

Ardea Biosciences, Inc./DE  
Form 10-K  
March 09, 2012  
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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-K**

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 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**  
*(State or other jurisdiction of  
incorporation or organization)*

**94-3200380**  
*(I.R.S. Employer  
Identification No.)*

**4939 Directors Place**  
**San Diego, CA**  
*(Address of principal executive offices)*

**92121**  
*(Zip Code)*

**Registrant's telephone number, including area code:**

(858) 652-6500

**Securities registered pursuant to Section 12(b) of the Act:**

## Edgar Filing: Ardea Biosciences, Inc./DE - Form 10-K

Title of each class: **Common Stock, par value \$0.001 per share**  
Name of each exchange on which registered: **The Nasdaq Global Select Market**  
Securities registered pursuant to Section 12(g) of the Act:

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant 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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2011 totaled approximately \$347,000,000 based on the closing price of \$25.46 as reported by the Nasdaq Global Select Market. As of March 2, 2012, there were 36,739,135 shares of the Company's common stock (\$0.001 par value) outstanding.

### Documents Incorporated by Reference

Portions of the proxy statement for the registrant's 2012 annual meeting of stockholders are incorporated by reference into Part III.

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**FORWARD-LOOKING STATEMENTS**

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. These statements include, but are not limited to, statements regarding our development programs, our capabilities, our goals, the expected timeline for achievement of our clinical milestones, the expected properties and benefits of our product candidates, the results of clinical and other studies, the size of the market and commercial opportunity for our products and our financial results. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, ongoing, expect, management believes, we believe, we intend and similar words or phrases. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed or implied in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed in this report or incorporated by reference.

Because the factors discussed in this report, and even factors of which we are not yet aware, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by or on behalf of us, you should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. We have included important factors in the cautionary statements included in this report, particularly under Item 1A. Risk Factors, and in our SEC filings, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. These and other risks are also detailed and occasionally modified or updated in our reports filed from time to time under the Securities Act and/or the Exchange Act. You are encouraged to read these filings as they are made.

Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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### **PART I**

In this report, all references to Ardea, we, our, and us, refer to Ardea Biosciences, Inc., a Delaware corporation, and our wholly owned subsidiary.

#### **ITEM 1. BUSINESS.**

##### **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**

<b>Product Candidate</b>	<b>Target Indication</b>	<b>Development Status</b>
Lesinurad (RDEA594)	Gout	Phase 3 ongoing
RDEA3170	Gout	Phase 1 ongoing
BAY 86-9766 (RDEA119)	Cancer	Phase 2 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-excretors 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 has been shown to normalize the amount of uric acid excreted by gout patients. Since the majority of gout patients are under-excretors, 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 uric acid 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 3.1 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 about 30 to 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 taking allopurinol alone, and 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. We are also developing lesinurad to be used as a monotherapy for those patients who are intolerant to either allopurinol or febuxostat.

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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 resulted in a response rate of 79 percent for the 600 mg dose using the more rigorous intent-to-treat 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 analysis, which was the method utilized for the U.S. Food and Drug Administration, or FDA, 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 period of Study 203 demonstrated consistent, sustained reductions in sUA levels, with 90 percent of patients on combination therapy at week 44 reaching the medically recommended target of 6 mg/dL and 81 percent reaching less than 5 mg/dL. In addition, at the lowest dose of 200 mg, patients experienced continued sUA reductions out to 16 weeks and a 27 percent decline in sUA at week 44. All patients continuing in the ongoing extension period have completed a total of 48 weeks of blinded treatment. The combination of lesinurad and allopurinol was generally well tolerated in the main 28-day dosing period and has been generally well tolerated in the ongoing extension period, with adverse events similar to allopurinol alone.

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.

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 the subset of patients with mild to moderate renal impairment. Lesinurad was generally well tolerated in these studies with a similar safety profile in subjects with normal or impaired renal function.

Results from a thorough QT study of 54 healthy subjects in which lesinurad was administered as a single therapeutic dose of 400 mg and as a single supratherapeutic dose of 1600 mg demonstrated no signal for lesinurad on any ECG interval, including cardiac repolarization.

Based on findings thus far, single doses of lesinurad from 5 mg to 1600 mg given alone, and multiple doses of lesinurad from 100 mg to 600 mg given either alone or in combination with allopurinol or febuxostat, appear to be generally well tolerated.



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We have initiated a Phase 3 development program for lesinurad that includes the following main studies:

An open-label, Phase 4 interventional study of allopurinol in gout patients, called **LASSO**. Given the low response rate typically observed with allopurinol and its well-established side effect profile, we expect a significant 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 and tophus resolution after 12 months of dosing.

An identical 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 and tophus resolution 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 80 mg febuxostat for the treatment of hyperuricemia in gout patients with tophi. 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 and physical function disability assessment after 12 months of dosing.

We will need to successfully complete these pivotal Phase 3 clinical trials of lesinurad, as well as potential additional non-pivotal clinical trials, in order to be approved for marketing by the 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. Initial results have shown sustained reductions in sUA of up to 60 percent after a single 40 mg dose of RDEA3170 was administered to healthy volunteers in a Phase 1 study.

### **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.



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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.

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. 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 are ongoing and are being conducted by our global development and commercialization licensee, Bayer. See Bayer Relationship below.

## **Market Opportunity**

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

We believe that there is a significant need for new products for the treatment and prevention of gout as many chronic gout sufferers are unable to achieve target reductions in uric acid with current treatments.

There have been only two new products approved in the United States for the treatment of gout in the last 40 years. According to Decision Resources, an estimated 19.7 million adults in seven major markets (the United States, Japan, France, Germany, Italy, Spain and United Kingdom) suffer from gout. The prevalence of gout is increasing in the United States. According to the Annals of Rheumatic Diseases, there was a 288% increase in gout-related hospitalizations from 1988 to 2005 and over \$11.2 billion in gout-related hospital costs were incurred in 2005 in the United States.

We are developing products for the treatment of hyperuricemia and gout that inhibit URAT1. We believe there may also be opportunities to develop uric acid-lowering agents to treat diseases other than gout. Evidence suggests that hyperuricemia may also have systemic consequences, including an increased risk for kidney dysfunction, elevated C-reactive protein, hypertension and possibly other cardiovascular risk factors.

We believe that there is growing interest in targeted therapies, including kinase inhibitors, for the treatment of both cancer and inflammatory disease. Worldwide sales of products used in the treatment of cancer were \$52.4 billion in 2009, according to IMS Health Incorporated, fueled by strong acceptance of innovative and effective targeted therapies. In addition to cancer, MEK appears to play a role in inflammatory diseases, and we believe that BAY 86-9766 (RDEA119) and our next generation MEK inhibitors, if successfully developed, approved and commercialized, could help address these growing markets.

## **Bayer Relationship**

In April 2009, we entered into a global 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)

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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 were responsible for completion of the Phase 1 and Phase 1/2 studies that were underway when we entered into the agreement. 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 is 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 advanced 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. To date, the first, and only Phase 2 development-based contingent event-based payment related to BAY 86-9766 (RDEA119) has 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 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.

## **Clinical Supplies and Manufacturing**

We have no in-house manufacturing capabilities. We rely on third-party contract manufacturers to make the material used to support the development of our product candidates. We purchase the material used in our clinical trial activities from various companies and suppliers.

## **Sales and Marketing**

We do not currently have sales or marketing capabilities. In order to commercially market any pharmaceutical product that we successfully advance through preclinical and clinical development and for which we obtain regulatory approval, we must either develop a sales and marketing infrastructure or collaborate with third parties with sales and marketing capabilities. Because of the early stage of our pharmaceutical development programs, we have not yet developed a sales and marketing strategy for any pharmaceutical products that we may successfully develop.

## **Customers and Distribution**

We do not currently sell or distribute pharmaceutical products.

## **Competition**

The biotechnology and pharmaceutical industries are extremely competitive. Our potential competitors in the field are many in number and include major pharmaceutical and specialized biotechnology companies. Many

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of our potential competitors have significantly more financial, technical and other resources than we do, which may give them a competitive advantage. In addition, they may have substantially more experience in effecting strategic combinations, in-licensing technology, developing drugs, obtaining regulatory approvals and manufacturing and marketing products. We cannot give any assurances that we can compete effectively with these other biotechnology and pharmaceutical companies.

Any products that we may develop or discover will compete in highly competitive markets. Our potential competitors in these markets may succeed in developing products that could render our products and those of our collaborators obsolete or non-competitive. In addition, many of our competitors have significantly greater experience than we do in the fields in which we compete.

## **Intellectual Property**

Our success will depend in large part on our ability to:

obtain and maintain international and domestic patent and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;

prosecute and defend our patents;

preserve our trade secrets; and

operate without infringing the patents and proprietary rights of other parties.

We intend to continue to seek appropriate patent protection for the lead product candidates in our research and development programs and their uses by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where possible, claims for composition of matter, medical uses, processes for preparation and formulations.

We own a total of 15 issued United States patents, 31 pending United States non-provisional applications, 11 pending United States provisional applications, seven pending international applications, over 30 issued foreign patents and over 400 pending foreign patent applications.

Although we believe that our rights under patent applications we own provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes, and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. Any patents or patent rights that we obtain may be circumvented, challenged or invalidated by our competitors.

We also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. We seek protection of these trade secrets, proprietary know-how and any continuing innovation, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide meaningful protection for, or adequate remedies to protect, our technology in the event of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

## **Government Regulation**

### ***Pharmaceutical Regulation***

If and when we market any pharmaceutical products in the United States, they will be subject to extensive government regulation. Likewise, if we seek to market and distribute any such products abroad, they would also be subject to extensive foreign government regulation.



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In the United States, the FDA regulates pharmaceutical products. FDA regulations govern the testing, manufacturing, advertising, promotion, labeling, sale and distribution of pharmaceutical products, and generally require a rigorous process for the approval of new drugs. We also may be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are tested or marketed abroad. The approval process outside the United States varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

### ***Regulation in the United States***

The FDA testing and approval process requires substantial time, effort and money. We cannot assure you that any of our products will ever obtain approval. The FDA approval process for new drugs includes, without limitation:

preclinical studies;

submission of an Investigational New Drug application, or IND, for clinical trials;

adequate and well-controlled human clinical trials to establish safety and efficacy of the product;

review of a New Drug Application, or NDA; and

inspection of the facilities used in the manufacturing of the drug to assess compliance with the FDA's current Good Manufacturing Practices, or cGMP, regulations.

Preclinical studies include laboratory evaluation of the product, as well as animal studies to assess the potential safety and effectiveness of the product. Most of these studies must be performed according to good laboratory practices, a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which we are required to file before we can commence any clinical trials for our product candidates in the United States. Clinical trials may begin 30 days after an IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, an IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. We have filed and received approval for INDs for our lead clinical candidates, BAY 86-9766 (RDEA119) and lesinurad, and we may file additional INDs in the future. We cannot assure you that submission of any additional IND for any of our preclinical product candidates will result in authorization to commence clinical trials.

Clinical trials involve the administration of the product candidate that is the subject of the trial to volunteers or patients under the supervision of a qualified principal investigator. Each clinical trial must be reviewed and approved by an independent institutional review board at each institution at which the study will be conducted. The institutional review board will consider, among other things, ethical factors, safety of human subjects and the possible liability of the institution arising from the conduct of the proposed clinical trial. Also, clinical trials must be performed according to good clinical practices, which are enumerated in FDA regulations and guidance documents.

