stockholder meetings;
- authorize our Board of Directors to issue blank check preferred stock to increase the number of outstanding shares; and
- limit who may call stockholder meetings.

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

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

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

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ITEM 6. EXHIBITS

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

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

* Management contract or compensatory plan, contract or arrangement.

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

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

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SIGNATURES

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

Ardea Biosciences, Inc.

Date: November 4, 2011

/s/ Barry D. Quart
Barry D. Quart, Pharm.D.
President and Chief Executive Officer

(On behalf of the Registrant)

/s/ John W. Beck
John W. Beck
Senior Vice President, Finance and Operations

and Chief Financial Officer

(As Principal Financial and Accounting Officer)

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ARDEA BIOSCIENCES, INC.

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