Clinical trials typically are conducted in sequential phases: Phases 1, 2, 3 and 4. The phases may overlap. The FDA may require that we suspend clinical trials at any time on various grounds, including if the FDA makes a finding that the subjects participating in the trial are being exposed to an unacceptable health risk.

In Phase 1 clinical trials, a drug is usually tested on a small number of healthy volunteers to determine safety, any adverse effects, proper dosage, absorption, metabolism, distribution, excretion and other drug effects.

In Phase 2 clinical trials, a drug is usually tested on a limited number of subjects (generally up to several hundred) to preliminarily evaluate the efficacy of the drug for specific, targeted indications, determine dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks.



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In Phase 3 clinical trials, a drug is usually tested on a larger number of subjects (up to several thousand), in an expanded patient population and at multiple clinical sites.

In Phase 4 clinical trials or other post-approval commitments, additional studies and patient follow-up are conducted to gain experience from the treatment of patients in the intended therapeutic indication. Additional studies and follow-up are also conducted to document a clinical benefit where drugs are approved under accelerated approval regulations and based on surrogate endpoints. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. Failure to promptly conduct Phase 4 clinical trials and follow-up could result in expedited withdrawal of products approved under accelerated approval regulations.

We cannot assure you that any of our current or future clinical trials will result in approval to market our products.

An NDA must include comprehensive and complete descriptions of the preclinical testing, clinical trials and the chemical, manufacturing and control requirements of a drug that enable the FDA to determine the drug's safety and efficacy. A NDA must be submitted, filed and approved by the FDA before any product that we may successfully develop can be marketed commercially in the United States.

The facilities, procedures and operations for any of our contract manufacturers must be determined to be adequate by the FDA before product approval. Manufacturing facilities are subject to inspections by the FDA for compliance with cGMP, licensing specifications and other FDA regulations before and after a NDA has been approved. Foreign manufacturing facilities are also subject to periodic FDA inspections or inspections by foreign regulatory authorities. Among other things, the FDA may withhold approval of NDAs or other product applications if deficiencies are found at the facility. Vendors that may supply us with finished products or components used to manufacture, package and label products are also subject to similar regulations and periodic inspections.

In addition, the FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, injunctions and criminal prosecution. Any of these actions could have a material adverse effect on us.

### ***Regulation Outside the United States***

If we market our products in foreign countries, we also will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for such approvals may differ substantially from that required for FDA approval. There is no assurance that any future FDA approval of any of our clinical trials or drugs will result in similar foreign approvals or vice versa.

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### ***Additional Regulation***

#### ***Third-Party Reimbursement***

In the United States, physicians, hospitals and other healthcare providers that purchase pharmaceutical products generally rely on third-party payors, principally private health insurance plans, Medicare and, to a lesser extent, Medicaid, to reimburse all or part of the cost of the product and procedure for which the product is being used. Even if a product is approved for marketing by the FDA, there is no assurance that third-party payors will cover the cost of the product and related medical procedures. If they do not, end-users of the drug would not be eligible for any reimbursement of the cost, and our ability to successfully market any such drug would be materially and adversely impacted.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis. In many foreign markets, including markets in which we hope to sell our products, the pricing of prescription pharmaceuticals is subject to government pricing control. In these markets, once marketing approval is received, pricing negotiations could take significant additional time. As in the United States, the lack of satisfactory reimbursement or inadequate government pricing of any of our products would limit their widespread use and lower potential product revenues.

#### ***Fraud and Abuse Laws***

Federal and state anti-kickback and anti-fraud and abuse laws, as well as the federal Civil False Claims Act may apply to certain drug and device research and marketing practices. The Civil False Claims Act prohibits knowingly presenting or causing to be presented a false, fictitious or fraudulent claim for payment to the United States. Actions under the Civil False Claims Act may be brought by the Attorney General or by a private individual acting as an informer or whistleblower in the name of the government. Violations of the Civil False Claims Act can result in significant monetary penalties. The federal government is using the Civil False Claims Act, and the threat of significant liability, in its investigations of healthcare providers, suppliers and drug and device manufacturers throughout the country for a wide variety of drug and device marketing and research practices, and has obtained multi-million dollar settlements. The federal government may continue to devote substantial resources toward investigating healthcare providers, suppliers and drug and device manufacturers compliance with the Civil False Claims Act and other fraud and abuse laws. We may have to expend significant financial resources and management attention if we ever become the focus of such an investigation, even if we are not guilty of any wrong doings.

#### ***HIPAA***

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, requires the use of standard transactions, privacy and security standards and other administrative simplification provisions by covered entities, which include many healthcare providers, health plans and healthcare clearinghouses. HIPAA instructs the Secretary of the Department of Health and Human Services to promulgate regulations implementing these standards in the United States.

#### ***Other Laws***

We are also subject to other federal, state and local laws of general applicability, such as laws regulating working conditions, and various federal, state and local environmental protection laws and regulations, including those governing the discharge of material into the environment.

### **Employees**

As of March 2, 2012, we employed 107 regular full-time employees (including 23 people who have a Ph.D., three people who have a M.D. and one person who has a Pharm.D.), 86 of whom are involved full time in



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research and development activities. All members of our senior management team have had prior experience with pharmaceutical or biotechnology companies. We believe that we have been successful in attracting skilled and experienced personnel, but competition for personnel is intense and there can be no assurance that we will be able to attract and retain the individuals needed. None of our employees are covered by a collective bargaining agreement and management considers relations with our employees to be good.

## **Company Information**

We were incorporated in the State of Delaware in January 1994. Our corporate offices are located at 4939 Directors Place, San Diego, CA 92121. Our telephone number is (858) 652-6500. Our website address is [www.ardeabio.com](http://www.ardeabio.com). We make available free of charge through our Internet website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

## **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 annual report on Form 10-K. 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.*

### **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 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.

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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 ongoing 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 received advice from the European Medicines Agency, or EMA, and have incorporated input from these regulatory agencies in the design of our Phase 3 clinical development plan for lesinurad.

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 might 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.

***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 our next-generation compound for the chronic treatment of gout, RDEA3170. The amounts paid to advance lesinurad and RDEA3170 will continue to increase substantially, and may be higher than anticipated. Lesinurad, RDEA3170 and any other compounds we may 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.***

## Edgar Filing: Ardea Biosciences, Inc./DE - Form 10-K

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

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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.

***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



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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 intentionally 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.

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.

***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.***

## Edgar Filing: Ardea Biosciences, Inc./DE - Form 10-K

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

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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.

***If our efforts to develop and commercialize lesinurad are unsuccessful, we may be required to obtain rights to new products or product candidates from other 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 other parties. We may be unable to obtain suitable product candidates or products from other 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 other 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, including the funds received from our recent public offering, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. The amounts paid to advance lesinurad and RDEA3170 will continue to increase substantially in the near term, and may be higher than anticipated. 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.

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***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 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 experience 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, U.S. corporate debt securities, U.S. and foreign commercial paper 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

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the U.S. government and other factors, which have affected various sectors of the financial markets and caused credit and liquidity issues. For the year ended December 31, 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 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 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, because there have only been two new products for the treatment of gout approved and introduced in the U.S. in the last 40 years there is very limited data on the gout market available. Accordingly, the market size, appropriate pricing and customer demand for lesinurad, if approved, is difficult to estimate.

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

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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.

***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. We currently work with a limited number of outside manufacturers. 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.

***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,

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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:

assumption and exposure to unknown liabilities of an acquired business;



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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.***

## Edgar Filing: Ardea Biosciences, Inc./DE - Form 10-K

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,

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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.

***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

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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 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.

## Edgar Filing: Ardea Biosciences, Inc./DE - Form 10-K

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

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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.

### ***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

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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.

***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





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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.

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

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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.

### **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 30% 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.



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*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.

### **ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

### **ITEM 2. PROPERTIES.**

We currently sub-lease a facility in San Diego, California covering a total of approximately 52,000 square feet. Our facility includes our research and development laboratories and our corporate offices and warehouse. The building sub-lease expires in February 2015. We have one option to extend the term of the sub-lease agreement until March 2017. The lease is subject to an escalation clause that provides for annual rent increases. We believe that this facility will be adequate to meet our needs for the near term.

### **ITEM 3. LEGAL PROCEEDINGS.**

We are not currently a party to any legal proceedings.

### **ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

## **PART II**

### **ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

#### **Unregistered Sales of Equity Securities and Use of Proceeds**

On September 29, 2009 and July 26, 2010 the Company issued 11,862 and 19,166 unregistered shares of common stock, respectively, to two accredited investors in reliance on Rule 144 of the Securities Exchange Act of 1933, as amended, pursuant to the net exercise provision of certain outstanding warrants. Accordingly, the Company did not receive any proceeds from the exercise of these warrants.

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### **Information About Our Common Stock**

Our common stock trades on the Nasdaq Global Select Stock Market under the symbol RDEA. Set forth below are the high and low sales prices for our common stock for each full quarterly period within the two most recent fiscal years.

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2011</b>		
First Quarter	\$ 30.61	\$ 25.08
Second Quarter	\$ 29.45	\$ 22.10
Third Quarter	\$ 26.95	\$ 13.15
Fourth Quarter	\$ 21.95	\$ 13.79

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2010</b>		
First Quarter	\$ 19.43	\$ 13.77
Second Quarter	\$ 27.78	\$ 19.58
Third Quarter	\$ 24.97	\$ 17.80
Fourth Quarter	\$ 26.97	\$ 20.75

### **Holders**

The number of record holders of our common stock as of March 2, 2012 was approximately 57.

### **Dividend Policy**

We have never paid dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future.

### **Information About Our Equity Compensation Plans**

Information regarding our equity compensation plans is incorporated by reference in Item 12 of Part III of this annual report on Form 10-K.

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### Stock Performance Graph

This information, including the graph below, is not soliciting material or deemed to be filed with the Securities and Exchange Commission, and is not incorporated by reference into any prior or subsequent filing by us under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, without regard to any general incorporation language contained in such filing.

The following graph compares the cumulative total stockholder return on our common stock for the five years ended December 31, 2011 with the Center for Research in Securities Prices ( CRSP ) Total Return Index for the Nasdaq Global Market (U.S. Companies) and the CRSP Total Return Index for Nasdaq Pharmaceutical Stocks (comprising all companies listed in the Nasdaq Global Market under SIC 283) for the same period. The graph assumes that \$100 was invested on December 31, 2006 in our common stock and each index and that all dividends were reinvested. No cash dividends have been declared on our common stock. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011
Ardea Biosciences, Inc.	\$ 100	\$ 350.92	\$ 274.54	\$ 321.10	\$ 596.33	\$ 385.55
Nasdaq US	\$ 100	\$ 108.47	\$ 66.35	\$ 95.38	\$ 113.19	\$ 113.81
Nasdaq Pharmaceuticals	\$ 100	\$ 105.17	\$ 97.85	\$ 109.95	\$ 119.19	\$ 127.71

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA.**

The following Selected Financial Data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 and the consolidated financial statements and related notes thereto beginning on page F-3 of this annual report on Form 10-K.

	2011	Year Ended December 31,				2007
		2010	2009	2008		
(In thousands, except per share amounts)						
Consolidated Statements of Operations Data:						
Revenues:						
Milestones	\$	\$ 15,000	\$	\$	\$	
License fees	4,306	8,100	20,442			
Sponsored research	391	358		304	3,095	
Reimbursable research and development costs	2,608	3,961	2,494			
Total revenues	7,305	27,419	22,936	304	3,095	
Operating expenses:						
Research and development	74,425	52,110	42,198	44,858	23,103	
General and administrative	19,539	16,452	10,689	11,921	7,566	
Loss from operations	(86,659)	(41,143)	(29,951)	(56,475)	(27,574)	
Other income (expense):						
Interest income	383	364	386	1,524	2,128	
Interest expense	(314)	(866)	(1,323)	(215)		
Other income, net	9	14	21	171	375	
Total other income (expense)	78	(488)	(916)	1,480	2,503	
Net Loss	(86,581)	(41,631)	(30,867)	(54,995)	(25,071)	
Non-cash dividends on Series A preferred stock				(60)	(240)	
Net loss applicable to common stockholders	\$ (86,581)	\$ (41,631)	\$ (30,867)	\$ (55,055)	\$ (25,311)	
Basic and diluted net loss per share applicable to common stockholders	\$ (3.26)	\$ (1.91)	\$ (1.70)	\$ (3.79)	\$ (2.55)	
Shares used in computing basic and diluted net loss per share applicable to common stockholders	26,543	21,823	18,158	14,544	9,934	
Balance Sheet Data:						
Cash, cash equivalents and short-term investments	\$ 95,996	\$ 80,612	\$ 50,891	\$ 57,743	\$ 66,215	
Working capital	\$ 78,560	\$ 77,367	\$ 30,943	\$ 49,463	\$ 62,548	
Total assets	\$ 104,229	\$ 100,454	\$ 55,065	\$ 61,475	\$ 68,840	
Noncurrent portion of obligations under capital leases and notes payable	\$ 229	\$ 251	\$ 3,315	\$ 6,132	\$	
Accumulated deficit	\$ (475,720)	\$ (389,041)	\$ (347,410)	\$ (316,543)	\$ (261,488)	
Total stockholders' equity	\$ 82,247	\$ 77,123	\$ 24,741	\$ 45,958	\$ 63,739	

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### **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

#### **Introduction**

Management's discussion and analysis of financial condition and results of operations is provided as a supplement to the accompanying consolidated financial statements and notes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. Our discussion is organized as follows:

*Overview.* This section provides a general description of our business and operating expenses.

*Recent developments.* This section provides a general description of recent events and significant transactions that we believe are important in understanding our financial condition and results of operations.

*Critical accounting policies and estimates.* This section contains a discussion of the accounting policies that we believe are important to our financial condition and results of operations and that require significant judgment and estimates on the part of management in their application. In addition, all of our significant accounting policies, including the critical accounting policies and estimates, are summarized in Note 2 to the accompanying consolidated financial statements.

*Results of operations.* This section provides an analysis of our results of operations presented in the accompanying consolidated statements of operations by comparing the results for the year ended December 31, 2011 to the results for the year ended December 31, 2010 and comparing the results for the year ended December 31, 2010 to the results for the year ended December 31, 2009.

*Liquidity and capital resources.* This section provides an analysis of our cash flows and a discussion of our outstanding commitments and contingencies that existed as of December 31, 2011. Included in this discussion is our financial capacity to fund our future commitments and a discussion of other financing arrangements.

#### **Overview**

We are a biotechnology company focused on the development of small-molecule therapeutics for the treatment of serious diseases. We have the following product candidates in development, including:

**Lesinurad (RDEA594):** An inhibitor of the URAT1 kidney transporter for the treatment of gout;

**RDEA3170:** Next generation URAT1 kidney transporter inhibitors for the treatment of gout; and

**BAY 86-9766 (RDEA119):** A MEK inhibitor for the treatment of cancer.

#### **Revenue**

To date, our revenue has come from upfront license fees, milestones, research and development funding, including reimbursable research and development costs and sponsored research, in connection with collaboration arrangements.

We anticipate that the majority of our revenues in the near future will be derived from research and development funding. We may receive additional milestone and other contingent event-based payments in the future upon the occurrence of certain events as set forth in our license agreement with Bayer.



***Research and Development Expense***

Research and development expenses primarily consist of costs associated with the development and clinical trials of our product candidates, salaries and share-based compensation for research and development personnel and facility costs.

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At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates and lead compounds from our research programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for commercialization. Other than costs for outsourced services associated with our clinical programs, we generally do not track our research and development expenses by project; rather, we track such expenses by the type of cost incurred. Due to these same factors, we are unable to determine the anticipated completion dates for our current research and development projects.

We expect our research and development expenses to increase significantly in 2012 due to the initiation of our Phase 3 development program for lesinurad in the fourth quarter of 2011. Our Phase 3 development program includes four Phase 3 studies and one Phase 4 study which are expected to include an aggregate of approximately 4,000 patients at sites around the world. The Phase 3 development program is much more robust than any of the earlier stage clinical studies we have initiated to date. The lengthy process of completing our clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing our clinical trials, or in obtaining regulatory approvals, could cause a delay in the commencement of product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations. We do not expect lesinurad, our lead product candidate, to be commercially available in major markets before 2014, if at all.

### ***General and Administrative Expense***

General and administrative expense primarily consists of salaries, share-based compensation and other related costs for personnel in executive, finance and accounting, business development, investor relations, information technology, legal and human resource functions. Other general and administrative costs include professional fees for legal, accounting and other general corporate purposes, and facility costs not otherwise included in research and development expense.

### ***Other Income (Expense)***

Other income (expense) primarily consists of the interest earned on our cash, cash equivalents and short-term investments available-for-sale, net of interest expense.

### **Recent Developments**

In February 2012, we completed an underwritten public offering of 9,775,000 shares of our common stock, including the full exercise of the over-allotment option granted to the underwriters, at a price to the public of \$17.00 per share. Net proceeds from the sale of the shares, before expenses and after deducting underwriter discounts and commissions, were approximately \$157.6 million.

On December 19, 2011, we announced the initiation of the first of four planned Phase 3 clinical trials in our development program for lesinurad. The lesinurad Phase 3 development program is expected to involve approximately 2,000 gout patients at sites around the world.

### **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 assumptions that we believe to be reasonable under the circumstances, the results of which

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form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following critical accounting policies involve significant judgments and estimates used in the preparation of our 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 by us.

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. In accordance with ASC Topic 605-25, *Revenue Recognition Multiple Element Arrangements*, 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.

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### **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 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.

### **New Accounting Pronouncements**

See Note 2 to the consolidated financial statements included in Item 15 of this Annual Report on Form 10-K.

## **Results of Operations**

### ***Years Ended December 31, 2011 and 2010***

#### **Revenues**

For the year ended December 31, 2011, revenues decreased to \$7.3 million from \$27.4 million for the same period in 2010. The decrease in revenues in 2011 as compared to 2010 was primarily due to the recognition in 2010 of the first \$15.0 million milestone payment under our license agreement with Bayer. In addition, the decrease was due to a decrease in license fee revenue recognized under our license agreement with Bayer to \$4.3 million in 2011 from \$8.1 million for the same period in 2010. The \$35.0 million upfront license fee was originally being recognized on a straight-line basis over a period of approximately 13 months, which was the original period in which we 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 modifications to our ongoing BAY 86-9766 (RDEA119) clinical trials, extending it to 38 months. The balance of the license fee as of the date of the change in estimate is being recognized over the revised timeline.

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

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Lesinurad and RDEA3170-related outsourced costs	\$ 47,245	\$ 28,468
BAY 86-9766 (RDEA119)-related outsourced costs*	2,436	4,499
Personnel and related costs	14,771	10,063
Share-based compensation expense	4,615	3,546
Facility-related costs	2,577	2,548
Other miscellaneous	2,781	2,986
<b>Total Research and Development Expense</b>	<b>\$ 74,425</b>	<b>\$ 52,110</b>

\* These amounts represent costs for the ongoing clinical trials of BAY 86-9766 (RDEA119) which are reimbursed by Bayer, under the terms of our 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 consolidated statement of operations.

For the year ended December 31, 2011, research and development expense increased to \$74.4 million from \$52.1 million for the same period in 2010. The increase in research and development expense for the year ended December 31, 2011 was primarily the result of an increase in development expenses due to the progression of lesinurad into Phase 3 clinical trials and the initiation of a Phase 1 study for RDEA3170, which resulted in increased spending of approximately \$18.8 million on clinical research organizations, investigator grants and consultants. In addition, the increase in research and development expense was due to an increase in personnel and related costs of approximately \$4.7 million mainly due to additional headcount and infrastructure to support the increased development activities noted above, as well as an increase in non-cash, share-based compensation expense of approximately \$1.1 million. 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 our license agreement with Bayer, after the completion of the ongoing clinical trials, all subsequent development efforts will be performed solely by Bayer.

**General and Administrative Expense**

For the year ended December 31, 2011, general and administrative expense increased to \$19.5 million from \$16.5 million for the same period in 2010. The increase in general and administrative expense was primarily a result of an increase in consulting and professional outside services and personnel and related costs of approximately \$3.9 million. These increases were partially offset by a net decrease in non-cash, share-based compensation expense of \$1.2 million mainly due to approximately \$3.8 million in non-recurring compensation expense recorded in 2010 as a result of the departure of certain employees, partially offset by an increase in share-based compensation in 2011 for existing personnel.

**Other Income (expense)**

For the year ended December 31, 2011, other income (expense) increased to \$0.1 million net other income from \$(0.5) million net other expense for the same period in 2010. The increase in net other income was primarily a result of a decrease in interest expense due to the continued amortization of our growth capital loan, tenant improvements loan and capital lease obligations entered into in the second half of 2008.

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### Years Ended December 31, 2010 and 2009

#### Revenues

For the year ended December 31, 2010, revenues increased to \$27.4 million from \$22.9 million for the year ended December 31, 2009. The increase in revenues in 2010 as compared to 2009 was primarily due to the recognition in 2010 of the first \$15.0 million milestone payment under our license agreement with Bayer. In addition, the increase was due to an increase in reimbursable research and development costs associated with the continued progression of the ongoing clinical trials of BAY 86-9766 (RDEA119). These increases were partially offset by a decrease in license fee revenue recognized under our license agreement with Bayer to \$8.1 million in 2010 from \$20.4 million for the same period in 2009. The \$35.0 million upfront license fee was originally being recognized on a straight-line basis over a period of approximately 13 months, which was the original period in which we 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 modifications to our ongoing BAY 86-9766 (RDEA119) clinical trials, extending it to 38 months. The balance of the license fee as of the date of the change in estimate is being recognized over the revised timeline.

#### Research and Development Expense

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

	December 31,	
	2010	2009
Lesinurad and RDEA3170-related outsourced costs	\$ 28,468	\$ 16,989
BAY 86-9766 (RDEA119)-related outsourced costs*	4,499	4,330
HIV related outsourced costs		4,201
Personnel and related costs	10,063	9,285
Share-based compensation expense	3,546	2,386
Facility-related costs	2,548	2,524
Other miscellaneous	2,986	2,483
Total Research and Development Expense	\$ 52,110	\$ 42,198

\* These amounts represent costs for the ongoing clinical trials of BAY 86-9766 (RDEA119). Beginning in May 2009, these costs were reimbursed by Bayer, under the terms of our 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 consolidated statement of operations.

For the year ended December 31, 2010, research and development expense increased to \$52.1 million from \$42.2 million for the same period in 2009. The increase in research and development expense for the year ended December 31, 2010 was primarily due to the continued development and progression of lesinurad and RDEA3170, resulting mainly from increased spending of approximately \$11.5 million on clinical research organizations, investigator grants and consultants. In addition, the increase in research and development expense was due to an increase in non-cash, share-based compensation expense of approximately \$1.2 million resulting primarily from the termination of certain employees during the third quarter of 2010. These increases were partially offset by a decrease in research and development expense for the HIV program, as further development of this program was discontinued in 2010.

#### General and Administrative Expense

For the year ended December 31, 2010, general and administrative expense increased to \$16.5 million from \$10.7 million for the same period in 2009. The increase in general and administrative expense was primarily a

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result of an increase in non-cash, share-based compensation expense of approximately \$3.8 million mainly due to the departure of certain employees during the third quarter of 2010. General and administrative expense also increased as a result of an increase in personnel and related costs and consulting and professional outside services of approximately \$1.5 million.

### **Other Income (expense)**

For the year ended December 31, 2010, other income (expense) decreased to \$(0.5) million net other expense from \$(0.9) million net other expense for the same period in 2009. The decrease in other expense was primarily a result of a decrease in interest expense due to the continued amortization our growth capital loan, tenant improvements loan and capital lease obligations entered into in the second half of 2008.

## **Liquidity and Capital Resources**

From inception of the Company through December 31, 2011, we have incurred a cumulative net loss of approximately \$475.7 million, of which \$239.5 million was incurred subsequent to the closing of the asset acquisition from Valeant and the commencement of operating activities as Ardea Biosciences, Inc. 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 2012, we completed an underwritten public offering of 9,775,000 shares of our common stock, including the full exercise of the overallotment option granted to the underwriters, at a price to the public of \$17.00 per share. Net proceeds from the sale of shares, before expenses and after deducting underwriting discounts and commissions, were approximately \$157.6 million.

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 to the public 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 underwriter 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 to the public 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 underwriter discounts and commissions and offering expenses.

In April 2009, we entered into a 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. 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.

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As of December 31, 2011, we had approximately \$96.0 million in cash, cash equivalents, and short-term investments, and \$1.4 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 primarily due 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. 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.

The following table summarizes our contractual obligations as of December 31, 2011. Long-term debt and capital lease obligations include interest.

	Total	Payment due by period			More than 5 years
		Less than 1 year	1-3 years (In thousands)	3-5 years	
Long-term debt obligations	\$ 154	\$ 45	\$ 90	\$ 19	\$
Operating lease obligations	3,579	1,126	2,253	200	
Capital lease obligations	226	65	129	32	
Purchase Obligations	4,217	4,217			
<b>Total</b>	<b>\$ 8,176</b>	<b>\$ 5,453</b>	<b>\$ 2,472</b>	<b>\$ 251</b>	<b>\$</b>

\* The table above does not include up to \$41 million of potential future contingent event-based payments under the asset purchase agreement with Valeant. Due to the contingent nature of these payments, we are unable to estimate with certainty the amount and timing of future payments under the Valeant agreement. We intend to use our current financial resources to fund our obligations, if any, under the Valeant agreement.

At December 31, 2011, purchase obligations primarily consisted of commitments with third-party manufacturers of materials to be used in our clinical and preclinical studies, as well as commitments with various vendors for preclinical studies. Approximately \$2.9 million of the total purchase obligations were not included in our consolidated financial statements for the year ended December 31, 2011. We intend to use our current financial resources to fund our commitments under these purchase obligations.



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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, including the funds received from our recent public offering, 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 7A. *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 December 31, 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.

### **ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.***

The financial statements and supplementary data required by this item are incorporated by reference in Item 15 of Part IV of this annual report on Form 10-K.

### **ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.***

None.

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**ITEM 9A. CONTROLS AND PROCEDURES.**

*(a) Disclosure Controls and Procedures; Changes in Internal Control Over Financial Reporting*

Our management, with the participation of our principal executive and principal financial and accounting officers, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act )) as of December 31, 2011. Based on this evaluation, our principal executive and principal financial and accounting officers concluded that our disclosure controls and procedures were effective as of December 31, 2011.

There was no change in our internal control over financial reporting during the quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

*(b) Management Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework.

Based on our assessment, management concluded that, as of December 31, 2011, our internal control over financial reporting was effective based on those criteria.

The independent registered public accounting firm that audited the consolidated financial statements that are included in this Annual Report on Form 10-K has issued an audit report on our internal control over financial reporting. The report appears below.

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*(c) Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting*

To the Board of Directors and Stockholders of

Ardea Biosciences, Inc.

We have audited Ardea Biosciences, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

In our opinion, Ardea Biosciences, Inc. maintained, in all material aspects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet as of December 31, 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended of Ardea Biosciences, Inc. and our report dated March 9, 2012 expressed an unqualified opinion.

/s/ Marcum LLP

Irvine, California

March 9, 2012

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**ITEM 9B. *OTHER INFORMATION.***

None.

**PART III**

**ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.***

Information required by this item will be contained in our Definitive Proxy Statement for our 2012 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2011. Such information is incorporated herein by reference.

We have adopted a code of conduct that applies to our Principal Executive Officer, Principal Financial and Accounting Officer, and to all of our other officers, directors and employees. The code of conduct is available at the Corporate Governance section of the Investor Center page on our website at [www.ardeabio.com](http://www.ardeabio.com). We intend to disclose future waivers or material amendments to certain provisions of our code of conduct on the above website within four business days following the date of such waiver or amendment.

**ITEM 11. *EXECUTIVE COMPENSATION.***

Information required by this item will be contained in our Definitive Proxy Statement for our 2012 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2011. Such information is incorporated herein by reference.

**ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.***

Information required by this item will be contained in our Definitive Proxy Statement for our 2012 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2011. Such information is incorporated herein by reference.

**ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.***

Information required by this item will be contained in our Definitive Proxy Statement for our 2012 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2011. Such information is incorporated herein by reference.

**ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES.***

Information required by this item will be contained in our Definitive Proxy Statement for our 2012 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2011. Such information is incorporated herein by reference.

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**PART IV**

**ITEM 15. *EXHIBITS, FINANCIAL STATEMENT SCHEDULES.***

(a) Documents filed as part of this report.

1. The following consolidated financial statements of Ardea Biosciences, Inc. are filed as part of this report under Item 8 Financial Statements and Supplementary Data:

<u>Report of Independent Registered Public Accounting Firm (Marcum LLP)</u>	F-1
<u>Report of Independent Registered Public Accounting Firm (Stonefield Josephson, Inc.)</u>	F-2
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Stockholders' Equity</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

2. Financial Statement Schedules.

These schedules are omitted because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

3. Exhibits.

The exhibit index attached to this report is incorporated by reference herein.

<b>Exhibit</b>	<b>Document Description</b>
2.1	Asset Purchase Agreement with Valeant Research & Development and Valeant Pharmaceuticals International dated December 21, 2006(1)
3.1	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(11)
4.4	Form of Warrant issued by the Company pursuant to the Securities Purchase Agreement dated December 17, 2008(6)
4.5	Registration Rights Agreement, dated December 17, 2008, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto(7)

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10.1	Form of Indemnity Agreement(8)
10.2*	Senior Executive Severance Benefit Plan, as amended and restated on November 7, 2008(11)
10.3*	Executive Severance Benefit Plan, as amended and restated on November 7, 2008(11)
10.4*	2002 Non-Officer Equity Incentive Plan and related documents, as amended on February 3, 2003(9)

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<b>Exhibit</b>	<b>Document Description</b>
10.5	Noncompetition Agreement with Valeant Research & Development dated December 21, 2006(1)
10.6*	Amended and Restated Executive Employment Agreement, effective November 7, 2008, between the Company and Barry Quart(11)
10.7*	Executive Employment Agreement, effective December 21, 2006, between the Company and Kimberly J. Manhard(1)
10.8*	Ardea Biosciences, Inc. 2000 Employee Stock Purchase Plan(20)
10.9*	Executive Employment Agreement, effective March 22, 2007, between the Company and Christopher W. Krueger(10)
10.10*	Amended and Restated 2004 Stock Incentive Plan(17)
10.11	Securities Purchase Agreement, dated December 19, 2007, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto(4)
10.12	Sublease by and between Verenium Corporation and the Company dated October 2007(12)
10.13*	Executive Employment Agreement, effective as of May 27, 2008, between the Company and John W. Beck(13)
10.14	Loan and Security Agreement, dated November 12, 2008, by and among Ardea Biosciences, Inc. and Oxford Finance Corporation and Silicon Valley Bank(11)
10.15	Securities Purchase Agreement, dated December 17, 2008, by and among Ardea Biosciences, Inc. and the Purchasers listed on the signature pages thereto(7)
10.16	Development and Commercialization License Agreement, dated April 27, 2009, by and among Ardea Biosciences, Inc. and Bayer HealthCare AG(14)
10.17*	Executive Employment Agreement, effective April 6, 2010, between the Company and Stephen R. Davis(15)
10.18*	Form of Stock Issuance Agreement Under 2004 Stock Incentive Plan(16)
10.19*	Executive Employment Agreement, effective February 28, 2011, between the Company and David T. Hagerty(18)
10.20*	Summary Description of Ardea Biosciences, Inc. 2011 Executive Bonus Plan(19)
23.1	Consent of Independent Registered Public Accounting Firm (Marcum LLP)
23.2	Consent of Independent Registered Public Accounting Firm (Stonefield Josephson, Inc.)
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.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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\* Management contract or compensatory plan, contract or arrangement.

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

- (1) Incorporated by reference to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on December 28, 2006.
- (2) Incorporated by reference to our Form 10-Q (File No. 001-33734) filed with the Securities and Exchange Commission on November 13, 2008.
- (3) Incorporated by reference to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on August 2, 2007.
- (4) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 20, 2007.
- (5) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on January 10, 2008.
- (6) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 19, 2008.
- (7) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on December 22, 2008.
- (8) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-95461) initially filed with the Securities and Exchange Commission on January 27, 2000 as subsequently amended.
- (9) Incorporated by reference to our Form 10-K (File No. 000-29993) filed with the Securities and Exchange Commission on March 31, 2003.
- (10) Incorporated by reference to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on May 8, 2007.
- (11) Incorporated by reference to our Form 10-K (File No. 001-33734) filed with the Securities and Exchange Commission on March 13, 2009.
- (12) Incorporated by reference to our Form 10-K (File No. 001-33734) filed with the Securities and Exchange Commission on March 24, 2008.
- (13) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on May 13, 2008.



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- (14) Incorporated by reference to our Form 10-Q (File No. 001-33734) filed with the Securities and Exchange Commission on August 7, 2009.
- (15) Incorporated by reference to our Form 10-Q (File No. 001-33734) filed with the Securities and Exchange Commission on August 6, 2010.
- (16) Incorporated by reference to our Form 10-Q (File No. 001-33734) filed with the Securities and Exchange Commission on November 9, 2010.
- (17) Incorporated by reference to our Form 10-K (File No. 001-33734) filed with the Securities and Exchange Commission on March 12, 2010.
- (18) Incorporated by reference to our Form 10-Q (File No. 001-33734) filed with the Securities and Exchange Commission on May 9, 2011.
- (19) Incorporated by reference to our Form 8-K (File No. 001-33734) filed with the Securities and Exchange Commission on May 25, 2011.
- (20) Incorporated by reference to our Form 10-K (File No. 001-33734) filed with the Securities and Exchange Commission on March 11, 2011.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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.

BY: /s/ BARRY D. QUART

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ BARRY D. QUART	President and Chief Executive Officer	March 9, 2012
Barry D. Quart, Pharm. D.	<i>(Principal Executive Officer)</i>	
/s/ JOHN W. BECK	Senior Vice President, Finance and Operations and Chief Financial Officer	March 9, 2012
John W. Beck	<i>(Principal Financial and Accounting Officer)</i>	
/s/ FELIX J. BAKER	Director	March 9, 2012
Felix J. Baker, Ph.D.		
/s/ WENDY L. DIXON	Director	March 9, 2012
Wendy L. Dixon, Ph.D.		
/s/ HENRY J. FUCHS	Director	March 9, 2012
Henry J. Fuchs, M.D.		
/s/ CRAIG A. JOHNSON	Director	March 9, 2012
Craig A. Johnson		
/s/ JOHN W. POYHONEN	Director	March 9, 2012
John W. Poyhonen		

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/s/ KEVIN C. TANG

Director

March 9, 2012

Kevin C. Tang

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Ardea Biosciences, Inc.

We have audited the accompanying consolidated balance sheets of Ardea Biosciences, Inc. (the Company) as of December 31, 2011 and December 31, 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2011. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Ardea Biosciences, Inc. as of December 31, 2011, and the consolidated results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 9, 2012 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Marcum LLP

Irvine, California

March 9, 2012

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Ardea Biosciences, Inc.

We have audited the consolidated statements of operations, stockholders' equity, and cash flows of Ardea Biosciences, Inc. for the year ended December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Ardea Biosciences, Inc. as of December 31, 2009, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ STONEFIELD JOSEPHSON, INC.

Irvine, California

March 11, 2010

**Table of Contents****ARDEA BIOSCIENCES, INC.****CONSOLIDATED BALANCE SHEETS**

	December 31, 2011 (In thousands, except per share and par value amounts)	December 31, 2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,440	\$ 15,926
Short-term investments, available-for-sale	91,556	64,686
Receivables	1,398	16,959
Prepays and other current assets	2,704	518
Total current assets	100,098	98,089
Property and equipment, net	2,766	2,007
Other assets	1,365	358
Total assets	\$ 104,229	\$ 100,454
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,837	\$ 3,073
Accrued clinical liabilities	8,807	5,681
Accrued payroll and employee liabilities	3,113	2,802
Other accrued liabilities	2,554	1,550
Current portion of deferred revenue	2,153	4,306
Current portion of obligations under capital lease	37	97
Current portion of obligations under notes payable	37	3,213
Total current liabilities	21,538	20,722
Deferred rent	215	205
Non-current portion of deferred revenue		2,153
Non-current portion of obligations under capital lease	129	114
Non-current portion of obligations under notes payable	100	137
Commitments and contingencies (see Note 5)		
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value: 5,000,000 shares authorized; no shares outstanding at December 31, 2011 and 2010		
Common stock, \$0.001 par value: 70,000,000 shares authorized; 26,913,223 and 23,366,979 shares issued and outstanding at December 31, 2011 and 2010, respectively	27	23
Additional paid-in capital	557,927	466,110
Accumulated other comprehensive income	13	31
Accumulated deficit	(475,720)	(389,041)
Total stockholders' equity	82,247	77,123
Total liabilities and stockholders' equity	\$ 104,229	\$ 100,454

See accompanying notes.



**Table of Contents****ARDEA BIOSCIENCES, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2011	2010	2009
	(In thousands, except per share amounts)		
Revenues:			
Milestones	\$	\$ 15,000	\$
License fees	4,306	8,100	20,442
Sponsored research	391	358	
Reimbursable research and development costs	2,608	3,961	2,494
Total revenues	7,305	27,419	22,936
Operating expenses:			
Research and development	74,425	52,110	42,198
General and administrative	19,539	16,452	10,689
Total operating expenses	93,964	68,562	52,887
Loss from operations	(86,659)	(41,143)	(29,951)
Other income (expense)			
Interest income	383	364	386
Interest expense	(314)	(866)	(1,323)
Other income, net	9	14	21
Total other income (expense)	78	(488)	(916)
Net loss	\$ (86,581)	\$ (41,631)	\$ (30,867)
Basic and diluted net loss per share	\$ (3.26)	\$ (1.91)	\$ (1.70)
Shares used in computing basic and diluted net loss per share	26,543	21,823	18,158

See accompanying notes.



**Table of Contents****ARDEA BIOSCIENCES, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Accumulated Deficit	Total Stockholders Equity
	Shares	Amount					
<b>Balances at December 31, 2008</b>	17,836	\$ 17	\$ 362,345	\$ 139		\$ (316,543)	\$ 45,958
Issuance of common stock under Employee Stock Purchase Plan	62		490				490
Issuance of common stock upon exercise of stock options	595	1	3,477				3,478
Issuance of common stock upon exercise of warrants	12						
Share-based compensation expense			5,779				5,779
Comprehensive loss:							
Net loss						(30,867)	(30,867)
Unrealized loss on securities				(97)			(97)
Comprehensive loss							(30,964)
<b>Balances at December 31, 2009</b>	18,505	\$ 18	\$ 372,091	\$ 42		\$ (347,410)	\$ 24,741
Issuance of common stock in a public offering, net	4,025	4	76,810				76,814
Issuance of common stock under Employee Stock Purchase Plan	54		558				558
Issuance of common stock upon exercise of stock options	739	1	5,890				5,891
Issuance of common stock upon exercise of warrants	19						
Issuance of restricted stock	25						
Share-based compensation expense			10,761				10,761
Comprehensive loss:							
Net loss						(41,631)	(41,631)
Unrealized loss on securities				(11)			(11)
Comprehensive loss							(41,642)
<b>Balances at December 31, 2010</b>	23,367	\$ 23	\$ 466,110	\$ 31		\$ (389,041)	\$ 77,123
Issuance of common stock in a public offering, net	3,163	3	78,059				78,062
Issuance of common stock under Employee Stock Purchase Plan	53		737				737
Issuance of common stock upon exercise of stock options	303	1	2,437				2,438
Issuance of common stock upon exercise of warrants	31						
Restricted stock shares traded for taxes	(4)					(98)	(98)
Share-based compensation expense			10,584				10,584
Comprehensive loss:							
Net loss						(86,581)	(86,581)
Unrealized loss on securities				(18)			(18)
Comprehensive loss							(86,599)

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<b>Balances at December 31, 2011</b>	26,913	\$	27	\$	557,927	\$	13	\$	(475,720)	\$	82,247
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See accompanying notes.

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**Table of Contents****ARDEA BIOSCIENCES, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	2011	Year Ended December 31, 2010 (In thousands)	2009
<b>Operating activities:</b>			
Net loss	\$ (86,581)	\$ (41,631)	\$ (30,867)
Adjustments to reconcile net loss to net cash used for operating activities:			
Share-based compensation	10,584	10,761	5,779
Depreciation and amortization	741	599	668
Amortization of debt discount and debt issuance costs	96	282	429
(Gain) loss on disposal of property and equipment	(1)	22	17
Deferred rent	10	45	76
Amortization of premium on short-term investments	990	942	356
Realized gain on short-term investments	(15)	(23)	(24)
Change in operating assets and liabilities:			
Receivables	15,561	(15,526)	(1,049)
Prepays and other current assets	(2,186)	(303)	22
Other assets	(1,065)	36	(24)
Accounts payable	1,764	1,157	(344)
Accrued clinical liabilities	3,126	1,609	1,794
Accrued payroll and employee liabilities	311	664	380
Other accrued liabilities	1,004	381	224
Deferred revenue	(4,306)	(8,100)	14,559
Net cash used for operating activities	(59,967)	(49,085)	(8,004)
<b>Investing activities:</b>			
Purchases of short-term investments	(205,797)	(109,625)	(56,632)
Proceeds from sale or maturity of short-term investments	177,934	83,338	33,066
Proceeds from sale of property and equipment	12	40	10
Purchases of property and equipment	(1,458)	(563)	(346)
Net cash used for investing activities	(29,309)	(26,810)	(23,902)
<b>Financing activities:</b>			
Payments on capital lease and note payable obligations	(3,349)	(3,004)	(2,051)
Net proceeds from issuance of common stock	81,139	83,263	3,968
Net cash provided by financing activities	77,790	80,259	1,917
Net (decrease) increase in cash and cash equivalents	(11,486)	4,364	(29,989)
Cash and cash equivalents at beginning of year	15,926	11,562	41,551
Cash and cash equivalents at end of year	\$ 4,440	\$ 15,926	\$ 11,562
<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	\$ 650	\$ 610	\$ 912
<b>Supplemental schedule of non-cash information:</b>			
Capital lease obligations incurred for property and equipment	\$ 53	\$ 144	\$
Net unrealized loss on short-term investments	\$ (18)	\$ (11)	\$ (97)

See accompanying notes.

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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Business**

Ardea Biosciences, Inc. (the Company), of San Diego, California, is a biotechnology company focused on the development of small-molecule therapeutics for the treatment of serious diseases.

**2. Summary of Significant Accounting Policies**

***Principles of Consolidation***

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

***Use of Estimates***

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosures made in the accompanying notes to the 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.

***Cash, Cash Equivalents and Short-Term Investments***

Cash and cash equivalents consist of cash and highly liquid investments with original maturities from purchase date of three months or less.

Short-term investments consist of securities with maturities from purchase date of greater than three months. The Company has classified its short-term investments as available-for-sale securities in the accompanying consolidated financial statements. Available-for-sale securities are stated at fair market value, with unrealized gains and losses reported in other comprehensive income (loss) and realized gains and losses included in interest income. The cost of securities sold is based on the specific-identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

***Fair Value of Financial Instruments***

Financial instruments, including cash and cash equivalents, receivables, prepaid expenses, other current assets, accounts payable and accrued expenses, are carried at cost, which is considered to be representative of their respective fair values because of the short-term maturity of these instruments. Short-term available-for-sale investments are carried at fair value. None of the Company's debt or capital lease instruments that were outstanding at December 31, 2011 have readily available ascertainable market values, however, the carrying values are considered to approximate their fair values. See footnote 3 for further details regarding the fair value of financial instruments.

***Concentration of Credit Risk***

Cash, cash equivalents and short-term investments are financial instruments which potentially subject the Company to concentrations of credit risk. The Company deposits its cash in financial institutions. At times, such deposits may be in excess of insured limits. The Company invests its excess cash primarily in United States

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### **ARDEA BIOSCIENCES, INC.**

#### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

government and agency obligations, United States corporate debt and money market funds. The Company has established guidelines relative to the diversification of its cash investments and their maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

#### ***Property and Equipment***

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets (primarily five years). Leasehold improvements are stated at cost and amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term.

#### ***Impairment of Long-Lived Assets***

If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and records the impairment as a reduction in the carrying value of the related asset with a corresponding charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from actual results.

#### ***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.

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.

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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

***Research and Development Expenses***

All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, share-based compensation, fees paid to outside service providers and consultants, facilities costs, travel costs, dues and subscriptions, depreciation and materials used in the clinical and preclinical trials and research and development. The Company reviews and accrues clinical costs based on work performed, which relies on estimates of the progress of the trials and the related expenses incurred. Clinical trial-related contracts vary significantly in length, and may be for a fixed amount, based on milestones or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development costs, however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

***Patent Costs***

The Company incurs fees of outside legal counsel in connection with filing and maintaining its various patent applications. All patent costs are expensed as incurred and included in general and administrative expense in the consolidated statement of operations.

***Share-Based Compensation Expense***

The Company estimates the fair value of share-based payment awards using the Black-Scholes-Merton, or Black-Scholes, option valuation model. This fair value is then amortized using the straight-line single-option method of attributing the value of share-based compensation to expense over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of highly complex and subjective assumptions, including each option's expected life and price volatility of the underlying stock. Expected volatility is based on the Company's historical stock price volatility.

**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

***Valuation and Expense Information***

The following table summarizes share-based compensation expense (in thousands) related to employee and director stock options, restricted stock and ESPP purchases for the years ended December 31, 2011, 2010 and 2009:

	2011	December 31, 2010	2009
Research and development	\$ 4,615	\$ 3,546	\$ 2,386
General and administrative	5,969	7,215	3,393
Share-based compensation expense included in operating expenses	\$ 10,584	\$ 10,761	\$ 5,779

As of December 31, 2011, there was \$25,363,000 of total unrecognized compensation cost related to non-vested, share-based payment awards granted under all of the Company's equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize this compensation cost over a weighted-average period of 2.9 years.

For the years ended December 31, 2011, 2010, and 2009, the Company estimated the fair value of each option grant and ESPP purchase right on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

***Options:***

	2011	December 31, 2010	2009
Risk-free interest rate	1.6%	2.1%	2.5%
Dividend yield	%	%	%
Volatility	71.8%	76.4%	77.1%
Expected life (years)	5.5-6.1	5.5-6.1	5.5-6.1

***ESPP:***

	2011	December 31, 2010	2009
Risk-free interest rate	0.2%	0.3%	0.6%
Dividend yield	%	%	%
Volatility	50.8%	52.3%	83.0%
Expected life (years)	1.20	1.16	1.24

The weighted-average fair values of options granted were \$13.35, \$14.81 and \$9.60 for the years ended December 31, 2011, 2010 and 2009, respectively. The weighted-average purchase price of shares purchased through the ESPP was \$13.84, \$10.37 and \$7.90 for the years ended December 31, 2011, 2010 and 2009, respectively.



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**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The risk-free interest rate assumption is based on observed interest rates on United States Treasury debt securities with maturities close to the expected term of the Company's employee and director stock options and ESPP purchases.

The dividend yield assumption is based on the Company's history and expectation of dividend payouts. The Company has never paid dividends on its common stock and the Company does not anticipate paying dividends in the foreseeable future.

The Company uses its historical stock price to estimate volatility.

The expected life of employee and non-employee director stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. The Company has elected to use the simplified method, as the Company does not have enough historical exercise experience to provide a reasonable basis upon which to estimate the expected term and the stock option grants are considered plain vanilla options.

***Warrants***

The Company issued warrants to purchase shares of its common stock in conjunction with its Growth Capital Loan and December 2008 equity fundraising. The terms of the warrants were evaluated to determine the appropriate classification as equity or a liability. As of December 31, 2011, all warrants issued are classified as equity.

***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 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 years ended December 31, 2011, 2010 and 2009, the number of outstanding stock options, unvested common shares subject to repurchase and warrants not included in the computation totaled 5,211,409, 4,241,016 and 4,111,133, respectively.

***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):

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Net loss	\$ (86,581)	\$ (41,631)	\$ (30,867)
Net unrealized losses on short-term investments	(18)	(11)	(97)
Comprehensive net loss	\$ (86,599)	\$ (41,642)	\$ (30,964)

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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Income Taxes***

On January 1, 2007, the Company adopted the provisions of ASC 740, Accounting for Uncertainty in *Income Taxes*, which clarifies the accounting for uncertain tax positions. This provision requires that the Company recognize the impact of a tax position in its financial statements if the position is more likely than not to be sustained upon examination and on the technical merits of the position. The impact of the adoption of this provision was immaterial to the Company's consolidated financial statements. The total amount of unrecognized tax benefits as of December 31, 2011 was \$2,728,000 which, if recognized, would affect other tax accounts, primarily deferred taxes in future periods, and would not affect the Company's effective tax rate since the Company maintains a full valuation allowance against its deferred tax assets.

***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. In addition, in December 2011, FASB issued ASU No. 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU 2011-05* (ASU 2011-12), which defers the requirement in ASU 2011-05 that companies present reclassification adjustments for each component of accumulated other comprehensive income. ASUs 2011-05 and 2011-12 are 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 and ASU 2011-12 in the first quarter of 2012. The Company does not expect the adoption of these ASUs 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

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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

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.

**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	Fair Value Measurements at Reporting Date Using Quoted Prices in			
	Balance at December 31, 2011	Active Markets for Identical Assets (Level 1)*	Significant Other Observable Inputs (Level 2)*	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 3,198	\$ 3,198	\$	\$
United States government and agency obligations	37,149		37,149	
United States corporate debt securities	32,918		32,918	
United States commercial paper	9,996		9,996	
Foreign commercial paper	8,495		8,495	
United States certificate of deposit	2,998		2,998	
Total	\$ 94,754	\$ 3,198	\$ 91,556	\$

	Fair Value Measurements at Reporting Date Using Quoted Prices in			
	Balance at December 31, 2010	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	\$	\$
United States government and agency obligations	51,431	4,998	46,433	
United States corporate debt securities	8,257		8,257	
United States 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 years ended December 31, 2011 and 2010.

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.

**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company considers the carrying amount of cash and cash equivalents, receivables, prepaid expenses and other current assets, 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 value 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 years ended December 31, 2011, 2010 and 2009, the Company recognized approximately \$18,000, \$11,000 and \$97,000 in net unrealized losses, respectively, associated with 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 years ended December 31, 2011, 2010 and 2009, the Company recognized approximately \$15,000, \$23,000 and \$24,000 in net realized gains, respectively, associated with its short-term investments.

**4. Balance Sheet Details*****Short-Term Investments***

The following is a summary of the Company's short-term, available-for-sale securities (in thousands):

	<b>December 31, 2011</b>			<b>Estimated Fair Value</b>
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	
United States Government agency obligations	\$ 37,136	\$ 13	\$	\$ 37,149
United States corporate debt	32,919	10	(11)	32,918
United States commercial paper	9,996			9,996
Foreign commercial paper	8,492	3		8,495
United States certificate of deposit	3,000		(2)	2,998
Total	\$ 91,543	\$ 26	\$ (13)	\$ 91,556

	<b>December 31, 2010</b>			<b>Estimated Fair Value</b>
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	
United States Government agency obligations	\$ 49,401	\$ 32	\$ (1)	\$ 49,432
United States corporate debt	4,458			4,458
United States commercial paper	5,497			5,497
Foreign commercial paper	5,299			5,299
Total	\$ 64,655	\$ 32	\$ (1)	\$ 64,686

As of December 31, 2011, the Company's short-term investments consisted of approximately \$51,668,000 of available-for-sale securities with contractual maturities of one year or less and approximately \$39,888,000 with contractual maturities not to exceed 15 months.



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The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The Company regularly monitors and evaluates the realizable value of its marketable securities. The Company did not recognize any impairment losses for the years ended December 31, 2011 and 2010.

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**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Receivables***

Receivables consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Amounts due under collaboration arrangements for milestones	\$	\$ 15,000
Amounts due for reimbursable research and development costs	833	1,196
Amounts due for sponsored research	169	358
Interest on short-term investments	249	367
Vendor refunds	40	
Other	107	38
<b>Total Receivables</b>	<b>\$ 1,398</b>	<b>\$ 16,959</b>

***Property and Equipment***

Property and equipment is comprised of the following (in thousands):

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Laboratory equipment	\$ 2,119	\$ 1,595
Computer equipment and software	1,529	1,016
Furniture and fixtures	506	335
Leasehold improvements	1,252	976
	5,406	3,922
Less: accumulated depreciation and amortization	(2,640)	(1,915)
	<b>\$ 2,766</b>	<b>\$ 2,007</b>

Depreciation and amortization expense, which includes equipment under a capital lease, for the years ended December 31, 2011, 2010 and 2009 was approximately \$741,000, \$599,000 and \$668,000, respectively. Equipment acquired under capital leases included in property and equipment totaled approximately \$264,000 (net of accumulated amortization of \$285,000) and \$312,000 (net of accumulated amortization of \$184,000) at December 31, 2011 and 2010, respectively. Amortization expense associated with this equipment is included in depreciation expense for the years ended December 31, 2011, 2010 and 2009.

***Accrued Payroll and Employee Liabilities and Other Accrued Liabilities***

Accrued payroll and employee liabilities and other accrued liabilities consisted of the following (in thousands):

**December 31,**

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	2011	2010
Accrued employee salaries and benefits	\$ 1,210	\$ 1,499
Accrued bonuses	1,903	1,303
Total Accrued Payroll and Employee Liabilities	\$ 3,113	\$ 2,802

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**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Accrued professional fees	\$ 1,235	\$ 441
Accrued legal fees	222	242
Accrued accounts payable	1,069	359
Accrued interest	1	433
Other accrued liabilities	27	75
 Total Other Accrued Liabilities	 \$ 2,554	 \$ 1,550

**5. Commitments and Contingencies****Leases**

In October 2007, the Company entered into a non-cancelable operating lease for the sub-lease of a facility in San Diego, California covering a total of approximately 52,000 square feet. The facility includes the Company's research and development laboratories and its corporate offices and warehouse. The building sub-lease commenced on March 1, 2008 and expires in February 2015. The Company has one option to extend the term of the sub-lease agreement until March 2017. The lease is subject to an escalation clause that provides for annual rent increases. The difference between the straight-line expense over the term of the lease and actual amounts paid are recorded as deferred rent. Prior to March 2008, the Company leased its office and research facilities under a different operating lease.

In July 2008, the Company entered into a capital lease agreement for approximately \$318,000 to finance the purchase of certain equipment. The agreement was secured by the equipment, bore interest at 6.05% per annum, and was payable in monthly installments of principal and interest of approximately \$10,000 for 36 months beginning in August 2008. The capital lease was paid in full in the third quarter of 2011.

In September 2009, the Company entered into a non-cancellable operating lease for lab equipment. Under the terms of the lease agreement, it will make 36 monthly payments of approximately \$5,000 beginning in the fourth quarter of 2009.

Annual future minimum lease payments as of December 31, 2011 are as follows (in thousands):

	<b>Operating Leases</b>	<b>Capital Lease</b>
Years ended December 31,		
2012	\$ 1,126	\$ 65
2013	1,108	65
2014	1,145	64
2015	200	32
2016		
Thereafter		
 Total	 \$ 3,579	 226
 Less amount representing interest		 (60)
 Present value of net minimum lease payments		 166
Less current portion		(37)
 Noncurrent portion of capital lease obligation		 \$ 129

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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Rent expense under all operating leases totaled approximately \$1,212,000, \$1,168,000 and \$989,000 for the years ended December 31, 2011, 2010 and 2009, respectively.

***Notes Payable***

In March 2008, the Company exercised its right under its sub-lease agreement with its landlord to borrow \$250,000 for costs incurred and paid for tenant improvements. The note bears interest at 7.00% per annum and is payable in monthly installments of principal and interest of approximately \$4,000 for 84 months beginning in June 2008.

In November 2008, the Company entered into an agreement with two lenders, pursuant to which the lenders provided the Company with an approximately three-year, \$8,000,000 loan. Interest accrued at a rate of 12% per annum, with monthly interest only payments required during a period beginning on the loan funding date and continuing through February 28, 2009, followed thereafter by equal monthly payments of principal and interest over a period of 33 months. The loan was collateralized by the Company's general assets, excluding intellectual property. There were no financial covenants associated with the loan. The Company calculated an effective interest rate for this loan at approximately 18.57% per annum, which takes into account the debt issuance costs of approximately \$527,000 and the debt discount of approximately \$343,000 (see below for further details). As of December 31, 2011, the Company had repaid this loan in full and has no further obligations under the loan agreement.

In connection with this loan, the Company incurred debt issuance costs of approximately \$527,000, which consisted of commitment fees of \$480,000 and legal fees of approximately \$47,000. Of the total commitment fees incurred, \$80,000 was paid upon entering into the agreement and the remaining \$400,000 paid at the end of the term of the loan. The debt issuance costs were recorded as a deferred charge and classified as other assets on the Consolidated Balance Sheet and the loan was recorded and classified as current and non-current note payable obligations. The debt issuance costs were amortized as a component of interest expense over the term of the loan using the effective interest rate method and were fully amortized as of December 31, 2011. The aggregate unamortized debt issuance costs as of December 31, 2010 was approximately \$58,000.

Furthermore, in conjunction with this loan, the Company issued to the lenders warrants to purchase an aggregate of up to 56,010 shares of the Company's common stock at an exercise price of \$8.57 per share. The warrants met all of the criteria for classification as equity, including being indexed to the Company's common stock. The warrants were valued using the Black-Scholes model assuming a risk-free interest rate of 3.00%, a dividend yield of 0%, expected volatility of 77.04% and a contractual life of the warrants of seven years. The estimated fair value of the warrants was \$343,000 and was recorded as a debt discount. The debt discount was amortized as additional interest expense over the term of the loan using the effective interest rate method and was fully amortized as of December 31, 2011. The aggregate unamortized debt discount as of December 31, 2010 was approximately \$38,000.

**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following is a summary of the notes payable obligations as of December 31, 2011 (in thousands):

	<b>Notes Payable</b>
Years ended December 31,	
2012	\$ 45
2013	45
2014	45
2015	19
2016	
Thereafter	
Total	154
Less unamortized discount	
Less amount representing interest	(17)
Present value of net minimum notes payable payments	137
Less current portion	(37)
Noncurrent portion of notes payable	\$ 100

***Executive Severance Agreements***

The Company has entered into employment agreements with its executive officers and certain other key employees that, under certain cases, provide for the continuation of salary and certain other benefits if terminated under specified circumstances. These agreements generally expire upon voluntary termination by the executive officer or key employee, termination for cause or when the Company has met its obligations under these agreements. In the third quarter of 2010, the Company incurred expenses of approximately \$464,000 related to continuation of salary and other benefits under employment agreements due to the departure of certain employees. The Company made the final required payment under these agreements in October 2011.

***Clinical Development Agreements***

The Company has entered into agreements with various vendors for the research and development of its product candidates, which are generally cancellable at the option of the Company at any time. Under the terms of these agreements, the vendors provide a variety of services including conducting preclinical development, research, manufacturing clinical compounds, enrolling and recruiting patients, monitoring studies, data analysis and regulatory filing assistance. Payments under these agreements typically include fees for services and reimbursement of expenses. In addition, under certain agreements, we are subject to penalties in the event we permanently discontinue performance under these agreements.

***Purchase Obligations***

At December 31, 2011, purchase obligations of approximately \$4,217,000 primarily consisted of commitments with third-party manufacturers of materials to be used in our clinical and pre-clinical studies, as well as commitments with various vendors for preclinical studies. Approximately \$2,892,000 of the total purchase obligations were not included in the Company's consolidated financial statements for the year ended December 31, 2011. The Company intends to use its current financial resources to fund its commitments under these purchase obligations.

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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. Restructuring**

In May 2009, the Company committed to a restructuring plan (the "Restructuring Plan") which provided affected employees with severance payments upon termination, continued benefits for a specified period of time and outplacement assistance. The Company incurred total restructuring charges of approximately \$818,000, primarily for severance-related costs in connection with the Restructuring Plan. The Company did not incur any expense related to contractual or lease obligations or other exit costs. For the year ended December 31, 2009, approximately \$791,000 of the total restructuring charge was included in research and development expense and approximately \$27,000 was included in general and administrative expense. The Company made the final payment under the Restructuring Plan in April 2010.

**7. Valeant Transaction**

On December 21, 2006, the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") with Valeant Research and Development, Inc. ("Valeant"), pursuant to which the Company acquired intellectual property and other assets related to the non-nucleoside reverse transcriptase inhibitor HIV program ("RDEA806 program"), the next generation non-nucleoside reverse transcriptase inhibitor HIV program ("next generation NNRTI program"), the mitogen-activated ERK kinase program ("BAY 86-9766 (RDEA119) program") and the next generation mitogen-activated ERK kinase program ("next generation MEK inhibitor program").

Under the Asset Purchase Agreement, 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 potential future development- and regulatory-based contingent event-based payments under the Asset Purchase Agreement to \$41,000,000.

Concurrent with the Asset Purchase Agreement, the Company entered into a Master Services Agreement with Valeant under which the Company agreed to advance a preclinical program in the field of neuropharmacology on behalf of Valeant. Under the two-year agreement term, Valeant agreed to pay the Company quarterly payments totaling up to \$3,500,000 per year, and up to \$1,000,000 in milestone payments. The first milestone totaling \$500,000 was paid in August 2007. Due to the early achievement of this milestone, the Company's efforts under the agreement were reduced throughout 2008 and the agreement expired by its terms on December 21, 2008. Total revenues, including the milestone payment, amounted to \$3,095,000 for 2007, and \$304,000 for 2008.

**8. 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,



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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 are 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 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 years ended December 31, 2011, 2010 and 2009, the Company recognized revenue of approximately \$4,306,000, \$8,100,000 and \$20,442,000, respectively, as license fees in the 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 years ended December 31, 2011, 2010 and 2009, the Company recognized revenue of approximately \$2,608,000, \$3,961,000 and \$2,494,000, respectively, as reimbursable research and development costs in the consolidated statement of operations.

For the years ended December 31, 2011 and 2010, the Company recognized \$391,000 and \$358,000, respectively, as sponsored research in its consolidated statements of operations. The Company did not recognize any revenue for sponsored research for the year ended December 31, 2009.

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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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 years ended December 31, 2011, 2010 and 2009, the Company did not recognize any revenue from other contingent event-based 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.

**9. Stockholders' Equity**

***Preferred Stock***

As of December 31, 2011, the Company's Board of Directors is authorized to issue 5,000,000 shares of preferred stock with a par value of \$0.001 per share, in one or more series. As of December 31, 2011 there were no shares of preferred stock issued and outstanding.

***Common Stock***

In April 2010, the Company completed a public offering of 4,025,000 shares of its common stock, including 525,000 shares sold pursuant to the full exercise of an overallotment option granted to the underwriters, at a price to the public of \$20.00 per share. The net proceeds to the Company from the sale of shares in the offering, after expenses and underwriting discounts and commissions, were approximately \$76,814,000.

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 to the public 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.

**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Common Stock Reserved for Future Issuance**

Shares of Company common stock reserved for future issuance at December 31, 2011 were as follows:

Warrants	624,332
Stock Incentive plan	5,483,214
Employee stock purchase plan	117,911
Total shares reserved for future issuance	6,225,457

**Warrants**

On November 12, 2008, in conjunction with the \$8,000,000 loan, the Company issued to the lenders warrants to purchase an aggregate of 56,010 shares of its common stock at an exercise price of \$8.57 per share. The warrants were immediately exercisable and expire seven years from the date of issuance. As of December 31, 2011, all of the warrants had been exercised using the conversion right provision in the warrant agreement, which resulted in the net issuance of 11,862 and 19,166 shares of common stock, in September 2009 and July 2010, respectively, and no net cash proceeds to the Company.

In conjunction with the December 2008 private placement, the Company issued warrants to purchase an aggregate of 684,332 shares of its common stock at an exercise price of \$11.14 per share. The warrants were first exercisable on June 17, 2009 and expire on December 19, 2013. The warrants met all of the criteria for classification as equity, including being indexed to the Company's common stock. The warrants were valued using the Black-Scholes model assuming a risk-free interest rate of 1.35%, a dividend yield of 0%, expected volatility of 77.66% and a contractual life of the warrants of five years. The estimated fair value of the warrants was \$4,528,000. The net effect of recording the fair value of the warrants to equity was zero. As of December 31, 2011, 60,000 warrants had been exercised using the conversion right provision in the warrant agreement, which resulted in the net issuance of 30,939 shares of common stock in August 2011 and no net cash proceeds to the Company. The remaining warrants are outstanding and 624,332 shares of common stock have been reserved for issuance upon exercise of such warrants.

**Stock Option Plans**

In 2002, the Company adopted its 2002 Non-Officer Equity Incentive Plan (the "2002 Plan"), which provides for the grant of stock awards, stock bonuses and rights to acquire restricted common stock to employees who are not officers, to executive officers not previously employed by the Company as an inducement to entering into an employment relationship with the Company, and to consultants of the Company. These awards have up to a 10-year contractual life and are subject to various vesting periods, as determined by the Company's Compensation Committee or the Board of Directors.

In 2004, the Company adopted its 2004 Stock Incentive Plan (the "2004 Plan"), which provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to employees, directors, consultants and advisors of the Company. These awards have up to a 10-year contractual life and are subject to various vesting periods, as determined by the Company's Compensation Committee or the Board of Directors. The 2004 Plan also provides for automatic fixed grants to non-employee directors of the Company.

The number of shares of the Company's common stock available for issuance under the 2004 Plan automatically increases on the first trading day of January of each calendar year during the term of the 2004 Plan.

**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

beginning with calendar year 2005, by an amount equal to five percent of the sum of the following share numbers: (i) the total number of shares of the Company's common stock outstanding on the date and (ii) the number of shares of the Company's common stock into which the outstanding shares of Series A preferred stock are convertible on that date, not to exceed 2,000,000 shares in any given year. In accordance with the preceding formula, the shares available for issuance under the 2004 Plan were increased by 1,168,349 on January 3, 2011, by 925,245 on January 4, 2010 and by 891,787 on January 2, 2009. In addition, the shares available for issuance under the 2004 Plan increased by 1,345,661 shares on January 3, 2012.

A summary of the Company's stock option activity and related data follows:

	<b>Options Available for Grant</b>	<b>Number of Shares</b>	<b>Outstanding Options Weighted- Average Exercise Price</b>
Balance at December 31, 2008	480,580	3,676,089	\$ 9.54
Additional shares authorized	891,787		
Granted	(557,350)	557,350	\$ 14.19
Exercised		(595,168)	\$ 5.89
Cancelled	246,476	(246,476)	\$ 10.95
Balance at December 31, 2009	1,061,493	3,391,795	\$ 10.84
Additional shares authorized	925,245		
Granted	(986,920)	961,920	\$ 22.07
Exercised		(739,139)	\$ 7.97
Cancelled	76,385	(76,385)	\$ 12.70
Balance at December 31, 2010	1,076,203	3,538,191	\$ 14.46
Additional shares authorized	1,168,349		
Granted	(1,354,580)	1,354,580	\$ 20.83
Exercised		(303,361)	\$ 8.03
Cancelled	16,917	(16,917)	\$ 21.31
Shares traded for taxes	3,832		\$
Balance at December 31, 2011	910,721	4,572,493	\$ 16.75

For the year ended December 31, 2011, options cancelled (included in the above table) consisted of 15,420 options forfeited with a weighted-average exercise price of approximately \$21.10 and 1,497 options expired with a weighted-average exercise price of approximately \$23.54.

As of December 31, 2011, options exercisable have a weighted-average remaining contractual term of 6.2 years. The total intrinsic value of stock option exercises, which is the difference between the exercise price and closing price of the Company's common stock on the date of exercise, during the years ended December 31, 2011, 2010, and 2009 was approximately \$5,192,000, \$10,280,000 and \$6,218,000, respectively. As of December 31, 2011 the total intrinsic value of options outstanding and exercisable was approximately \$11,166,000 and \$9,742,000, respectively, which is the difference between the exercise price and closing price of the Company's common stock.

**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	2011		Years Ended December 31, 2010		2009	
	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price
Exercisable at end of year	2,268,893	\$ 13.26	1,768,985	\$ 10.89	1,559,117	\$ 9.85
Weighted-average fair value of options granted during the year	\$ 13.35		\$ 14.81		\$ 9.60	

Exercise prices and weighted-average remaining contractual lives for the options outstanding as of December 31, 2011 were:

Options Outstanding	Range of Exercise Prices	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price of Options Exercisable
457,950	\$ 2.76 - \$ 9.46	4.91	\$ 4.90	448,803	\$ 4.80
473,005	\$10.68 - \$12.16	6.95	\$ 10.96	364,044	\$ 11.04
487,793	\$12.64 - \$14.29	5.63	\$ 13.85	448,256	\$ 13.85
531,881	\$14.42 - \$15.50	8.16	\$ 15.00	214,165	\$ 14.84
519,272	\$15.69 - \$16.47	6.43	\$ 15.83	443,417	\$ 15.73
153,500	\$16.49 - \$18.83	5.55	\$ 17.28	89,249	\$ 16.67
698,080	\$18.94	9.80	\$ 18.94		\$
247,850	\$19.19 - \$23.15	8.50	\$ 21.33	88,536	\$ 21.41
551,162	\$23.66	8.84	\$ 23.66	137,109	\$ 23.66
452,000	\$23.68 - \$28.70	8.99	\$ 26.53	35,314	\$ 25.78
4,572,493	\$ 2.76 - \$28.70	7.59	\$ 16.75	2,268,893	\$ 13.26

At December 31, 2011, the Company has reserved 5,483,214 shares of common stock for future issuance upon exercise of options granted or to be granted under the 2002 Plan and the 2004 Plan.

**Employee Stock Purchase Plan**

In 2000, the Company adopted the ESPP, under which shares of common stock are reserved for sale to eligible employees, as defined in the ESPP.

Employees may purchase common stock under the ESPP every six months (up to but not exceeding 15% of each employee's base salary or hourly compensation, subject to certain limitations) over the offering period at 85% of the fair market value of the common stock at specified dates. The offering period may not exceed 24 months. During the years ended December 31, 2011, 2010 and 2009, 53,276, 53,776 and 62,134 shares of common stock were issued under the ESPP, respectively. As of December 31, 2011, 239,346 shares of common stock have been issued under the ESPP and 117,911 shares of common stock are available for future issuance.

The ESPP included an annual evergreen provision which provided that on December 31st of each year, the number of reserved shares were increased automatically by the lesser of (i) one percent of the total amount of shares of common stock outstanding on such anniversary date, or (ii) such lesser amount as approved by the Board of Directors. The evergreen provision expired on December 31, 2008.



**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Income Taxes**

Taxes on income vary from the statutory federal income tax rate applied to earnings before tax on income as follows (in thousands):

	2011	December 31, 2010	2009
Statutory federal income tax rate of 34% applies to earnings before income taxes	\$ (29,437)	\$ (14,155)	\$ (10,494)
States taxes net of federal benefit	(5,347)	(2,598)	(2,224)
Meals and entertainment	14	11	9
Share-based compensation	1,015	676	238
Federal research and development credit	(1,410)	(1,083)	(872)
162(m) Executive compensation limitation	274	1,186	160
NOL adjustment due to 382 study			(9,437)
R&D credit adjustment			334
APIC valuation allowance	(21)	(4)	(39)
Change in valuation allowance	34,145	15,684	22,204
Other	767	283	121
	\$	\$	\$

Deferred income tax assets and liabilities arising from differences between accounting for financial statement purposes and tax purposes, less valuation allowance at year end are as follows (in thousands):

	December 31, 2011	2010
Deferred tax assets:		
Net operating loss carryforwards	\$ 95,738	\$ 61,944
Research and development credits	8,475	6,285
Intangibles	2,196	1,440
Share-based compensation	7,008	5,395
Other, net	2,185	3,684
Total deferred tax assets	115,602	78,748
Deferred tax liabilities:		
Deferred state taxes	(8,307)	(5,598)
Net deferred tax assets	107,295	73,150
Valuation allowance for net deferred tax assets	(107,295)	(73,150)
Net deferred taxes	\$	\$

Deferred income tax assets and liabilities are recorded for differences between the financial statement and tax basis of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted laws and rates applicable to the periods in which the differences

are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.



**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company has evaluated the available evidence supporting the realization of its gross deferred tax assets, including the amount and timing of future taxable income, and has determined it is more likely than not that the assets will not be realized. Due to uncertainties surrounding the realizability of the deferred tax assets, the Company continually maintains a full valuation allowance against its deferred tax assets at fiscal year ended December 31, 2011.

As of December 31, 2011, the Company had federal and California income tax net operating loss carryforwards of approximately \$226,999,000 and \$209,936,000, respectively. The difference between the federal and California tax loss carryforwards is primarily attributable to the capitalization of research and development expenses and expiring carryforwards for California income tax purposes. In addition, the Company has federal and California research and development tax credit carryforwards of \$4,951,000 and \$3,525,000, respectively. The federal and California net operating loss carryforwards will expire through 2031, unless previously utilized. The federal research tax credit carryforwards will expire through 2031 unless previously utilized and the California research and development credit carryforwards will carry forward indefinitely until utilized.

Internal Revenue Code Section 382 and 383 can limit the amount of net operating losses and credits which may be utilized if certain changes to a company's ownership occur. The Company regularly monitors its equity financing transactions and other ownership shifts to determine the extent to which its ability to utilize its net operating loss and credit carryforwards is limited. Based on the most recent 382/383 study, which includes activity from the equity fundraising completed in February 2012, the Company has undergone five ownership changes as described in Internal Revenue Code Section 382, most recently in May 2003. Accordingly, in a prior year, the Company adjusted its deferred tax assets related to net operating loss and credit carryforwards to reflect the 382/383 limitations applicable to prior years, however, the adjustment did not have a financial statement impact due to our full valuation allowance position. Any future financing transactions or other ownership shifts may impact the Company's ability to utilize its net operating loss and credit carryovers for which deferred taxes have been provided.

Deferred tax assets pertaining to windfall tax benefits on exercise of share awards and the corresponding credit to additional paid-in capital are recorded if the related tax deduction reduces tax payable. The Company has elected the "with-and-without" approach regarding ordering of windfall tax benefits to determine whether the windfall tax benefit did reduce taxes payable in the current year. Under this approach, the windfall tax benefits would be recognized in additional paid-in capital only if an incremental tax benefit is realized after considering all other tax benefits presently available to the Company. The Company's deferred tax assets as of December 31, 2011 do not include \$5,067,000 of excess tax benefits from employee stock option exercises that are a component of its net operating loss carryovers. Stockholders' equity will be increased by \$5,067,000 if and when such excess tax benefits are ultimately realized.

A reconciliation of the beginning and ending balance of unrecognized tax benefits is as follows (in thousands):

	<b>December 31, 2011</b>
Balance at December 31, 2009	\$ 1,340
Gross increase (decrease)	657
Balance at December 31, 2010	1,997
Gross increase (decrease)	731
Balance at December 31, 2011	\$ 2,728

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**ARDEA BIOSCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company does not anticipate any material change in the total amount of unrecognized tax benefits will occur within the next twelve months.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's consolidated balance sheets at December 31, 2011, and has not recognized interest and/or penalties in the consolidated statement of operations for the period ended December 31, 2011, since the unrecognized tax benefits do not result in tax liabilities.

The Company is subject to taxation in the United States and state jurisdictions. The Company's tax years for 2003 and forward are subject to examination by the United States and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

Recently enacted tax laws may also affect the tax provision on the Company's financial statements. Beginning in 2011, the State of California now allows taxpayers to make an election to adopt a single sales factor apportionment formula and to determine its sales apportionment based on market-sourcing rules. Due to the uncertainty in profitability, the Company has not committed to utilizing the single sales factor during the reversal period of deductible temporary differences.

**11. Employee Benefit Plan**

The Company has established a 401(k) defined contribution retirement plan (the "401(k) Plan"), conforming to Section 401(k) of the Internal Revenue Code (the "IRC"). All full-time employees may elect to have a portion of their salary deducted and contributed to the 401(k) Plan up to the maximum allowable limitations of the IRC. The Company does not match employee contributions or otherwise contribute to the 401(k) Plan.

**12. Subsequent Events**

In February 2012, the Company completed an underwritten public offering of 9,775,000 shares of its common stock, including the full exercise of the overallotment option granted to the underwriters, at a price to the public of \$17.00 per share. The net proceeds to the Company from the sale of shares in this offering before expenses and after underwriter discounts and commissions, were approximately \$157,557,000.

**Table of Contents****ARDEA BIOSCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. Summary of Quarterly Financial Data (unaudited)**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2011 and 2010:

	2011			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(In thousands, except per share amounts)			
Revenues:				
Milestones	\$	\$	\$	\$
License fees	1,077	1,077	1,076	1,076
Sponsored research	90	132	96	73
Reimbursable research and development costs	603	967	518	520
Total revenues	1,770	2,176	1,690	1,669
Expenses:				
Research and development	12,715	15,527	19,293	26,890
General and administrative	4,249	4,769	4,907	5,614
Loss from operations	(15,194)	(18,120)	(22,510)	(30,835)
Interest income	107	98	95	83
Interest expense	(134)	(98)	(60)	(22)
Other income, net	3	6		
Net Loss	\$ (15,218)	\$ (18,114)	\$ (22,475)	\$ (30,774)
Basis and diluted net loss per share	\$ (0.59)	\$ (0.68)	\$ (0.84)	\$ (1.15)

	2010			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(In thousands, except per share amounts)			
Revenues:				
Milestones	\$	\$	\$	\$ 15,000
License fees	2,426	2,426	2,171	1,077
Sponsored research				358
Reimbursable research and development costs	847	1,095	1,123	896
Total revenues	3,273	3,521	3,294	17,331
Expenses:				
Research and development	10,251	12,884	14,687	14,288
General and administrative	2,926	3,319	6,669	3,538
Loss from operations	(9,904)	(12,682)	(18,062)	(495)
Interest income	69	111	100	84
Interest expense	(261)	(229)	(204)	(172)

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Other income, net	13	13	1	(13)
Net Loss	\$ (10,083)	\$ (12,787)	\$ (18,165)	\$ (596)
Basis and diluted net loss per share	\$ (0.54)	\$ (0.57)	\$ (0.79)	\$ (0.03)

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